

Clozapine REMS Program

Frequently Asked Questions

General Section

1. What is a REMS?

A REMS or Risk Evaluation and Mitigation Strategy is an FDA required risk management plan that uses risk minimization strategies beyond the professional labeling to ensure that the benefits of prescription drugs outweigh their risk.

2. What is the Clozapine REMS Program?

The Clozapine REMS Program is an FDA-mandated program implemented by the manufacturers of clozapine. It is intended to help Healthcare Providers (HCPs) ensure the safety of patients taking clozapine. The Clozapine REMS Program is a single shared patient registry with requirements for prescribers, pharmacists, patients, and distributors, and replaces the multiple individual clozapine patient registries.

3. What are the goals of the Clozapine REMS Program?

The goals of the Clozapine REMS Program are to mitigate the risk of severe neutropenia associated with the use of clozapine by:

- Educating prescribers and pharmacists about the risk of severe neutropenia and appropriate monitoring requirements
- Informing patients about the risk of severe neutropenia and appropriate monitoring requirements
- Ensuring compliance with the monitoring frequency for absolute neutrophil count (ANC) prior to dispensing clozapine
- Ensuring the prescriber documents a risk-benefit assessment when the patient's ANC falls below the acceptable range as described in the Prescribing Information
- Establishing long-term safety and safe-use of clozapine by enrolling all patients who receive clozapine in the registry

Download program enrollment forms [here](#)

4. Where can I obtain the Prescribing Information for clozapine?

For current Prescribing Information for clozapine, visit the Resources page on the Clozapine REMS Program Website at www.clozapinerems.com.

5. What are the different roles of healthcare staff in the Clozapine REMS Program?

There are 4 different roles in the Clozapine REMS Program:

- Prescriber
- Prescriber Designee
- Pharmacy Staff
- Pharmacy Authorized Representative

Please refer to the description of each of these roles and determine which one best describes your duties in the Clozapine REMS Program. There are instances where a Healthcare Provider can serve in more than one role in the Clozapine REMS Program (click [here](#) for details). The high-level enrollment and/or certification requirements for each role are presented in the table below.

<u>Role</u>	<u>Certify or Enroll?</u>	<u>Description</u>
Prescriber	Certify	<p><u>Prescriber Certification Process</u></p> <ul style="list-style-type: none"> • Complete the <i>Clozapine REMS Prescriber Enrollment Form</i> online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Pass the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center
Prescriber Designee	Enroll	<p><u>Prescriber Designee Enrollment Process</u></p> <ul style="list-style-type: none"> • Complete the <i>Clozapine REMS Prescriber Designee Enrollment Form</i> online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Become associated in the system with a certified prescriber • Be approved by a certified prescriber

<u>Role</u>	<u>Certify or Enroll?</u>	<u>Description</u>
Authorized Representative (Non-chain Pharmacy)	Certify	<u>Authorized Representative Certification Process</u> <ul style="list-style-type: none"> • Complete the <i>Clozapine REMS Outpatient Pharmacy Enrollment Form</i> or the <i>Clozapine REMS Inpatient Pharmacy Enrollment Form</i> online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Pass the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center • Renew certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment
Authorized Representative (Chain Pharmacy)	Certify	<u>Chain Pharmacy Authorized Representative Certification Process</u> <ul style="list-style-type: none"> • Work with an account manager from your pharmacy network system (i.e., the “switch”) provider to complete the certification process • Pass the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Renew certification of their pharmacies in the Clozapine REMS Program every two years from initial enrollment
Pharmacy Staff	Enroll	<u>Pharmacy Staff Enrollment Process</u> <ul style="list-style-type: none"> • Enroll online as pharmacy staff at www.clozapinerems.com • Become associated in the system with a pharmacy

Prescriber

<u>Definition</u>	<u>Responsibilities</u>
<p>A prescriber is any healthcare professional who prescribes clozapine to a patient</p> <p>**An inpatient pharmacy operates within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).</p>	<p><u>Certification Process</u></p> <ul style="list-style-type: none"> • A prescriber must certify in the Clozapine REMS Program: <ul style="list-style-type: none"> ○ Review the Prescribing Information for clozapine ○ Review <i>Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</i> ○ Complete the <i>Clozapine REMS Prescriber Enrollment Form</i> ○ Pass the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> • Prescribers who order clozapine to be dispensed from an inpatient pharmacy** <u>are not required</u> to become certified in the Clozapine REMS Program <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> • Prescribers who order clozapine to be dispensed from an outpatient pharmacy are required to become certified in the Clozapine REMS Program and must adhere to the following requirements: <ul style="list-style-type: none"> ○ Enroll every new patient in the Clozapine REMS Program ○ Counsel each patient (or their caregiver) about the risk of severe neutropenia which can lead to serious infection and death ○ Check the ANC for each patient according to the monitoring requirements ○ Submit and verify ANC according to the patient's monitoring frequency on file with the Clozapine REMS Program: <ul style="list-style-type: none"> ▪ For weekly monitoring frequency, ANC must be submitted within 7 days of the lab draw* date ▪ For every two weeks monitoring frequency, ANC must be submitted within 15 days of the lab draw* date ▪ For monthly monitoring frequency, ANC must be submitted within 31 days of the lab draw* date <p style="color: red;">*Assumes the lab draw date is day 0</p> <p>In the future¹, a lab that is not current according to the patient's monitoring frequency will prevent a patient from receiving clozapine. The Clozapine REMS Program will then require the ANC to be aligned with the patient's monitoring frequency. In the interim, warning messages will alert the pharmacy if the ANC is overdue.</p>

<u>Definition</u>	<u>Responsibilities</u>
	<ul style="list-style-type: none"> • Provide a “Treatment Rationale” to authorize the continuation of clozapine therapy for patients with moderate or severe neutropenia if it is determined that: <ul style="list-style-type: none"> ○ The benefits of clozapine therapy outweigh the risks ○ The patient has documented benign ethnic neutropenia (BEN) <p>¹Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and will also be available on the Clozapine REMS Program Website.</p>

Prescriber Designee

<u>Definition</u>	<u>Responsibilities</u>
<p>A Healthcare Provider, office staff member, or pharmacist designated by a certified prescriber to act on their behalf</p>	<p><u>Enrollment Process</u></p> <ul style="list-style-type: none"> • Complete the <i>Clozapine REMS Prescriber Designee Enrollment Form</i> online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876 • Become associated in the system with a certified prescriber • Be approved by the associated prescriber <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> • A prescriber designee can: <ul style="list-style-type: none"> ○ Enroll general population patients ○ Counsel patients ○ Check ANCs ○ Submit ANCs on the prescriber’s behalf ○ Change a patient’s monitoring frequency • A prescriber designee cannot: <ul style="list-style-type: none"> ○ Enroll a patient with benign ethnic neutropenia (BEN) ○ Provide a <i>Treatment Rationale</i> for a patient ○ Designate a patient as a hospice patient

Authorized Representative for Outpatient Pharmacy

<u>Definition</u>	<u>Responsibilities</u>
<p>For outpatient pharmacies with a single location, the authorized representative may be a:</p> <ul style="list-style-type: none"> • Pharmacy Manager, or • Staff Pharmacist <p>If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement processes for all the pharmacies in your organization, the authorized representative may be a:</p> <ul style="list-style-type: none"> • Director of Pharmacy Services, or • Corporate Executive over-seeing Pharmacy Service <p>The authorized representative represents the pharmacy and is responsible for ensuring the processes and procedures within the pharmacy are in place to comply with the Clozapine REMS Program requirements</p>	<p><u>Certification Process</u></p> <ul style="list-style-type: none"> • An authorized representative for an outpatient pharmacy must certify in the Clozapine REMS Program by: <ul style="list-style-type: none"> ○ Reviewing the Prescribing Information for clozapine ○ Certifying their pharmacy in the Clozapine REMS Program by: <ul style="list-style-type: none"> • Reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</i> • Completing the <i>Clozapine REMS Outpatient Pharmacy Enrollment Form</i> • Passing the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> ○ Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements ○ Putting processes and procedures in place to verify: <ul style="list-style-type: none"> • The prescriber is certified in the Clozapine REMS Program prior to dispensing clozapine • The patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine • The ANC result is current according to the patient’s monitoring frequency: <ul style="list-style-type: none"> ▪ For weekly monitoring frequency, the submitted ANC result must have been drawn* within 7 days prior to the “Predispense Authorization” (PDA) transaction date ▪ For every two weeks monitoring frequency, the submitted ANC result must have been drawn* within 15 days prior to the PDA transaction date ▪ For monthly monitoring frequency, the submitted ANC result must have been drawn* within 31 days prior to the PDA transaction date • The submitted ANC is within acceptable range or a certified prescriber has provided a <i>Treatment Rationale</i> to authorize the continuation of clozapine treatment <p style="color: red; font-size: small;">*Assumes the lab draw date is day 0</p>

<u>Definition</u>	<u>Responsibilities</u>
	<ul style="list-style-type: none"> ○ Renewing certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> ● Coordinate the activities required in the Clozapine REMS Program ● Establish and implement processes and procedures to ensure compliance with the safe-use conditions required in the Clozapine REMS Program

Authorized Representative for Inpatient Pharmacy

<u>Definition</u>	<u>Responsibilities</u>
<p>For inpatient pharmacies with a single location, the authorized representative may be a:</p> <ul style="list-style-type: none"> ● Pharmacy Manager, or ● Staff Pharmacist <p>If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement process for all the pharmacies in your organization, the authorized representative may be a:</p> <ul style="list-style-type: none"> ● Director of Pharmacy Services, or ● Corporate Executive overseeing Pharmacy Service <p>The authorized representative represents the pharmacy and is responsible for ensuring the processes and procedures within the pharmacy are in place to comply with the Clozapine</p>	<p><u>Certification Process</u></p> <ul style="list-style-type: none"> ● An authorized representative for a pharmacy must certify in the Clozapine REMS Program by: <ul style="list-style-type: none"> ○ Reviewing the Prescribing Information for clozapine ○ Certifying their pharmacy in the Clozapine REMS Program by: <ul style="list-style-type: none"> ● Reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</i> ● Completing the <i>Clozapine REMS Inpatient Pharmacy Enrollment Form</i> ● Passing the <i>Clozapine REMS Knowledge Assessment for Healthcare Providers</i> ○ Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements ○ Putting processes and procedures in place to verify the patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine ○ Renewing certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> ● Coordinate the activities required in the Clozapine REMS Program ● Establish and implement processes and procedures to ensure compliance with the safe-use conditions required in the Clozapine REMS Program ● Verify every patient receiving clozapine is enrolled in the Clozapine REMS Program prior to dispensing

<u>Definition</u>	<u>Responsibilities</u>
REMS Program requirements	<ul style="list-style-type: none"> • Before dispensing clozapine, inpatient pharmacies can: <ul style="list-style-type: none"> ○ Verify the ANC is current (within 7 days of the “Eligibility Check” date for weekly monitoring, 15 days for every 2 weeks monitoring, and 31 days for monthly monitoring) ○ Verify ANC is within the acceptable range or a certified prescriber has provided a <i>Treatment Rationale</i> to authorize the continuation of clozapine treatment ○ Inpatient pharmacists are encouraged to submit the patient's ANC to the Clozapine REMS Program at intervals consistent with the patient's monitoring frequency.

Pharmacy Staff

<u>Definition</u>	<u>Responsibilities</u>
Any pharmacist or pharmacy employee may assume the role of pharmacy staff member associated with a pharmacy to conduct basic program functions	<p><u>Enrollment Process</u></p> <ul style="list-style-type: none"> • Enroll online as pharmacy staff • Associate with a pharmacy <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> • Outpatient pharmacy staff must: <ul style="list-style-type: none"> ○ Verify a prescriber is certified in the Clozapine REMS Program ○ Verify the pharmacy is certified ○ Verify a patient is enrolled in the Clozapine REMS Program ○ Obtain a PDA before dispensing clozapine to a patient ○ May submit an ANC for a patient • Inpatient pharmacy staff must: <ul style="list-style-type: none"> ○ Verify a patient is enrolled in the Clozapine REMS Program using the <i>Eligibility Check</i> ○ Verify patient has an ANC on file and the ANC is current and within acceptable range via an <i>Eligibility Check</i> and/or review of the patient’s medical record ○ Dispense clozapine to patients only after verifying safe-use conditions have been met ○ May submit an ANC for a patient

6. Can a Healthcare Provider fulfill multiple roles in the Clozapine REMS Program?

Yes; the Clozapine REMS Program allows Healthcare Providers with multiple roles in the Clozapine REMS Program to create multiple website user accounts using the same email address.

One example of multiple roles a Healthcare Provider might have in the Clozapine REMS Program includes being a pharmacy authorized representative and a prescriber designee.

If you have any questions, call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

7. How does a Healthcare Provider certify in more than one role in the Clozapine REMS Program (i.e., as a pharmacy staff and a prescriber designee)? Can the same email address be used for multiple roles in the Clozapine REMS Program?

Yes; to certify in more than one role in the Clozapine REMS Program, you must create a Clozapine REMS Program Website user account for each role. The same email address may be used for each role. If you have any questions, call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

8. Why are white blood cell (WBC) counts no longer being collected?

FDA has determined that the absolute neutrophil count (ANC) is more relevant to drug-induced neutropenia than is the white blood cell (WBC) count. Therefore, WBC counts are no longer required. An [ANC calculator](#) is available on the Clozapine REMS Program Website.

9. How frequently should a patient's ANC be monitored?

A patient's monitoring frequency depends on the patient's ANC and the amount of time a patient has been on treatment. For details regarding what monitoring frequency a patient should be on, refer to the Prescribing Information.

The [ANC Monitoring Table](#) can be found on the Clozapine REMS Program Website:

- Home Page → Resources → Program Materials → Prescriber Tab → ANC Monitoring Table

10. When should I submit a patient's ANC to the Clozapine REMS Program?

Patient ANC information should be submitted to the Clozapine REMS Program as soon as possible after the patient blood draw occurs but must be submitted according to the table below, which is consistent with patient monitoring frequency.

The monitoring frequency and corresponding blood draw dates can be found in the table below:

<u>Monitoring Frequency</u>	<u>ANC Blood Draw Date</u>
Weekly	ANC must be submitted within 7 days of the lab draw* date
Every two weeks	ANC must be submitted within 15 days of the lab draw* date
Monthly	ANC must be submitted within 31 days of the lab draw* date

*Assumes the lab draw date is day 0

Presently, although the 'Lab Not Current' will not prevent a patient from receiving medication, i.e., will not prevent a PDA from being provided; a warning message will be sent to the pharmacy advising that the lab is not current and to contact the prescriber for a current ANC. In the future when the Clozapine REMS Program is fully implemented, a lab that is not current with the patient's monitoring frequency will prevent the patient from receiving clozapine. (Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and will be available on the Clozapine REMS Program Website.) In the interim, warning messages will be provided if the ANC is overdue.

A prescriber must ensure patients are on the appropriate monitoring frequency and adhere to the appropriate corresponding blood draw dates in order for the patient to receive clozapine.

11. How do I contact the Clozapine REMS Program?

For additional information about the Clozapine REMS Program, please call 844-267-8678. For additional contact methods, please see the [Contact Us](#) page.

12. How does a Healthcare Provider report an adverse event, product complaint, or obtain medical information about clozapine?

Promptly report suspected adverse events associated with the use of a clozapine directly to the Clozapine REMS Program Contact Center at 844-267-8678. You should also report adverse event information to the FDA MedWatch Reporting System by telephone at (800) FDA-1088, by mail using Form 3500, or online. Downloadable reporting forms and online reporting forms are available at <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>.

To report a product complaint, or if you require medical information, you may also call the Clozapine REMS Program Contact Center at 844-267-8678.

13. What is the new certification deadline for prescribers and outpatient pharmacies?

The decision to extend the deadlines was made in consultation with the FDA to minimize treatment disruption for patients while allowing more time for pharmacies and prescribers to complete certification. Please refer to the categories below for specific dates.

Pharmacies

All pharmacies are required to become certified in the Clozapine REMS Program by February 28, 2019.

Outpatient Prescribers

All prescribers who prescribe clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems must be certified in the Clozapine REMS Program by February 28, 2019.

Inpatient Prescribers

In February 2019, prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) will not be required to become certified in the Clozapine REMS Program. However, in order to initiate clozapine therapy in an inpatient setting, a certified prescriber must enroll the patient in the Clozapine REMS Program before the first dose can be dispensed.

For more information on this program change for prescribers who prescribe clozapine in an inpatient setting, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

14. How is monitoring frequency determined in the Clozapine REMS Program?

Monitoring frequency is calculated by the Clozapine REMS Program automatically, based on the patient's history of consistently acceptable ANC values submitted to the program. The guidelines for determining monitoring frequency are described in the Prescribing Information.

If a patient's monitoring frequency is incorrect, the prescriber can modify a patient's monitoring frequency by attesting in the patient's profile via the Clozapine REMS Program Website. Prescribers and prescriber designees can also modify a patient's monitoring frequency by calling the Clozapine REMS Program Contact Center at 844-267-8678 or by faxing the update via the *Clozapine REMS ANC Lab Reporting Form* to the Clozapine REMS Program Contact Center for processing.

Note: A pharmacy cannot update a patient's monitoring frequency. Pharmacies should work with the patient's prescriber to update a patient's monitoring frequency.

The [ANC Monitoring Table](#) can be found on the Clozapine REMS Program Website:

- Home Page → Resources → Program Materials → Prescriber Tab → ANC Monitoring Table

15. Why did established patients with monthly monitoring frequency get converted to weekly monitoring frequency?

The Clozapine REMS Program made every effort to consolidate ANC data for patients with laboratory data in multiple individual manufacturer registries to create complete patient records. Patients with complete profile information in the individual manufacturer registries were migrated to the Clozapine REMS Program successfully, but may have had different monitoring frequencies across multiple individual manufacturer registries and/or had a significant gap in ANC data when patient data was consolidated from the multiple individual manufacturer registries.

In accordance with the approved clozapine Prescribing Information, if the patient had consistent ANCs submitted over the previous 12-month period, the patient was migrated with a monthly monitoring frequency.

If a patient's ANCs were inconsistently submitted to the registries in the previous 12-month period and/or there was a time-frame longer than 56 days between blood draw dates, the patient was migrated with a weekly monitoring frequency.

The guidelines outlined above for assigning a new monitoring frequency are consistent with the clozapine [Prescribing Information](#).

If a prescriber needs to change a patient's monitoring frequency, the prescriber can do so on the prescriber dashboard on the Clozapine REMS Program Website. The prescriber or a prescriber designee may also update a patient's monitoring frequency by calling the Clozapine REMS Program Contact Center at 844-267-8678.

16. My existing clozapine patient was not migrated from the individual manufacturer registries and therefore the Clozapine REMS Program identifies this patient as new and has aligned this patient to a weekly monitoring frequency. How can I update the system so my patient is correctly returned to monthly monitoring frequency?

The Clozapine REMS Program made every effort to consolidate ANC data for patients with laboratory data in multiple individual manufacturer registries to create complete patient records. In some instances, data was incomplete, creating gaps in ANC histories. These gaps resulted in some patients who were previously on a monthly monitoring frequency in an individual manufacturer registry to revert to a weekly monitoring frequency in the Clozapine REMS Program.

If a prescriber needs to change a patient's monitoring frequency, the prescriber can do so on the prescriber dashboard on the Clozapine REMS Program Website. The prescriber or the prescriber designee can also update a patient's monitoring frequency by calling the

Clozapine REMS Program Contact Center at 844-267-8678, or by faxing the update via the *Clozapine REMS ANC Lab Reporting Form* to the Clozapine REMS Program Contact Center for processing.

Prescriber

17. How can a prescriber become certified in the single shared Clozapine REMS Program?

Any prescriber who wants to initiate clozapine therapy in a patient must be certified in order for the patient to be enrolled in the Clozapine REMS Program.

Prescribers who prescribe clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems must certify in the Clozapine REMS Program and adhere to the Clozapine REMS Program requirements. Prescribers may certify online through the Clozapine REMS Program Website or by submitting the *Clozapine REMS Prescriber Enrollment Form* and *Clozapine REMS Knowledge Assessment for Healthcare Providers* via fax to the Clozapine REMS Program Contact Center at 844-404-8876.

To complete certification on the Clozapine REMS Program Website:

- From the Home Page, use the “Start Prescriber Certification” button. You will be taken to the Prescriber Certification page, which will explain what is expected and required in the Clozapine REMS Program.
- From that certification page, use the “Begin Now!” button to begin certification in the Clozapine REMS Program.

Prescribers who have completed the Clozapine REMS Program certification requirements will receive notification that they are certified in the program.

During the February 2019 Clozapine REMS Program Modification, prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) will not be required to become certified in the Clozapine REMS Program. Patients in this setting are required to be enrolled in the Clozapine REMS Program in order to receive clozapine. If a patient in this setting is not enrolled, they must be enrolled by a certified prescriber before they will be allowed to receive clozapine.

For further information, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678. For a faxed copy of the certification forms, call the Clozapine REMS Program Contact Center at 844-267-8678.

18. When do I need to complete certification?

The new deadline for prescriber certification is February 28, 2019. If you are not certified by this date your patient may not be eligible to receive clozapine. Prescribers are highly encouraged to certify in the Clozapine REMS Program as soon as possible.

For further information on this change for prescribers who prescribe clozapine in an inpatient setting, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

19. What are the changes for prescribers in an inpatient setting with the February 2019 Clozapine REMS Program Modification?

During the February 2019 Clozapine REMS Program Modification, prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) will not be required to become certified in the Clozapine REMS Program.

Patients in this setting are required to be enrolled in the Clozapine REMS Program in order to receive clozapine. If a patient in this setting is not enrolled, they must be enrolled by a certified prescriber before they will be allowed to receive clozapine.

For further information on prescribers who prescribe clozapine in an inpatient setting, please call the Clozapine REMS Program Contact Center at 844-267-8678.

20. If a prescriber is going to be out of the office for an extended period of time, can another prescriber cover during the absence?

Yes; however, the covering prescriber must be certified in the Clozapine REMS Program and it may be beneficial for the new prescriber to associate themselves with those patients in the program or call the Clozapine REMS Program Contact Center at 844-267-8678 to have the patient assigned to that covering prescriber.

21. If a prescriber is going to be out of the office for a short period of time, can another prescriber write a prescription for the patient during the absence?

Yes; the covering prescriber can write a prescription for another prescriber's patient as long as the covering prescriber is certified in the Clozapine REMS Program. When the eligibility of the patient to receive clozapine is checked, it does not look for an established relationship between the prescriber and patient.

22. Can a nurse practitioner, physician assistant, resident, or intern certify as a prescriber in the Clozapine REMS Program?

Yes; any medical professional with prescribing privileges can become certified in the Clozapine REMS Program.

23. Can a member of the prescriber's office staff help manage patients in the Clozapine REMS Program?

Yes; the Clozapine REMS Program allows a certified prescriber to identify a prescriber designee to perform some duties or functions on behalf of the prescriber. The prescriber's designee(s) will need to enroll in the Clozapine REMS Program and become certified

before they can perform any duties or functions for their associated prescriber(s). A prescriber may have more than one prescriber designee.

A notification will be sent to the prescriber when the designee enrolls. Before a designee can act on behalf of a prescriber, the prescriber will need to approve the person acting on his or her behalf. Once the designee has been approved by the certified prescriber, they will be able to engage in patient management through the Clozapine REMS Program Website.

24. How can a prescriber find a list of pharmacies that are certified in the Clozapine REMS Program?

A prescriber can obtain a list of participating pharmacies by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If a prescriber knows the pharmacy's DEA, or NPI, or NCPDP number, the prescriber can also confirm that a pharmacy is certified by using the feature "Certification Lookup" on the Resources tab of the Clozapine REMS Program Website at www.clozapinerems.com.

25. Where can I find the Patient ID for the *Clozapine REMS ANC Lab Reporting Form*?

The Patient ID can be found on the Prescriber Dashboard on the patient tab. The Patient ID is also known as the Patient Enrollment ID.

Note: The Patient ID is an optional field on the *Clozapine REMS ANC Lab Reporting Form*.

Prescriber Designee

26. What actions can a prescriber designee perform in the Clozapine REMS Program?

A prescriber designee can perform the following actions on behalf of the prescriber:

- Enroll general population patients
- Counsel patients
- Submit ANCs on the prescriber's behalf
- View patient lists and patient ANC history
- Change monitoring frequency

A prescriber designee **cannot perform** the following actions on behalf of a prescriber:

- Enroll patients with documented benign ethnic neutropenia
- Provide a *Treatment Rationale* for a patient
- Designate a patient as a hospice patient

To download the *Clozapine REMS Prescriber Designee Enrollment Form* or *Clozapine REMS Patient Enrollment Form*, visit the Clozapine REMS Program Website.

Download program enrollment forms [here](#)

Patient Management

27. Do patients need to be enrolled in the Clozapine REMS Program in order to receive clozapine?

Yes; any patient prescribed clozapine, whether in an inpatient or outpatient setting must be enrolled in the Clozapine REMS Program by the patient's prescriber or the prescriber designee. To enroll a patient, please visit www.clozapinerems.com or fax the completed *Clozapine REMS Patient Enrollment Form* to the Clozapine REMS Program Contact Center at 844-404-8876.

Note: An acceptable ANC or *Treatment Rationale* must also be on file with the Clozapine REMS Program for patients to receive clozapine in an outpatient setting

28. How are patients enrolled into the Clozapine REMS Program?

Prescribers and prescriber designees can enroll patients into the Clozapine REMS Program. General population patients can be enrolled by both prescribers and prescriber designees online, by phone, or by faxing the *Clozapine REMS Patient Enrollment Form*.

Only a prescriber can enroll patients with benign ethnic neutropenia (BEN). The prescriber must indicate BEN status as part of the enrollment process on the Clozapine REMS Program Website or on the *Clozapine REMS Patient Enrollment Form* to be faxed; patients with BEN cannot be enrolled by phone. Phone enrollment is only available for general population patients.

For assistance in enrolling your patient, please call the Clozapine REMS Program Contact Center at 844-267-8678.

To download the *Clozapine REMS Patient Enrollment Form*, visit the Clozapine REMS Program Website.

Download program enrollment forms [here](#).

29. Can a Healthcare Provider not certified in the Clozapine REMS Program submit an ANC?

If you are a Healthcare Provider directly involved in the treatment of a clozapine patient, you can call the Clozapine REMS Program Contact Center at 844-267-8678 and submit an ANC over the phone even if you aren't certified in the Clozapine REMS Program. You may be required to provide specific identifying patient information when you submit the ANC results.

An ANC can also be faxed to the Clozapine REMS Program Contact Center at 844-404-8876 for data entry.

For organizations with high laboratory volumes, a simple automated interface can be implemented to electronically send ANC data for entry into the Clozapine REMS Program.

Please call the Clozapine REMS Program Contact Center at 844-267-8678 for more information on this process.

30. Will the program send notices if the patient experiences a low ANC or substantial drop?

The Clozapine REMS Program uses an automated system that will notify the patient's associated prescriber if a patient experiences mild, moderate, or severe neutropenia as defined in the approved clozapine Prescribing Information for both patients in the general population and for patients with documented benign ethnic neutropenia.

Substantial drops are not defined in the clozapine Prescribing Information, so safety notices will not be sent if the patient experiences such a drop. A notice will be sent if the ANC meets criteria for mild, moderate, or severe neutropenia.

31. What is a Treatment Status?

A patient's *Treatment Status* describes a patient's status in the clozapine treatment process.

There are four Treatment Statuses in the Clozapine REMS Program:

- *Pre-Treatment*: new patient with no baseline ANC submitted who has not started clozapine
- *Active*: receiving clozapine at regular intervals consistent with their monitoring frequency
- *Interrupted*: clozapine usage has stopped temporarily pending next actions before resuming therapy or being permanently discontinued
- *Discontinued*: clozapine usage has stopped

Treatment Status is automatically updated based on the ANC values entered into the system.

- For general population patients:
 - An ANC between 500 and 999/ μL (moderate neutropenia) will cause Treatment Status to update to *Interrupted*
 - An ANC below 500/ μL (severe neutropenia) will cause Treatment Status to update to *Discontinued*
- For patients with documented benign ethnic neutropenia (BEN):
 - An ANC below 500/ μL (severe neutropenia) will cause Treatment Status to update to *Interrupted*

A Treatment Status of *Interrupted* or *Discontinued* will prevent a PDA from being provided and could result in a disruption of a patient's clozapine therapy. If a prescriber determines that the benefits of continuing clozapine outweigh the risks when a patient's Treatment Status was changed to *Interrupted*, the prescriber can provide a *Treatment Rationale* into the system and change the patient's Treatment Status back to *Active* thereby allowing clozapine to be dispensed.

If a patient's Treatment Status was changed to *Discontinued* because of a low ANC value, the Treatment Status will automatically return to *Active* only when a new/current lab is submitted with the patient's ANC value within acceptable range.

32. What is a *Treatment Rationale*?

A *Treatment Rationale* is required from a prescriber when he or she determines that a patient should continue clozapine treatment despite a low ANC.

To authorize the continuation of clozapine therapy for any patient with a Treatment Status of *Interrupted* or *Discontinued* because of a low ANC indicating severe neutropenia, the prescriber must take action by providing a *Treatment Rationale* to update the patient's Treatment Status back to *Active* to allow a PDA request to be approved.

The Clozapine REMS Program will alert the prescriber via the Clozapine REMS Program Website dashboard if a submitted ANC is below the recommended thresholds for a patient. Clozapine will not be dispensed to the patient unless the prescriber then provides a *Treatment Rationale* to authorize continued treatment. There are two *Treatment Rationale* options in the Clozapine REMS Program:

1. "Benefits outweigh risks" → In the prescriber's clinical judgment; the benefits of continuing clozapine treatment outweigh the risk of neutropenia
2. "Patient with documented BEN" → The ANC is within a range where treatment can continue for a patient with benign ethnic neutropenia (BEN)

Information provided in the Clozapine REMS Program is not a substitute for appropriate documentation in the patient's medical record regarding the prescriber's decision to continue, interrupt, or discontinue clozapine treatment.

33. How can I provide a *Treatment Rationale*?

Providing a *Treatment Rationale* confirms that the benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia when the prescriber wishes to continue clozapine treatment in a patient whose ANC value is low. The *Treatment Rationale* returns the patient's Treatment Status in the Clozapine REMS Program to *Active* and allows the Clozapine REMS Program to provide a PDA which permits the pharmacy to dispense clozapine.

Prescribers may confirm treatment continuation with a *Treatment Rationale* in the Clozapine REMS Program by:

1. Faxing a signed *Clozapine REMS ANC Lab Reporting Form* to 844-404-8876 containing a completed *Treatment Rationale* section, or
2. Accessing the Clozapine REMS Program Website to provide a *Treatment Rationale* online. To do so, perform the following steps:
 - a. **Log in to** the Clozapine REMS Program Website at www.clozapinerems.com.
 - b. **Access** the dashboard.

- c. **Select ‘Change *Treatment Rationale*’** from the drop-down menu and **click the GO** button.
- d. **Enter the lab information** on the ‘Lab Information’ screen and **click Next**. The user will be redirected back to the Dashboard after this step is complete.

34. What happened to patients previously on the National Non-Rechallenge Master File (NNRMF)?

The NNRMF was developed by the Novartis Pharmaceuticals Corporation to ensure that patients at risk of developing severe neutropenia (previously referred to as agranulocytosis) while on clozapine, regardless of the manufacturer, could not be restarted on clozapine. Due to updates to the clozapine Prescribing Information, the NNRMF is no longer applicable. Patients who were previously identified in the NNRMF will be identified in the Clozapine REMS Program with a flag on the Prescriber Dashboard.

Patients who were previously identified in the NNRMF may restart clozapine in certain circumstances as defined in the Prescribing Information. Monitoring requirements for patients previously identified in the NNRMF are the same as for patients new to clozapine.

35. How are patient ANCs submitted to the Clozapine REMS Program?

Patient ANCs can be submitted to the Clozapine REMS Program in a variety of ways:

- Prescribers and prescriber designees can log in to the Clozapine REMS Program Website and enter ANCs for a patient using their dashboard
- Pharmacy staff and pharmacy authorized representatives can submit an ANC via their dashboard on the Clozapine REMS Program Website
- All program roles can call the Clozapine REMS Program Contact Center at 844-267-8678
- All program roles can fax ANCs to the Clozapine REMS Program Contact Center at 844-404-8876

Download [Clozapine REMS ANC Lab Reporting Form](#)

36. Does the Clozapine REMS Program need to be advised when a patient is admitted to or discharged from an acute or long-term healthcare setting?

No; the Clozapine REMS Program does not track when patients are admitted or discharged. Patient association to a prescriber is updated automatically when a new prescriber enrolls a patient. There is no action required on the part of the previous prescriber.

If a prescriber wishes to remove a patient from their list, they can deactivate the patient via their dashboard.

37. When discontinuing treatment, does the patient's ANC need to be monitored for 4 weeks?

No; the duration and frequency of all patient ANC monitoring after discontinuation is dependent on that patient's ANC and clinical status (see Section 2.4 in the [clozapine Prescribing Information](#) for more details).

38. If a patient is eligible to reduce their monitoring frequency does the Clozapine REMS Program need to be notified?

No; the monitoring frequency recommendations are described in the Prescribing Information. In the Clozapine REMS Program, monitoring frequency is a calculated value, based on the patient's ANC history. Thus, if the patient is eligible to reduce their monitoring frequency, the system will automatically adjust their monitoring frequency.

If a patient's monitoring frequency is incorrect, the prescriber can modify the patient's monitoring frequency to monthly by performing an attestation in the patient's profile via the Clozapine REMS Program Website. Prescribers and prescriber designees can modify a patient's monitoring frequency to monthly by calling the Clozapine REMS Program Contact Center at 844-267-8678.

A prescriber can move a patient from monthly or every two weeks monitoring frequency to weekly by faxing the update via the *Clozapine REMS ANC Lab Reporting Form* to the Clozapine REMS Program Contact Center for processing.

39. If the patient or caregiver will not provide the required information needed to complete Patient Enrollment (i.e., Name, Date of Birth) can they still receive clozapine?

This information is needed in order for prescribers and pharmacies to identify the patient in the Clozapine REMS Program to submit ANCs and provide authorization to receive clozapine. If a patient and/or their caregiver will not provide the required information, the patient will not be able to receive clozapine therapy.

40. How does a patient in an inpatient setting become enrolled if prescribers in this setting are not required to be certified in the Clozapine REMS Program?

All patients are required to be enrolled in the Clozapine REMS Program in order to receive clozapine. If a patient in this setting is not enrolled, they must be enrolled by a certified prescriber before they will be allowed to receive clozapine.

Pharmacy Management

41. What are the different pharmacy certification types in the Clozapine REMS Program?

All pharmacies must certify in the Clozapine REMS Program to purchase and dispense clozapine.

Pharmacies participating in the Clozapine REMS Program must determine their pharmacy type based on the definitions below. The [certification requirements](#) are different for different pharmacy types.

<u>Pharmacy Type</u>	<u>Definition</u>
Chain Pharmacy	<ul style="list-style-type: none"> • A chain of retail pharmacies has an authorized representative located at a chain headquarters who is responsible for ensuring certification and training in the Clozapine REMS Program across all stores in the chain. • A chain pharmacy is contracted to participate with a pharmacy network provider. • Chain pharmacies must adjudicate claims through their Pharmacy Benefit Management System (PBMS) via electronic communication with the Clozapine REMS Program using established telecommunications standards (i.e., “the switch”).
Outpatient Pharmacy	<ul style="list-style-type: none"> • Pharmacies are considered outpatient if the pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems. • An outpatient pharmacy is an individual location or multiple stores with an authorized representative associated to the independent stores. The authorized representative is responsible for ensuring certification and training in the Clozapine REMS Program within the individual or multiple stores. • Even if a pharmacy has multiple locations, it is not considered a chain for the purposes of the REMS unless it has a single authorized representative at a corporate headquarters that is responsible for ensuring certification and training in the Clozapine REMS Program across all stores in the chain. • An outpatient pharmacy <u>may</u> be able to adjudicate claims via electronic communication with the Clozapine REMS Program using established telecommunications standards (i.e., “the switch”). • Outpatient pharmacies that cannot adjudicate claims via the switch must obtain a PDA via the Clozapine

<u>Pharmacy Type</u>	<u>Definition</u>
	REMS Program Website, or by calling the Clozapine REMS Program Contact Center.
Inpatient Pharmacy	<ul style="list-style-type: none"> • Pharmacies are considered inpatient if the pharmacy is within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition). • Inpatient pharmacies are required to perform an <i>Eligibility Check</i> to verify a patient is eligible to receive clozapine before dispensing. If the patient is found to not yet have been enrolled in the Clozapine REMS Program, he/she must be enrolled by a <u>certified prescriber</u> before being allowed to receive clozapine.

42. What is a *Predispense Authorization (PDA)*?

A *Predispense Authorization (PDA)* determines if a patient is eligible to receive clozapine and provides authorization for an outpatient pharmacy to dispense.

The PDA currently evaluates that the:

- Prescriber is certified; and,
- Pharmacy is certified; and,
- Patient is enrolled; and,
- Patient has an ANC on file; and,
- Patient's ANC is within acceptable range according to the Prescribing Information, or has a valid *Treatment Rationale* on file from the prescriber.

In addition, PDA responses provide the dispensing pharmacy with the following information:

- The most recent ANC value and the associated blood draw date
- Patient monitoring frequency

If the ANC is not current (i.e., within 7/15/31 days of the ANC draw date) based on the patient's monitoring frequency (either weekly, every 2 weeks or monthly), this **will not** prevent a PDA.

Upon full implementation of the Clozapine REMS Program, pharmacies will be required to verify the patient ANC is current. At that time, if the ANC is not current based on the patient's monitoring frequency, a PDA will not be provided and the patient will not be allowed to receive clozapine. (Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and available on the Clozapine REMS Program Website.)

Click [here](#) to access the *Clozapine REMS PDA Fact Sheet*.

43. What is an *Eligibility Check*?

The *Eligibility Check* (EC) determines if a patient is eligible to receive clozapine and provides an authorization for an inpatient pharmacy to dispense.

The EC evaluates the criteria of patient enrollment in the Clozapine REMS Program to determine if it is safe to dispense clozapine to the patient. Patients who are not enrolled in the Clozapine REMS Program are not “eligible” to receive clozapine and must be enrolled by a certified prescriber prior to their first dose of clozapine.

In addition, the EC will provide a warning message informing the pharmacy if the patient’s ANC is not on file, is not within acceptable ranges according to the Prescribing Information; or, when the ANC on file indicates moderate or severe neutropenia there is no valid *Treatment Rationale* on file from the prescriber. This warning message will not prevent a dispense for a patient as long as the patient is enrolled in the Clozapine REMS Program.

All EC responses will provide the following information:

- The most recent ANC value and the associated blood draw date
- Patient monitoring frequency

Pharmacy authorized representatives and pharmacy staff in an inpatient pharmacy can perform an EC from their dashboard. To perform an EC, the user enters the following data:

- Patient data: First Name, Last Name, Date of Birth, Zip Code (Required)
- Prescriber identifier: DEA or NPI (at least one identifier is required)
- Patient ANC data: ANC, Blood Draw Date (Optional)
- Dispense data: Date of Service, NDC, Days’ Supply, Quantity (Optional)

Click [here](#) to access a *Clozapine REMS Eligibility Check Fact Sheet*.

44. How is an *Eligibility Check* different from a *Predispense Authorization*?

The *Eligibility Check* is primarily used by inpatient pharmacies, whereas the PDA is used by outpatient pharmacies. Further specifics about the use of each and the steps required to perform each one can be obtained from the Clozapine REMS Program Website at www.clozapinerems.com by downloading and reviewing the *Clozapine REMS PDA Fact Sheet* and/or *Clozapine REMS Eligibility Check Fact Sheet*.

45. What is a “Dispense Rationale”?

The Clozapine REMS Program provides certified outpatient pharmacies with an opportunity to apply clinical judgment and continue to dispense clozapine to enrolled patients when a patient’s prescriber is not certified in the Clozapine REMS Program. In order to dispense to a patient who does not have an associated certified prescriber, the pharmacist must provide a *Dispense Rationale*.

The Clozapine REMS Program will alert the pharmacy if the prescriber is not certified in the Clozapine REMS Program when a PDA is requested. A PDA will not be provided for a clozapine dispense unless the pharmacy provides a *Dispense Rationale* to authorize a dispense.

In order for a patient to be eligible for a *Dispense Rationale*, that patient must:

- Be enrolled in the Clozapine REMS Program; and,
- Have an acceptable ANC value on file; or,
- Have a *Treatment Rationale* on file if the ANC on file is low indicating moderate or severe neutropenia.

The *Dispense Rationale* is valid for 72 hours (3 calendar days).

The *Dispense Rationale* will be limited to no more than three (3) *Dispense Rationales* for an individual patient within a rolling six (6) month period of time.

Pharmacies must fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.

46. How can I provide a *Dispense Rationale*?

Certified authorized representatives and enrolled pharmacy staff for certified pharmacies can provide a *Dispense Rationale* through the Clozapine REMS Program Website. The process varies slightly for providing a *Dispense Rationale* depending on whether your pharmacy requests a *Predispense Authorization* (PDA) by using the Clozapine REMS Program Website (see Section A. below) or by using the pharmacy network system, i.e., “switch” (see [Section B. below](#)). Alternatively, a *Dispense Rationale* may be provided via calling the Clozapine REMS Program Contact Center at 844-267-8678.

A. A Pharmacy using the Clozapine REMS Program Website to request a PDA, should:

1. **Log in to** the Clozapine REMS Program Website.
Note: You must be enrolled as a pharmacy staff or certified as an authorized representative for the pharmacy.
2. **Access** the dashboard.
3. **Select ‘*Predispense Authorization*’** from the drop-down menu and **click** the **Go** button.
4. **Enter the patient information** on the ‘*Predispense Authorization*’ screen and **click Submit** (see [screenshot below](#).) The ‘*Predispense Authorization* Result’ screen will appear with a reject message.

Predispense Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the Predispense Authorization information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the Predispense Authorization will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispense Authorization Request

Date of Service ?

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

5. Click on the 'Provide a *Dispense Rationale* for this patient' check box at the bottom of the '*Predispense Authorization Result*' screen and **click** the **Submit** button. (see screenshot below)

Patient's Lab History

Provide *Dispense Rationale* for this patient.

Cancel Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

6. If the *Dispense Rationale* was provided successfully, you will be taken to a success screen. (see [screenshot below](#))

Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>▲ Current ANC is not on file.</p> <p>A <i>Dispense Rationale</i> currently exists for this patient and will expire on 06/06/2018.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
DOB	
Authorization Number	

Patient's Lab History

For additional information about the Clozapine REMS Program, please call 844-267-8678.

B. A pharmacy using the pharmacy network system (i.e., “switch”) to request a PDA should:

1. **Log in** to the Clozapine REMS Program Website.
Note: You must be enrolled as a pharmacy staff or certified as an authorized representative for the switch pharmacy.
2. **Access** the dashboard.
3. **Select ‘Dispense Rationale’** from the drop-down menu and **click the Go** button. (see [screenshot below](#))

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾

My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications **Pharmacies** Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you do not see your pharmacy listed, please use **Add Pharmacy** button to add the pharmacy to the list.

Add Pharmacy

Search

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- <input type="button" value="Go"/>
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- <input type="button" value="Go"/>
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- <input type="button" value="Go"/>
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	<ul style="list-style-type: none">-- Please Select ---- Please Select --Remove PharmacyView/Update Pharmacy ProfileAdd LabPredispense AuthorizationDispense RationaleRecertify Pharmacy <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	-- Please Select -- <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 7 of 7 entries

< 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

4. Enter the patient information on the *Dispense Rationale* screen and click **Submit**. (see screenshot below)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Dispense Rationale

To request a *Dispense Rationale* for your patient, please complete the information below and **Submit**. If you have lab information for your patient, you can enter it here. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

Cancel Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

5. The "*Dispense Rationale Result*" screen will appear with a reject message similar to the switch reject message.

6. Click on the 'Provide a *Dispense Rationale* for this patient' check box at the bottom of the '*Dispense Rationale Result*' screen and click the **Submit** button (see screenshot below).

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Dispense Rationale Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name **Summer H**

DOB

Authorization Number

✖ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

⚠ Current ANC is not on file.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

Patient's Lab History

Provide *Dispense Rationale* for this patient.

Cancel Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

7. If the *Dispense Rationale* is provided successfully, you will be taken to a success screen. (see [screenshot below](#))

Dispense Rationale Result

✔ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

<p>Name Summer H</p> <p>DOB</p> <p>Authorization Number</p>	<p>▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>▲ Current ANC is not on file.</p> <p>A <i>Dispense Rationale</i> currently exists for this patient and will expire on 06/06/2018.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
--	--

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

8. **Reprocess the claim transaction** through the pharmacy switch system.
Note: **Please wait approximately 2 minutes** before going back to the switch to reprocess the claim transaction.

If you experience any issues, please call the Clozapine REMS Program Contact Center at 844-267-8678.

47. How does a pharmacy certify in the Clozapine REMS Program?

To certify in the Clozapine REMS Program, the authorized representative of a pharmacy must:

- Complete the *Clozapine REMS Inpatient Pharmacy Enrollment Form* or the *Clozapine REMS Outpatient Pharmacy Enrollment Form*

- Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- Complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

Non-chain pharmacies can also certify online through the Clozapine REMS Program Website at www.clozapinerems.com, or by submitting the completed *Clozapine REMS Inpatient Pharmacy Enrollment Form* or the *Clozapine REMS Outpatient Pharmacy Enrollment Form* via fax to the Clozapine REMS Program Contact Center at 844-404-8876.

Chain pharmacies should work with their account managers from their pharmacy management system (i.e., “switch”) provider to become certified.

For additional information, call the Clozapine REMS Program Contact Center at 844-267-8678.

48. How often must pharmacies recertify?

Pharmacies are required to recertify in the Clozapine REMS Program every two (2) years from the date of the pharmacy’s original certification to maintain ability to order and dispense clozapine.

49. How does a pharmacy recertify in the Clozapine REMS Program?

Recertification requires that the authorized representative of the pharmacy has (re)certified by reviewing of the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, (re)attesting to the program requirements on the appropriate *Clozapine REMS Enrollment Form* for the pharmacy type, and successful completion of the *Clozapine REMS Knowledge Assessment for Healthcare Providers*. Pharmacy recertification may then be completed after the authorized representative is (re)certified. Recertification tasks may be completed on the Clozapine REMS Program Website at www.clozapinerems.com; or, by downloading and completing the appropriate type of *Clozapine REMS Pharmacy Enrollment Form (Inpatient, Outpatient, or Chain Headquarters)* and the *Clozapine REMS Knowledge Assessment for Healthcare Providers*, and faxing the completed/signed forms to 844-404-8876.

Note: Chain Headquarters Pharmacies may recertify only by completing and faxing the *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form* and *Clozapine REMS Knowledge Assessment for Healthcare Providers* to the Clozapine REMS Program Contact Center at 844-404-8876.

Additional assistance for questions or problem resolution may be obtained by calling the Clozapine REMS Contact Center at 844-267-8678.

50. What happens if a pharmacy does not recertify every 2 years?

Pharmacies that do not recertify every two years from the date of their original certification in the Clozapine REMS Program will be deactivated and will be unable to order or dispense clozapine.

51. What happens if a pharmacy is deactivated?

Deactivated pharmacies will be unable to order or dispense clozapine. Previously certified pharmacies will be unable to obtain a *Predispense Authorization* from the Clozapine REMS Program until recertified.

52. If my pharmacy is “deactivated,” what must be done?

If your pharmacy has been deactivated from the Clozapine REMS Program due to failure to recertify every 2 years, the pharmacy authorized representative should immediately recertify online at www.clozapinerems.com; or, download and complete the appropriate type of *Clozapine REMS Pharmacy Enrollment Form (Inpatient, Outpatient, or Chain Headquarters)* and the *Clozapine REMS Knowledge Assessment for Healthcare Providers*, and fax the completed/signed forms to 844-404-8876.

Additional assistance for questions or problem resolution may be obtained by calling the Clozapine REMS Program Contact Center at 844-267-8678.

Pharmacy Authorized Representative

53. What is an authorized representative?

Please refer to the FAQ on different roles of healthcare staff in the Clozapine REMS Program in the [General Section](#) of the FAQs.

54. Who should act as the authorized representative in the pharmacy?

Please refer to the FAQ on different roles of healthcare staff in the Clozapine REMS Program in the [General Section](#) of the FAQs.

55. When does certification need to be completed?

The new deadline for pharmacy certification is February 28, 2019. If you are not certified by this date your patient may not be eligible to receive clozapine from a pharmacy.

Pharmacies are required to verify and/or update their pharmacy classification upon recertification in the program. This pharmacy reclassification may change prescriber certification and patient safety requirements.

For more information, visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

56. What is the difference between an inpatient pharmacy and an outpatient pharmacy?

- A pharmacy that dispenses clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition), the pharmacy will be classified as an “inpatient pharmacy.”
- A pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, the pharmacy will be classified as an “outpatient pharmacy.”

If you feel your pharmacy is incorrectly classified or if your pharmacy dispenses to both patient groups, please call the Clozapine REMS Program Contact Center for further instructions at 844-267-8678.

57. What if I am in a pharmacy that dispenses clozapine for both inpatient and outpatient use?

The authorized representative will need to complete both the inpatient pharmacy enrollment and outpatient pharmacy enrollment. The authorized representative can complete enrollment through the Clozapine REMS Program Website or by completing the *Clozapine REMS Inpatient Pharmacy Enrollment Form* and the *Clozapine REMS Outpatient*

Pharmacy Enrollment Form and faxing them to the Clozapine REMS Program at 844-404-8876.

For additional questions, please call the Clozapine REMS Program Contact Center at 844-267-8678.

58. What is “the switch”?

The term “the switch” refers to a technical solution that allows pharmacies to adjudicate prescription information simultaneously through both the Clozapine REMS Program to obtain the PDA and their Pharmacy Management System (PMS) to obtain insurance claim payments via electronic communication using established telecommunications standards.

59. What happens to patients who try to fill a prescription at a pharmacy that is not certified?

Beginning on February 28, 2019, if a pharmacy is not certified in the Clozapine REMS Program, a patient presenting a clozapine prescription at that pharmacy location will not receive clozapine regardless if the patient meets other program element requirements as defined by the Clozapine REMS Program (patient is enrolled and has ANC on file with acceptable values per the Prescribing Information).

Pharmacies must become certified in the Clozapine REMS Program by February 28, 2019 in order to obtain clozapine from a wholesaler.

60. Will pharmacies that are not certified be able to order and receive clozapine?

Starting on February 28, 2019, if a pharmacy is not certified in the Clozapine REMS Program, the pharmacy will not be able to order and receive clozapine, regardless if they were in any of the previous individual manufacturer registries.

Access the pharmacy certification procedure [here](#)

61. The pharmacy has been certified but the system is reporting that the pharmacy is not certified. What are the next steps?

Please ensure you have completed the steps listed on the certification page. If you are still experiencing issues, please call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

62. Will patients still need to have blood draws?

Yes; blood draws for ANC monitoring are required prior to dispensing. Monitoring frequency (i.e., weekly, every 2 weeks, or monthly) is determined by the patient's prescriber based on criteria in the clozapine Prescribing Information.

63. Can clozapine be dispensed to a patient without bloodwork?

No; patients must have ANC's that are current according to their monitoring frequency and in the acceptable range. If there is no ANC on file in the patient's lab history, an ANC will be required before a PDA is provided. After the Clozapine REMS Program is fully implemented, if the ANC on file is not current based on the patient's monitoring frequency, a more recent ANC will be required before dispensing clozapine. (Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and available on the Clozapine REMS Program Website.)

If the ANC meets the criteria for moderate or severe neutropenia, a patient must have an appropriate *Treatment Rationale* provided to the Clozapine REMS Program prior to dispensing clozapine.

64. What actions are required if the prescribing physician isn't certified?

Prescribers who prescribe clozapine for outpatient use must be certified in the Clozapine REMS Program by February 28, 2019.

Prescribing clozapine for patients receiving inpatient care does not require prescriber certification in the Clozapine REMS Program if the patient is already enrolled in the program. If the patient is to be initiated on clozapine while admitted to an inpatient setting, a certified prescriber must enroll the patient in the Clozapine REMS Program prior to receiving the first dose of clozapine.

We encourage you to contact the prescriber to advise him or her of the need to certify in the Clozapine REMS Program. The Clozapine REMS Program *Dispense Rationale* provides certified outpatient pharmacies with an opportunity to apply clinical judgment and continue to dispense clozapine to enrolled patients when a patient's prescriber is not certified in the Clozapine REMS Program.

65. What should a pharmacist do with the patient's *ANC Lab Reporting Form*?

The pharmacist should enter the patient's ANC via the Clozapine REMS Program Website or fax it to the Clozapine REMS Program Contact Center at 844-404-8876. Once the information has been entered, the pharmacist may keep the form for his or her records, if desired. The length of time these records are kept is based on the policies implemented by each individual pharmacy or organization.

66. The pharmacy just certified and needs to order clozapine today. What are the next steps?

The Pharmacy should contact its wholesaler/distributor to inform them that the pharmacy just certified in the Clozapine REMS Program. If the wholesaler needs to verify certification, they can access the Certification Look-up on the Clozapine REMS Program Website or call the Clozapine REMS Program Contact Center at 844-267-8678 to verify the pharmacy's certification in the program.

67. What if the authorized representative leaves the pharmacy?

If the authorized representative leaves the pharmacy, the new authorized representative must notify the Clozapine REMS Program of the change in the authorized representative by certifying in the Clozapine REMS Program as soon as possible.

68. If the patient's prescription is denied or the *Eligibility Check* indicates "do not dispense," will the Clozapine REMS Program system explain the reason?

Yes; when a prescription is denied (i.e., a PDA is not generated), an appropriate message will be displayed to the pharmacy staff member.

There are several rejection reasons that could be provided for a patient. The following are examples of the most common rejection messages (actual messages may vary):

Outpatient Pharmacy using the pharmacy management system:

"*REMS* - ANC results out of range. Results Last ANC: 400 01/12/16; MF=7d

"*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient."

"*REMS* - ANC results not on file. Contact prescriber"

Outpatient Pharmacy using web-based PDA:

"*REMS* - ANC results out of acceptable range"

"*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient."

"*REMS* - ANC results not on file. Contact prescriber"

Inpatient Pharmacy:

"*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient."

Wholesaler/Distributor

69. Does a distributor have to enroll in the Clozapine REMS Program?

Yes; clozapine is only available through the Clozapine REMS Program. As part of a restricted distribution REMS program, distributors will need to enroll in the Clozapine REMS Program in order to be able to purchase and distribute clozapine.

70. How can a distributor enroll in the Clozapine REMS Program?

To enroll in the Clozapine REMS Program, a distributor should contact info@clozapinedistributor.com to have a *Clozapine REMS Distributor Enrollment Form* sent to via email.

A Customer Manager will help the distributor to complete a *Clozapine REMS Distributor Enrollment Form*. In completing the enrollment form, the distributor is required to indicate that they understand that clozapine is available only through the Clozapine REMS Program and they will comply with the program requirements.

71. How can enrolled distributors access a list of pharmacies that participate in the Clozapine REMS Program?

After enrollment, distributors can access the current list of certified pharmacies by:

- Downloading a current list of certified pharmacies from a secure FTP site
- Using the “Certification Look-up” feature on the Resources tab of the Clozapine REMS Program Website at www.clozapinerems.com to verify a pharmacy
- Calling the Clozapine REMS Program Contact Center at 844-267-8678

72. A pharmacy has requested clozapine, but they are not yet certified in the Clozapine REMS Program. Can my company still distribute clozapine to them?

Starting February 28, 2019, a pharmacy is only eligible to receive clozapine if the pharmacy has certified in the Clozapine REMS Program. If the pharmacy is not on the current list of certified pharmacies, you must not ship clozapine to that pharmacy.

73. If a pharmacy has requested clozapine but is not eligible to receive clozapine, how do I notify them?

If a Pharmacy orders clozapine, but is not certified in the Clozapine REMS Program, distributors should reject the order per their standard procedures. At that point, the pharmacy can contact the Clozapine REMS Program and start the certification process.

Technical Support

74. What if I need help using the Clozapine REMS Program Website?

Call the Clozapine REMS Program Contact Center for assistance at 844-267-8678.

75. What browser types and versions does the Clozapine REMS Program Website support?

We support the latest and previous releases of all major browsers on a rolling basis. Each time a new version is released; we begin supporting that version and typically stop supporting the third most recent version. Major browsers include Internet Explorer, Chrome, Firefox, and Safari.

76. How does the Clozapine REMS Program Website use cookies?

Our technical cookies are used to display the correct alerts and notifications on your dashboard that assist you in complying with the Clozapine REMS Program requirements.

We never store your unencrypted sensitive information in a cookie. Refer to our privacy policy to find more information about how we use cookies.

77. What do I do if I can't view a document on the Clozapine REMS Program Website?

If you are attempting to open a document but nothing appears, you may have a pop-up blocker installed on your browser or, if you're unable to open a .pdf file, you may not have the Adobe Reader software installed. To rectify this, disable the feature in your browser for pop-up blockers. To install Adobe Reader, visit the Adobe site [here](#).

78. How do I report a problem with the Clozapine REMS Program Website?

If you experience an outage or need to report a problem with the Clozapine REMS Program Website, please call the Clozapine REMS Program Contact Center at 844-267-8678.

79. Why does the Clozapine REMS Program Website use Captcha?

The Captcha on the Create Account page is used to ensure that only humans obtain accounts on the Clozapine REMS Program Website. The Captcha has been implemented to prevent abuse by automated scripts. To complete the Captcha, the user must type the letters of a distorted image that appears on the screen. If the Captcha image is difficult to read, the user can reload the Captcha image.

80. How do I obtain a username and password for the Clozapine REMS Program Website?

You can create a user account for the Clozapine REMS Program Website. You will be asked to provide your contact information and create a username and password. Once the information is submitted online, you will be sent an email with a link to use in order to verify your account.

81. What if I do not receive the verification email after I created my account?

If you did not receive the email with the verification link, please check your junk mail folder or call the Clozapine REMS Program Contact Center at 844-267-8678.

82. What do I do if I forgot my password?

If you forgot your password, you can use the “Forgot Password?” option in the upper right-hand corner of the page in the sign in section. Fill in the requested information and submit it online. A temporary password will be sent to your email address on file.

83. What do I do if I forgot my username?

If you forgot your username, you can use the “Forgot Username?” option in the upper right-hand corner of the page in the sign in section. Fill in the requested information and submit it online. Your username will be sent to your email address on file.

84. What do I do if my user account is locked?

If your user account is locked, please call the Clozapine REMS Program Contact Center at 844-267-8678 so a Clozapine REMS Program support agent can assist you in unlocking it.

85. How do I change my username and/or password?

To change your username and/or password select the drop-down arrow displayed next to your name in the upper right corner and select “My Profile.” Select the appropriate tab and enter the information in the fields and submit the information online. You will be sent either your username or a temporary password.

86. How does a Healthcare Provider create multiple accounts with the same email address?

If you are a health care provider with multiple roles in the Clozapine REMS Program, you may create multiple accounts by following this procedure:

- In the Create an Account screen, you may enter the same email address in the My Information section for each account being set up. (see [screenshot below](#))

Create Account

Please complete the form below and press **Submit**. The information you provide for your Username must be unique within the Clozapine REMS Program Website. Once you have submitted this form you will receive a verification email that includes a link. Please use the link to complete the activation process for your new web account. All fields below are required.

My Information

Sign in

 Use Email Address as Username Suggest Username

 I'm not a robot 

For additional information about the Clozapine REMS Program, please call 844-267-8678.

In the Sign In section, do not use your email address as the username or select the checkbox to use email address as username. Please create a unique username for each account you create.

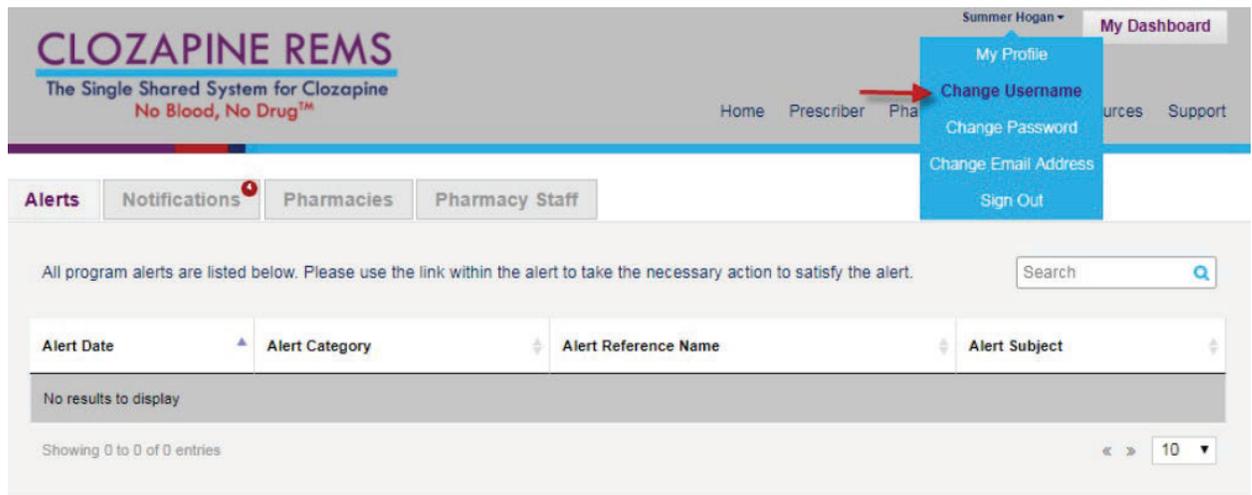
- You will need to log in to each account separately in order to access applicable role functionality.
 - For example, if you have an account as a prescriber designee and an account as a pharmacy staff, you would have to log out of one in order to access the other.

- A single log in for multiple roles is not available at this time.
- You will receive Clozapine REMS Program communications to a single email address if these steps are followed.

If you have any questions, call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

87. How does a Healthcare Provider change a website username if they wish to create multiple accounts and have already used their email address as the username previously?

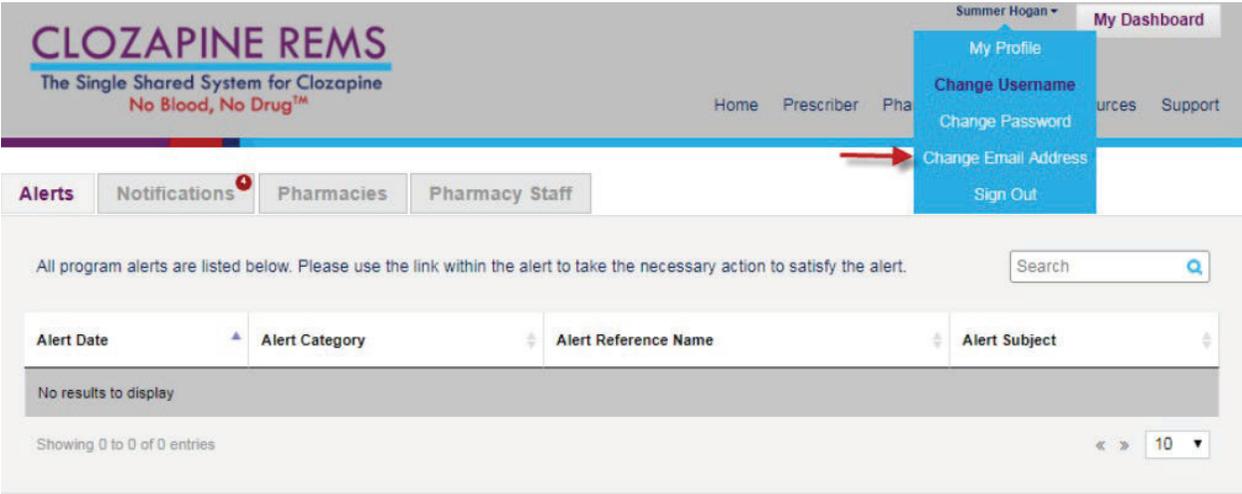
You may change your username by signing in to your account on the Clozapine REMS Program Website and selecting the Change Username option from the links below your account link in the upper right corner of the website. (see screenshot below)



For additional information about the Clozapine REMS Program, please call 844-267-8678.

88. How does a Healthcare Provider change the email address on their REMS profile if they previously created an account with an email address they no longer wish to use?

You may change your email address by signing in to your account on the Clozapine REMS Program Website and selecting the Change Email Address option from the links below your account link in the upper right corner of the website.



For additional information about the Clozapine REMS Program, please call 844-267-8678.

Patient

89. I am a clozapine patient. How do I know if I'm enrolled in the Clozapine REMS Program? If I'm not enrolled, how do I become enrolled in the Clozapine REMS Program?

Please contact your Healthcare Provider for information on whether you are currently enrolled or how to become enrolled in the Clozapine REMS Program.

90. Where do I find a list of local pharmacies that participate in the Clozapine REMS Program?

Your Healthcare Provider can help you find a participating pharmacy. Please contact your Healthcare Provider for additional information about the Clozapine REMS Program.

- The “**Eligibility Check**” (EC) evaluates criteria established by the Clozapine REMS Program to determine if it is safe to dispense clozapine to patients receiving inpatient medical care. This includes absolute neutrophil count (ANC) values.
- **An EC must be completed before dispensing an inpatient’s first dose of clozapine by using the Clozapine REMS Program Website at www.clozapinerems.com, or by calling the Clozapine REMS Program Contact Center at 844-267-8678.**
- **An EC requires an ANC value which may be obtained through the Clozapine REMS Program, or by checking the patient’s medical records.**
- Inpatient pharmacies are encouraged to submit the patient’s ANC via the Clozapine REMS Program Website, by phone, or by fax according to the patient’s monitoring frequency (i.e., within 7 days of the EC date for weekly monitoring, within 15 days for every two weeks monitoring and within 31 days for monthly monitoring).

HOW CAN I PERFORM AN ELIGIBILITY CHECK?

Option 1: Use the Clozapine REMS Program Website:

- **Log in to your account at www.clozapinerems.com**
- **Access** the dashboard
- **Select ‘Eligibility Check’** from the drop-down menu and **click** the **GO** button
- **Enter the patient information** on the ‘*Eligibility Check*’ screen and **click Submit**
- A success message will appear or you will receive a warning message that will inform you of next steps to take. Refer to page 2 of this *Clozapine REMS Eligibility Check Fact Sheet* for further guidance.

Option 2: Call the Clozapine REMS Program Contact Center at 844-267-8678.

HOW CAN I SUBMIT ANC VALUES?

Pharmacies are encouraged to submit ANC values to the Clozapine REMS Program according to the patient’s monitoring frequency by utilizing one of the following methods:

Option 1: Submit via the Clozapine REMS Program Website:

- **Log in to your account at www.clozapinerems.com**
- **Access** the dashboard
- **Select ‘Add Lab’** from the drop-down menu and **click** the **GO** button
- **Enter the patient information and ANC results** on the ‘Add Lab’ screen and **click Submit**
- User will be returned to the dashboard when complete

Option 2: Fax to the Clozapine REMS Program:

- **Visit www.clozapinerems.com**
- **Choose** the **Resources** tab
- **Click** on **Program Materials**
- **Select ‘Clozapine REMS ANC Lab Reporting Form’** from the list
- **Print and complete the form**
- **Fax the completed form to 844-404-8876**

Note: ANC values will be available immediately if submitted on the Clozapine REMS Program Website, but may be delayed up to 48 hours for processing of the paper form.

Option 3: Call the Clozapine REMS Program Contact Center at 844-267-8678.

ELIGIBILITY CHECK FACT SHEET

For INPATIENT PHARMACIES

Phone: 844-267-8678

Fax: 844-404-8876

www.clozapinerems.com

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

REMS PROGRAM ELEMENT EVALUATED BY THE <i>ELIGIBILITY CHECK</i>	POSSIBLE OUTCOMES	ELIGIBILITY TO RECEIVE CLOZAPINE	ACTION BY PHARMACY
Patient enrollment in the Clozapine REMS Program	Patient is enrolled.	<i>Eligibility Check Successful.</i>	No action necessary. Dispense.
	Patient is not enrolled.	<i>Eligibility Check Unsuccessful.</i>	Do not dispense. Contact a <u>certified</u> prescriber (or his designee) to enroll new patient.
Patient absolute neutrophil count (ANC) is on file	ANC on file.	<i>Eligibility Check Successful.</i>	Check if ANC is acceptable. Dispense.
	No ANC on file.	A warning message will be displayed but patient will remain eligible to receive clozapine.	Check inpatient's medical record to verify ANC. Apply clinical judgement whether to dispense. ² Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency. ¹
Last ANC value on file is acceptable	ANC is acceptable.	<i>Eligibility Check Successful.</i>	No action necessary. Dispense.
	ANC on file for patient indicates moderate or severe neutropenia; and a "Treatment Rationale" ³ is on file.	<i>Eligibility Check Successful.</i>	No action necessary. Dispense.
	ANC on file for patient indicates moderate or severe neutropenia; and a <i>Treatment Rationale</i> ³ is not on file.	A warning message will be displayed but patient will remain eligible to receive clozapine.	Check patient's inpatient medical record to verify ANC is acceptable. Apply clinical judgement whether to dispense. ²
ANC is current according to the patient's monitoring frequency ¹	ANC is current.	<i>Eligibility Check Successful.</i>	No action necessary. Dispense.
	ANC is not current.	A warning message will be displayed but patient will remain eligible to receive clozapine.	Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency. ¹ Apply clinical judgement whether to dispense. ²

¹Monitoring frequency:

- For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the *Eligibility Check* date.
- For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the *Eligibility Check* date.
- For monthly monitoring frequency, the ANC submitted to the Clozapine REMS must be drawn* within 31 days prior to the *Eligibility Check* date.

*Assumes lab draw date is day 0

²Apply clinical judgement to determine if the benefits of clozapine outweigh its risks if a patient has an ANC indicating moderate or severe neutropenia.

³*Treatment Rationale*: a justification provided by a certified prescriber which allows a patient having moderate or severe neutropenia to continue treatment with clozapine.

Reference ID: 4376730

BEFORE STARTING CLOZAPINE TREATMENT

- > Before starting treatment with clozapine, the baseline absolute neutrophil count (ANC) must be:
 - At least 1500/μL for the general population, or
 - At least 1000/μL for patients with documented benign ethnic neutropenia (BEN)
- > It is no longer necessary to check the National Non-Rechallenge Master File (NNRMF) before starting treatment.
 - The NNRMF is no longer available. All patients who were listed in the NNRMF were transferred into the Clozapine REMS Program. These patients are identified with a red flag  in the Clozapine REMS Program.

MONITORING AND DURING TREATMENT

LABS

- > Prescribers must submit ANC according to the patient's monitoring frequency (MF) on file with the Clozapine REMS Program:
 - For weekly MF, ANC must be submitted within 7 days of the lab draw* date
 - For every two weeks MF, ANC must be submitted within 15 days of the lab draw* date
 - For monthly MF, ANC must be submitted within 31 days of the lab draw* date

*Assumes the lab draw date is day 0
- > White blood cell (WBC) counts are not accepted. If you have a WBC count and differential, you may use the ANC calculator on the Clozapine REMS Program Website at www.clozapinerems.com to determine the ANC.
- > An ANC is normal if it is greater than or equal to 1500/μL for the general population, or greater than or equal to 1000/μL for patients with BEN.

MONITORING FREQUENCY

- > Patients may transition to less frequent ANC monitoring based on their history of continuous clozapine therapy and normal ANCs.
 - Weekly ANC monitoring is required for all patients during the first six months of treatment.
 - If the patient's ANC remains in the normal range for the first six months of therapy, MF may be reduced to once every two weeks.
 - If the patient's ANC continues to remain in the normal range for the second six months of treatment, ANC MF may be reduced to once monthly.
- > Monitoring frequency is calculated based on the patient's lab history in the Clozapine REMS Program. It is critical that all labs be submitted to the Clozapine REMS Program according to the patient's MF to ensure that the patient's monitoring frequency does not revert to a more frequent schedule.
 - The Clozapine REMS Program made every effort to consolidate ANC data for patients with laboratory data in multiple individual manufacturer registries to create complete patient records. Patients with complete profile information in the individual manufacturer registries were migrated to the Clozapine REMS Program successfully, but may have had different monitoring frequencies across multiple individual manufacturer registries and/or had a significant gap in ANC data when patient data was consolidated from the multiple individual manufacturer registries.
 - In accordance with the clozapine Prescribing Information, if the patient had consistent ANCs submitted over the previous 12-month period, the patient was migrated with a monthly MF.
 - If a patient's ANCs were inconsistently submitted to the registries in the previous 12-month period and there was a timeframe longer than 56 days between blood draw dates, the patient was migrated with a weekly MF.
 - The guidelines outlined above for assigning a new MF are consistent with the Prescribing Information.
 - If a prescriber needs to change a patient's MF, the prescriber may do so via the Prescriber Dashboard on the Clozapine REMS Program Website. The prescriber or prescriber designee may also update a patient's MF by calling the Clozapine REMS Program Contact Center at 844-267-8678.
 - During the phased implementation period, the Clozapine REMS Program will not deny clozapine dispensing based on MF data. However, once the REMS Program is fully implemented, the MF is utilized to determine if a patient's ANC is current. Therefore, accuracy of the MF is important as a factor in determining if a pharmacy will be authorized to dispense clozapine to the patient.

TREATMENT INTERRUPTIONS

- > Treatment interruptions are now recommended at lower ANC thresholds than in previous versions of the Prescribing Information.
 - For general population patients, interrupt treatment if neutropenia is suspected to be clozapine-induced for ANC less than 1000/μL.
 - For patients with documented BEN, interrupt treatment if neutropenia is suspected to be clozapine-induced for ANC less than 500/μL.
 - See Table 1 in the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or Tables 2 and 3 in the clozapine Prescribing Information for more detailed treatment guidance.
- > Prescribers may use clinical judgment to continue treatment with clozapine for patients with moderate or severe neutropenia if they determine that the benefits of clozapine therapy outweigh the risks. The prescriber must provide a "Treatment Rationale" in the Clozapine REMS Program to avoid treatment interruptions.
 - A prescriber can provide a *Treatment Rationale* via the Prescriber Dashboard on the Clozapine REMS Program Website or by calling the Clozapine REMS Program Contact Center at 844-267-8678.

BEN PATIENTS

- > Patients with documented BEN have specific treatment guidelines in the clozapine Prescribing Information (see Table 1 in the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or Table 3 in the clozapine Prescribing Information for details).

HOSPICE PATIENTS

- > Patients in hospice may be excluded from certain program requirements (see Section 8.8 of the clozapine Prescribing Information).

DISCONTINUING CLOZAPINE TREATMENT

- > Four weeks of weekly monitoring for patients who are discontinuing clozapine treatment is no longer required.
- > The duration and frequency of ANC monitoring is dependent on that patient's last ANC and clinical status (see Section 2.4 in the clozapine Prescribing Information for more details).

A “**Predispende Authorization**” (PDA) determines if a patient is eligible to receive clozapine and provides an authorization for an **outpatient pharmacy** to dispense. An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis, including but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

Outpatient pharmacies must obtain a PDA each time before dispensing clozapine. PDAs may be obtained through the pharmacy management system (via the switch network), via the Clozapine REMS Program Website at www.clozapinerems.com, or by calling the Clozapine REMS Program Contact Center at 844-267-8678.

CLOZAPINE REMS PROGRAM ELEMENT EVALUATED BY THE PREDISPENDE AUTHORIZATION	POSSIBLE OUTCOMES	ELIGIBILITY TO RECEIVE CLOZAPINE	ACTION BY PHARMACY
		All PDA responses will provide the dispensing pharmacy with the most recent absolute neutrophil count (ANC) value, the associated blood draw date, and the patient's monitoring frequency ¹	Pharmacies are encouraged to submit the patient's ANCs through the Clozapine REMS Program Website, by phone, or by fax according to the patient's monitoring frequency ¹
Patient enrollment in the Clozapine REMS Program	Patient is enrolled	PDA Successful	No action necessary. Dispense.
	Patient is not enrolled	PDA Unsuccessful	Contact a <u>certified</u> prescriber (or his designee) to enroll new patient. Do not dispense.
Prescriber Certification	Prescriber is certified	PDA Successful	No action necessary. Dispense.
	Prescriber is not certified	PDA Unsuccessful	Contact prescriber to inform them they must be certified. Pharmacy can provide a “Dispense Rationale” and reattempt PDA. ²
Pharmacy Certification	Pharmacy is certified	PDA Successful	No action necessary. Dispense.
	Pharmacy is not certified	PDA Unsuccessful	Contact Pharmacy Manager to inform them the pharmacy must be certified to order, purchase, and dispense clozapine. Do not dispense.
Patient ANC is on file	ANC on file	PDA Successful	No action necessary. Dispense.
	No ANC on file	PDA Unsuccessful: A warning message will be displayed, reattempt PDA ² after ANC is obtained	If the pharmacist is in possession of an ANC, they are encouraged to submit the ANC to the Clozapine REMS Program; if not, contact the patient's certified prescriber. Reattempt PDA ² after ANC is obtained.
Last ANC value on file is acceptable	ANC is acceptable	PDA Successful	No action necessary. Dispense.
	ANC indicates moderate or severe neutropenia; and a “Treatment Rationale” <u>is</u> on file	PDA Successful	No action necessary. Dispense.
	ANC on file for patient indicates moderate or severe neutropenia; and a <i>Treatment Rationale</i> <u>is not</u> on file	PDA Unsuccessful: A warning message will be displayed	Do not dispense , unless one of these two possible follow-up actions are successful: <ul style="list-style-type: none"> If the pharmacist is in possession of an ANC that is more current and acceptable, the pharmacist is encouraged to submit the ANC to the Clozapine REMS Program and reattempt PDA.² Contact the prescriber to provide a <i>Treatment Rationale</i> or current acceptable ANC, reattempt the PDA.²
ANC is current according to the patient's monitoring frequency: ¹	ANC is current	PDA Successful	No action necessary. Dispense.
	ANC is not current	PDA Successful: a warning message will be displayed	Dispense clozapine; and: <ul style="list-style-type: none"> Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency.¹ Contact Prescriber to inform them that the ANC is not current according to the patient's monitoring frequency.¹

¹Monitoring frequency:

- For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the PDA date.
- For every two weeks monitoring frequency, the last ANC result submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the PDA date.
- For monthly monitoring frequency, the last reported ANC result submitted to the Clozapine REMS must be drawn* within 31 days prior to the PDA date.

*Assumes lab draw date is day 0

²Wait approximately 2 minutes to reprocess the claim transaction through the pharmacy switch system.

HOW DO I REQUEST A PREDISPENSE AUTHORIZATION?

Pharmacies using a pharmacy management system (via the switch network):

1. **Process all clozapine claims, including cash claims,** through the pharmacy management system.
2. Responses:
 - a. A **success** message will appear; **displaying the PDA and recent ANC information, or**
 - b. A **warning** message will inform you of next steps to take. Refer to page 1 of this *Fact Sheet* for further guidance.

Pharmacies that do not use an electronic pharmacy management system (without switch network access):

Option 1: Use the Clozapine REMS Program Website to:

1. **Log in** to your account at www.clozapinerems.com
2. **Access the dashboard**
3. **Select 'Predispense Authorization' from the drop-down menu and click the GO button**
4. **Enter the patient information on the 'Predispense Authorization' screen and click Submit**
5. The '*Predispense Authorization Result*' screen will appear with a success or warning message. Refer to page 1 of this *Fact Sheet* for further guidance.

Option 2: Call the Clozapine REMS Program Contact Center at 844-267-8678.

HOW CAN I PROVIDE A DISPENSE RATIONALE?

When a PDA is denied with the warning message: "Prescriber not certified in the Clozapine REMS Program" for an enrolled patient, a certified authorized representative or enrolled pharmacy staff in a certified pharmacy may exercise clinical judgment and continue to dispense clozapine by providing a *Dispense Rationale* electronically via one of two processes below:

Option 1: Pharmacies using the Clozapine REMS Program Website to request a PDA should:

1. **Continue from Step 2b above at the PDA Result reject message screen.**
2. **Click the 'Provide a Dispense Rationale for this patient' check box** at the bottom of the 'PDA Result' screen and **click the Submit** button.
3. If the *Dispense Rationale* was provided successfully, a success screen will appear.

Option 2: Pharmacies using the pharmacy network system (i.e., "switch") to request a PDA should:

1. **Log in** to the Clozapine REMS Program Website at www.clozapinerems.com.
2. **Access** the dashboard.
3. **Select 'Dispense Rationale' from the drop-down menu and click the Go button. Enter the patient information on the Dispense Rationale screen and click Submit.**
4. The '*Dispense Rationale Result*' screen will appear with a reject message similar to the switch reject message.
5. **Click on the 'Provide a Dispense Rationale for this patient' check box at the bottom of the 'Dispense Rationale Result' screen and click Submit.**
6. If the *Dispense Rationale* is provided successfully, a **success screen** will appear.
7. **Wait approximately 2 minutes to reprocess the claim transaction** through the pharmacy switch system.

Option 3: Call in to the Clozapine REMS Program Contact Center at 844-267-8678

HOW DO I SUBMIT ANC VALUES?

Pharmacies are encouraged to submit the patient's ANC according to the patient's monitoring frequency by utilizing one of the following methods:

Option 1: Submit via the Clozapine REMS Program Website by:

1. **Logging in** at www.clozapinerems.com
2. **Accessing** the dashboard
3. **Selecting 'Add Lab'** from the drop-down menu and **click the GO button**
4. **Entering the patient information and ANC results** on the 'Add Lab' screen and **click Submit**
5. User will be returned to the dashboard when completed.

Option 2: Fax to the Clozapine REMS Program by:

1. **Logging in to your account** at www.clozapinerems.com
2. **Choosing** the *Resources* tab
3. **Clicking** on *Program Materials*
4. **Selecting 'Clozapine REMS ANC Lab Reporting Form'** from the list
5. Printing and completing the form
6. **Faxing the completed form to 844-404-8876.**

NOTE: ANC values will be available immediately when submitted via the Clozapine REMS Program Website, but are delayed up to 48 hours for processing of the paper form.

Option 3: Call in to the Clozapine REMS Program Contact Center at 844-267-8678

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

Website Screen Captures 02/2019 REMS Modification

Clozapine REMS Program

November 2018

Table of Contents

1.	Static Pages	10
1.1	Home Page	10
1.2	Site Guide – Prescriber Tab	11
1.3	Site Guide – Pharmacy Tab	12
1.4	Site Guide – Patient Tab	13
1.5	Site Guide – Designee Tab	14
1.6	Site Guide – Pharmacy Staff Tab.....	15
1.7	Prescriber Certification.....	16
1.8	Prescriber Designee Certification.....	17
1.9	Pharmacy Certification.....	18
1.10	Pharmacy Staff Enrollment.....	19
1.11	Patient Information – Home Page.....	20
1.12	Program Materials	21
1.13	Prescribing Information	23
1.14	Certification Lookup	24
1.15	Certification Lookup Results	25
1.16	Site Map	26
1.17	FAQs	27
1.18	FAQ – Pharmacy Authorized Representative	30
1.19	Contact Us	31
2.	User Identification and Record Search	32
2.1	User Identification.....	32
2.2	Phone/Fax User Prescriber Search.....	33
2.3	Phone/Fax User Prescriber Search with Results	34
2.4	Phone/Fax User Prescriber Designee Search.....	35
2.5	Phone/Fax User Prescriber Designee Search with Results	36
2.6	Phone/Fax User Pharmacy Search	37
2.7	Phone/Fax User Pharmacy Search with Results	38
2.8	Phone/Fax User	39
2.9	Phone/Fax User with Results	40
3.	Web Account	41

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

3.1	Create Account	41
3.2	Account Verification	42
3.3	Account Confirmation	43
4.	Prescriber Certification	44
4.1	Prescriber Intake	44
4.2	Prescriber Education Program	45
4.3	Prescriber Education Confirmation	46
4.4	Prescriber Intake Review	47
4.5	Prescriber Attestation	48
4.6	Prescriber Confirmation	49
5.	Prescriber Designee Certification.....	50
5.1	Prescriber Designee Intake.....	51
5.2	Prescriber Designee Education Program Page 1	52
5.3	Prescriber Designee Education Program Page 2.....	53
5.4	Prescriber Designee Knowledge Assessment.....	54
5.5	Prescriber Designee Knowledge Assessment Confirmation – Success	55
5.6	Prescriber Designee Knowledge Assessment Confirmation – Not Successful	56
5.7	Prescriber Designee Intake Review.....	57
5.8	Prescriber Designee Attestation	58
5.9	Prescriber Designee Confirmation.....	59
6.	Pharmacy Certification	60
6.1	Pharmacy Certification – Home Page	60
6.2	Role Selection – New User	61
6.3	Role Selection – Phone/Fax User	62
6.4	Role Selection Confirmation – Inpatient Pharmacy	63
6.5	Role Selection Confirmation – Outpatient Pharmacy	64
6.6	Role Selection Confirmation – Chain Headquarters Pharmacy	65
6.7	Authorized Representative Intake	66
6.8	Authorized Representative Confirmation	67
6.9	Pharmacy Intake	68
6.10	Pharmacy Re-classification	70

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

6.11	Pharmacy Education Program	76
6.12	Pharmacy Education Confirmation	77
6.13	Pharmacy Attestation – Inpatient Pharmacy	78
6.14	Pharmacy Attestation – Outpatient Pharmacy	79
6.15	Pharmacy Confirmation.....	80
6.16	Pharmacy Test Transactions	81
7.	Chain Pharmacy Certification.....	82
7.1	Chain Pharmacy Store Intake	82
7.2	Chain Pharmacy Store Confirmation	83
8.	Pharmacy Staff Enrollment.....	84
8.1	Enrollment Home Page	84
8.2	Pharmacy Search.....	85
8.3	Pharmacy Search Results.....	86
8.4	Pharmacy Staff Intake	87
8.5	Pharmacy Staff Attestation.....	88
8.6	Pharmacy Staff Confirmation	89
9.	Knowledge Assessment for Healthcare Providers.....	90
9.1	Knowledge Assessment for Healthcare Providers Landing Page	90
9.2	Knowledge Assessment Question 1	91
9.3	Knowledge Assessment Question 2	92
9.4	Knowledge Assessment Question 3	93
9.5	Knowledge Assessment Question 4	94
9.6	Knowledge Assessment Question 5	95
9.7	Knowledge Assessment Question 6	96
9.8	Knowledge Assessment Question 7	97
9.9	Knowledge Assessment Question 8	98
9.10	Knowledge Assessment Question 9	99
9.11	Knowledge Assessment Question 10.....	100
9.12	Knowledge Assessment Question 11.....	101
9.13	Knowledge Assessment Question 12.....	102
9.14	Knowledge Assessment Question 13.....	103
9.15	Knowledge Assessment Confirmation – Success.....	104

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

9.16	Knowledge Assessment Confirmation – Not Successful	105
10.	Patient Enrollment	106
10.1	Patient Intake.....	106
10.2	Patient Lab Intake.....	107
10.3	Patient Lab Intake with Treatment Rationale	108
10.4	ANC Calculator	109
11.	Stakeholder Profiles	110
11.1	Prescriber Profile.....	110
11.2	Prescriber Designee Profile	111
11.3	Authorized Representative Profile.....	112
11.4	Chain Headquarters Pharmacy Authorized Representative Profile	113
11.5	Chain Headquarters Pharmacy Profile	114
11.6	Pharmacy Staff Profile	115
12.	My Account	116
12.1	Forgot Username	116
12.2	Change Username.....	117
12.3	Change Username Confirmation.....	118
12.4	Change Password.....	119
12.5	Change Password Notification	120
12.6	Change Password Confirmation.....	121
12.7	Change Email Address	122
12.8	Change Email Address Confirmation	123
13.	Patient Groups	124
13.1	Manage Groups	124
13.2	Add Group	125
13.3	Change Group Name	126
13.4	Remove Group	127
13.5	Remove Group Warning	128
13.6	Reassign Patients.....	129
14.	Dashboard	130
14.1	Dashboard Alerts and Notifications	130
14.1.1	Dashboard Alerts	130

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.1.2	Dashboard Notifications	131
14.2	Prescriber Dashboard	132
14.2.1	Prescriber Dashboard Patient Tab Collapsed.....	132
14.2.2	Prescriber Dashboard Patient Tab Expanded	133
14.2.3	Definitions of Terms Pop-up.....	135
14.2.4	Add Lab, Change Treatment Status, and Change Monitoring Frequency for Prescribers	136
14.2.5	View Patient History Lab History Tab.....	137
14.2.6	View Patient History Treatment Status Tab	138
14.2.7	View Patient History Monitoring Frequency Tab	139
14.2.8	View Patient History Dispense Rationale Tab.....	140
14.2.9	View Patient Profile	141
14.2.10	Prescriber Dashboard Designees Tab	142
14.2.11	Add Designee with Results.....	143
14.2.12	Remove Designee.....	144
14.2.13	Approve Designee	145
14.3	Prescriber Designee Dashboard.....	146
14.3.1	Prescriber Designee Dashboard Patient Tab Collapsed.....	146
14.3.2	Prescriber Designee Dashboard Patient Tab Expanded.....	147
14.3.3	Definitions of Terms Pop-up.....	148
14.3.4	Add Lab and Change Treatment Status for Prescriber Designees	149
14.3.5	View Patient History: Lab History Tab	150
14.3.6	View Patient History: Treatment Status Tab.....	151
14.3.7	View Patient History: Monitoring Frequency Tab	152
14.3.8	View Patient History: Dispense Rationale Tab.....	153
14.3.9	View Patient Profile.....	154
14.3.10	Prescriber Designee Dashboard Prescribers Tab.....	155
14.3.11	Associate to Prescriber	156
14.3.12	Remove Designee Relationship.....	157
14.3.13	Cancel Designee Request	158
14.4	Pharmacy Dashboard – Inpatient Pharmacies	159
14.4.1	Inpatient Pharmacy Dashboard Pharmacies Tab	159

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.4.2	Add Lab	161
14.4.3	Add Lab – Successful	162
14.4.4	Add Lab – Unsuccessful	163
14.4.5	Eligibility Check	164
14.4.6	Eligibility Check Result – Successful	165
14.4.7	Eligibility Check Result – Successful with warning message	167
14.4.8	Eligibility Check Result – Unsuccessful	168
14.5	Pharmacy Dashboard – Outpatient Pharmacies	169
14.5.1	Dispense Rationale	171
14.5.2	Dispense Rationale Result Screen – Success	172
14.5.3	Dispense Rationale Result Screen – Success (After DR is issued)	173
14.5.4	Dispense Rationale Result Screen – Unsuccessful	174
14.6	Pharmacy Dashboard – Outpatient Pharmacies on switch	175
14.6.1	Predispense Authorization	177
14.6.2	Predispense Authorization Result – Successful	178
14.6.3	Predispense Authorization Result – Unsuccessful	179
14.6.4	Predispense Authorization Result – Success (After DR is issued)	180
14.6.5	View Pharmacy Profile	181
14.6.6	Remove Pharmacy	182
14.6.7	Recertify Pharmacy	183
14.6.8	Pharmacy Dashboard Pharmacy Staff Tab	192
14.6.9	Remove Pharmacy Staff	193
14.7	Chain Pharmacy Dashboard	194
14.7.1	Chain Pharmacy Dashboard Pharmacies Tab	194
14.7.2	View Pharmacy Profile	195
14.7.3	Remove Pharmacy	196
14.7.4	Chain Pharmacy Dashboard Pharmacy Staff Tab	197
14.7.5	Remove Pharmacy Staff	198
14.8	Pharmacy Staff Dashboard	199
14.8.1	Pharmacy Staff Dashboard Pharmacies Tab	199
14.8.2	Associate to Pharmacy	200
14.8.3	Eligibility Check	201

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.8.4	Eligibility Check Result – Unsuccessful	202
14.8.5	Predispense Authorization	203
14.8.6	Predispense Authorization Result – Unsuccessful	204
15.	Dispense Rationale – Static Pages.....	205
15.1	Home Page	205
16.	Dispense Rationale – Pharmacy Authorized Representative (Non-Switch).....	206
16.1	Pharmacy – Authorized Representative Dashboard.....	206
16.2	Pharmacy – Authorized Representative Predispense Authorization	207
16.3	Pharmacy – Authorized Representative Predispense Authorization Result - Successful	208
16.4	Pharmacy – Authorized Representative Predispense Authorization Result - Unsuccessful.....	209
16.5	Pharmacy – Authorized Representative Predispense Authorization Result – Successful	210
16.6	Pharmacy – Authorized Representative Predispense Authorization Result- Successful (After the Dispense Rationale is issued)	211
16.7	Pharmacy – Authorized Representative Predispense Authorization Result – Unsuccessful.....	212
17.	Dispense Rationale – Pharmacy Staff (Non-Switch)	213
	Pharmacy Staff Dashboard	213
17.1	Pharmacy Staff Predispense Authorization.....	214
17.2	Pharmacy Staff Predispense Authorization Result- Successful	215
17.3	Pharmacy Staff Predispense Authorization Result- Unsuccessful.....	216
17.4	Pharmacy Staff Predispense Authorization Result – Successful.....	217
17.5	Pharmacy Staff Predispense Authorization Result- Successful (After the Dispense Rationale is issued)	218
17.6	Pharmacy Staff Predispense Authorization Result – Unsuccessful	219
18.	Dispense Rationale – Pharmacy Authorized Representative (Switch)	220
18.1	Pharmacy – Authorized Representative Dashboard.....	220
18.2	Pharmacy – Authorized Representative Dispense Rationale	221
18.3	Pharmacy – Authorized Representative Dispense Rationale Result Screen-Success.....	222
18.4	Pharmacy – Authorized Representative Dispense Rationale Result Screen-Success (After DR is issued)	223

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

18.5 Pharmacy – Authorized Representative Dispense Rationale Result Screen - Unsuccessful	224
18.6 Pharmacy – Authorized Representative Eligibility Check Result-Successful	225
18.7 Pharmacy – Authorized Representative Eligibility Check Result-Unsuccessful	226
19. Dispense Rationale – Pharmacy Staff (Inpatient Pharmacy)	227
19.1 Pharmacy Staff Dashboard	227
19.2 Pharmacy Staff Eligibility Check	228
19.3 Pharmacy Staff Eligibility Check Result- Successful	229
19.4 Pharmacy Staff Eligibility Check Result	230
20. Dispense Rationale – Pharmacy Staff (Switch).....	231
20.1 Pharmacy Staff Dashboard	231
20.2 Pharmacy Staff Dispense Rationale	232
20.3 Pharmacy Staff Dispense Rationale Result- Success	233
20.4 Pharmacy Staff Dispense Rationale Result- Success (After DR is issued)	234
20.5 Pharmacy Staff Dispense Rationale Result- Unsuccessful.....	235
21. Dispense Rationale – Prescriber and Prescriber Designee	236
21.1 Prescriber and Prescriber Designee Dashboard	236
21.2 Prescriber and Prescriber Designee Dispense Rationale History	238

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1. Static Pages

1.1 Home Page

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

FAQs >>

Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Prescriber

All prescribers of clozapine products must certify in the Clozapine REMS Program. Certification requires prescribers to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

The 02/2019 Clozapine REMS Program Modification went live on 02/28/2019. Prescribers are required to certify in the Clozapine REMS Program as soon as possible to continue patient therapy. If prescribers are not certified at the time of the 02/2019 Clozapine REMS Program Modification, a dispense of clozapine will not be authorized for patients under their care. Click on the Important Program Update (IPU) button for more information.

[Start Prescriber Certification](#)

Pharmacy

All pharmacies dispensing clozapine products must certify in the Clozapine REMS Program. Certification requires pharmacies to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
- **Implement:** Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

The 02/2019 Clozapine REMS Program Modification went live on 02/28/2019. Pharmacies are required to certify in the Clozapine REMS Program. If pharmacies are not certified at the time of the 02/2019 Clozapine REMS Program Modification, a dispense of clozapine will not be authorized for patients under their care. Click on the Important Program Update (IPU) button for more information.

[Start Pharmacy Certification](#)

*****Important Program Update (as of 02/28/2019)*****

[Please click to open the IPU](#)

What is the Clozapine REMS Program?

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L), which can lead to serious and fatal infections. The requirements to prescribe, dispense, and receive clozapine are incorporated into a single shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the Food and Drug Administration (FDA) for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).

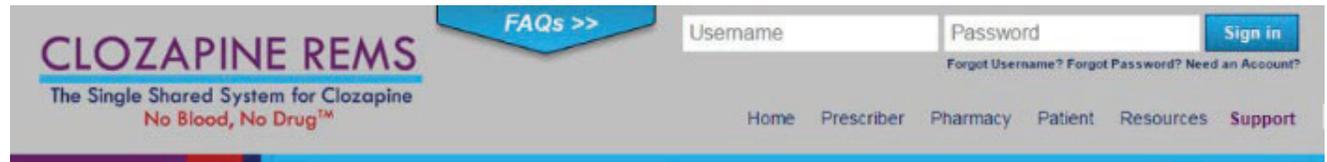
For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1.2 Site Guide – Prescriber Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists and patients. Additional information about the program is also available under the **Resources** and through the **FAQ's**, **Site Map**, and **Contact Us** links.

Prescriber	Pharmacy	Patient	Designee	Pharmacy Staff
-------------------	----------	---------	----------	----------------

Prescribers will begin the certification process by using the **Learn More** button below, which will navigate the prescriber to the certification landing page or by visiting the **Prescriber** link at the top of the page.

The **Prescriber** page provides specific steps that must be completed to prescribe clozapine. From the **Prescriber** page, prescribers can use the **Begin Now** button to start their certification process.

Once signed in to the site and your certification is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as enrolling new patients and adding ANC values. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

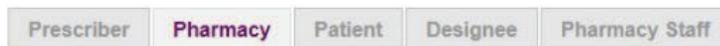
1.3 Site Guide – Pharmacy Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists and patients. Additional information about the program is also available under the **Resources** and through the **FAQ's**, **Site Map**, and **Contact Us** links.



Authorized representatives for a pharmacy will begin the certification process by using the **Learn More** button below, which will navigate the authorized representative to the certification landing page or by visiting the **Pharmacy** link at the top of the page.

The **Pharmacy** page provides specific steps that must be completed to dispense clozapine. From the **Pharmacy** page, authorized representatives can use the **Begin Now** button to start their certification process.

Once signed in to the site and your certification is complete, you can navigate to your **My Dashboard** to perform various activities that support the Clozapine REMS Program requirements such as adding ANC values and requesting predispose authorizations. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)



For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1.4 Site Guide – Patient Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists, and patients. Additional information about the program is also available under **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

Prescriber Pharmacy **Patient** Designee Pharmacy Staff

This site is for prescribers and pharmacists with patients on clozapine therapy. Patients must be enrolled in the program by a certified prescriber. If you believe you should be enrolled in the Clozapine REMS Program, please talk to your prescriber.

Additional information is available to patients by using the **Learn More** button below, which will navigate the patient to the patient information page or by visiting the **Patient** link at the top of the page.



[Learn More](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

1.5 Site Guide – Designee Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists and patients. Additional information about the program is also available under the **Resources** and through the **FAQ's**, **Site Map**, and **Contact Us** links.



Prescriber designees can learn more about the certification process by using the **Learn More** button below, which will navigate the prescriber designee to the to the certification landing page or by visiting the **Prescriber** link at the top of the page.

The **Prescriber Designee Certification** page provides specific steps that must be completed to become certified to prescribe clozapine. From the **Prescriber Designee** page, prescriber designees can use the **Begin Now** button to start their certification process.

Once signed in to the site and your certification is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as enrolling patients and adding ANC values. The **My Dashboard** page is the main portal for all activities performed on this site.

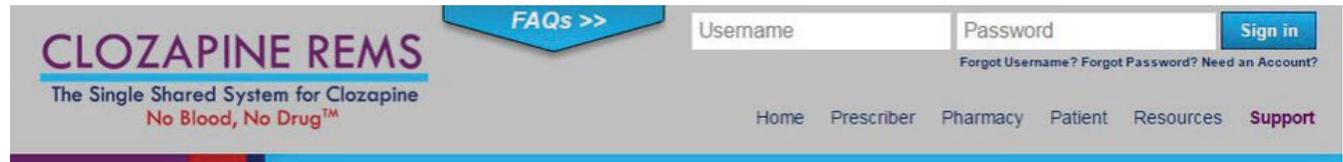
During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)



For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.6 Site Guide – Pharmacy Staff Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists and patients. Additional information about the program is also available under the **Resources** and through the **FAQ's**, **Site Map**, and **Contact Us** links.

Prescriber Pharmacy Patient Designee **Pharmacy Staff**

Pharmacy staff can learn more about the enrollment process by using the **Learn More** button below, which will navigate the pharmacy staff to the enrollment landing page or by visiting the **Pharmacy** link at the top of the page.

The **Pharmacy Staff** page provides specific steps that must be completed to dispense clozapine. From the **Pharmacy Staff Enrollment** page, pharmacy staff members can use the **Begin Now** button to start their enrollment process.

Once signed in to the site and your enrollment is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as adding ANC values and requesting *Predispense Authorizations*. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.7 Prescriber Certification

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[FAQs >>](#)

Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Prescriber Certification

Steps for Prescriber Certification

Prescribers must be certified in the Clozapine REMS Program to prescribe clozapine.

If you choose to allow designees to act on your behalf, each designee must be certified in the Clozapine REMS Program. For more information on the designee certification process, please go to [Prescriber Designee Certification](#).

Certification in the Clozapine REMS Program includes the following three steps:

- 1. Enroll:** Complete the Enrollment Form (name, address, NPI, DEA)
- 2. Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- 3. Assess:** Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [Clozapine REMS Prescriber Enrollment Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia](#)
- [Clozapine REMS How to Start Clozapine and Monitor Patients Fact Sheet](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

1.8 Prescriber Designee Certification



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Prescriber Designee Certification

Steps for Prescriber Designee Certification

The term designee refers to any person who has been designated or requested to perform some duty or function on behalf of a certified prescriber. Designees must be certified and approved in the Clozapine REMS Program before they can perform any duties or functions for their prescriber.

If you want to associate yourself to a pharmacy and have selected the Prescriber Designee Certification by accident, please go to [Pharmacy Staff Enrollment](#).

Prescriber Designee Certification in the Clozapine REMS Program includes the following three steps:

1. Enroll: Complete the Enrollment Form (name, address)

2. Educate: Review the REMS requirements

3. Confirm: Understanding of the requirements of the REMS

If the browser closes during certification, you can come back to the same point in the process

Please use the **Begin Now** button to start your certification today.

Begin Now!

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [Clozapine REMS Prescriber Designee Education Program](#)
-  [Clozapine REMS Prescriber Designee Enrollment Form](#)
-  [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
-  [Clozapine REMS Eligibility Check Fact Sheet](#)
-  [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.9 Pharmacy Certification

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

FAQs >>

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

Pharmacy Certification

Steps for Pharmacy Certification

All inpatient and outpatient pharmacies must be certified in the Clozapine REMS Program in order to purchase and dispense clozapine. Certification requires the identification of an authorized representative for the pharmacy to complete the certification process. The authorized representative must ensure all pharmacists with privileges to dispense understand that clozapine is only available to certified pharmacies through the Clozapine REMS Program.

Pharmacy Staff must enroll in the Clozapine REMS Program to obtain a *Predispense Authorization (PDA)* from the Clozapine REMS Program Website, to enter absolute neutrophil count (ANC), verify the prescriber is certified, or verify the patient is enrolled. If the pharmacy is a non-switch pharmacy to comply with the REMS, the pharmacy staff will either need to obtain a PDA by calling the program or by signing in to the website. For more information on the Pharmacy Staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Certification in the Clozapine REMS Program includes the following four steps:

1. Enroll: Complete the Enrollment Form (name, address, NPI, DEA)

2. Educate: Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*

3. Assess: Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

4. Implement: Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [Clozapine REMS Chain Headquarters Pharmacy Enrollment Form](#)
- [Clozapine REMS Inpatient Pharmacy Enrollment Form](#)
- [Clozapine REMS Outpatient Pharmacy Enrollment Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.10 Pharmacy Staff Enrollment

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[FAQs >>](#)

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

Pharmacy Staff Enrollment

Steps for Pharmacy Staff Enrollment

Pharmacy staff may include pharmacists or other individuals who assist in dispensing medication in a pharmacy. If your pharmacy is certified to dispense clozapine, pharmacy staff can enroll in the Clozapine REMS Program to have access to the Clozapine REMS Program Website. Pharmacy staff can link to multiple REMS-certified pharmacy locations.

Pharmacy staff enroll by creating an online account. Education is not required for enrollment but will be available after your enrollment is complete through your authorized representative.

For Outpatient Pharmacies: Pharmacy staff must enroll in the Clozapine REMS Program to obtain a *Predispose Authorization* (PDA) before dispensing each clozapine prescription. Pharmacy staff who are enrolled can obtain a PDA by calling the Clozapine REMS Program Contact Center or through electronic claim adjudication if your pharmacy has set up that process. Talk to your authorized representative if you are not sure how your pharmacy must obtain a PDA. Pharmacy staff must enroll to obtain a PDA through the Clozapine REMS Program Website.

For Inpatient Pharmacies: Pharmacy Staff must enroll to perform *Eligibility Checks* through the Clozapine REMS Program Website or the Clozapine REMS Program Contact Center.

Pharmacy staff enrollment in the Clozapine REMS Program includes the following two steps:

1. Enroll: Complete the Enrollment Form (name, address)

2. Attest: Complete and sign the Pharmacy Staff Attestation

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

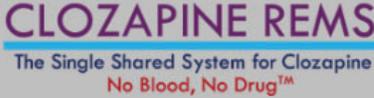
- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1.11 Patient Information – Home Page



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) **[Patient](#)** [Resources](#) [Support](#)

Patient Information

Because of the risk of developing severe neutropenia, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for clozapine.

The purpose of the Clozapine REMS Program is to make sure that the benefits of clozapine treatment outweigh the risks.

Prescribers must talk to their patients about the Clozapine REMS Program requirements and the risks of using clozapine. Patients should review the *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia* program material and talk with their prescriber if they have any questions or concerns about using clozapine.

Program Materials

-  [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

1.12 Program Materials

The screenshot displays the Clozapine REMS website interface. At the top, there is a navigation bar with the logo and tagline, a login section with 'Username' and 'Password' fields and a 'Sign in' button, and a menu with links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation bar, the 'Program Materials' section is active, showing a list of forms under the 'Forms' tab. The forms listed are: Clozapine REMS ANC Lab Reporting Form, Clozapine REMS Chain Headquarters Pharmacy Enrollment Form, Clozapine REMS Patient Enrollment Form, Clozapine REMS Inpatient Pharmacy Enrollment Form, Clozapine REMS Outpatient Pharmacy Enrollment Form, Clozapine REMS Prescriber Designee Enrollment Form, and Clozapine REMS Prescriber Enrollment Form. A 'Get ADOBE® READER' button is visible in the top right corner of the content area. At the bottom of the page, there is a footer with links for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us' and a note: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.'

Note: Resources included under the other tabs are listed below:

- Patient
 - *A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia*
- Pharmacy
 - *Clozapine REMS Eligibility Fact Check Sheet*
 - *Clozapine REMS PDA Fact Sheet*
 - *A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia*
 - *Dear Inpatient Pharmacy Letter*
 - *Dear Outpatient Pharmacy Using Web PDA Letter*
 - *Dear Outpatient Pharmacy Using Switch Letter*
 - *Clozapine REMS Inpatient Pharmacy Enrollment Form*
 - *Clozapine REMS Outpatient Pharmacy Enrollment Form*
 - *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form*

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

- *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* (Education Program and Knowledge Assessment)
- *Clozapine REMS Patient Enrollment Form*
- *Clozapine REMS ANC Lab Reporting Form*
- ANC Calculator
- ANC Monitoring Table

- Prescriber
 - *Clozapine REMS Prescriber Enrollment Form*
 - *Clozapine REMS Prescriber Designee Enrollment Form*
 - *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* (Education Program and Knowledge Assessment)
 - *A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia*
 - *Clozapine REMS How to Start Clozapine & Monitor Patients Fact Sheet*
 - *Clozapine REMS Patient Enrollment Form*
 - *Clozapine REMS ANC Lab Reporting Form*
 - ANC Calculator
 - ANC Monitoring Table
 - *Prescriber Designee Education Program*
 - *Prescriber Designee Acknowledgment Form*
 - *Dear Prescriber Letter*

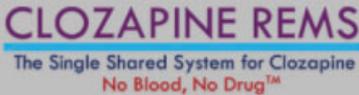
- Wholesaler/Distributor
 - Contact the Clozapine REMS Program by sending an email to info@clozapinedistributor.com

- Fact Sheets and Demos
 - *Clozapine REMS PDA Fact Sheet*
 - *Clozapine REMS Eligibility Check Fact Sheet*
 - *Clozapine REMS How to Start Clozapine & Monitor Patients Fact Sheet*
 - Prescriber Certification
 - Prescriber Designee Certification
 - Pharmacy Authorized Representative Certification and Pharmacy Certification
 - Pharmacy Staff Enrollment
 - How to View Prescriber Alerts and Notifications
 - How to Use the Prescriber Dashboard
 - How to Enter a *Treatment Rationale*
 - How Prescribers Enter ANCs and Manage Patients
 - How Prescribers Can Enter Labs
 - How Outpatient Pharmacies Obtain a Web *Predispense Authorization* (PDA)
 - How Outpatient Pharmacies Enter ANCs
 - How Inpatient Pharmacies Check Eligibility and Enter ANCs
 - How to Obtain a *Dispense Rationale*

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1.13 Prescribing Information



The Single Shared System for Clozapine
No Blood, No Drug™

FAQs >>

Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Prescribing Information

Products covered under the Clozapine REMS Program

Brand Name Products			
Trade Name	Generic Name	Company	Link
Clozaril®	Clozapine	HLS Therapeutics (USA), Inc.	Full Prescribing Information
FazaClo®	Clozapine, USP	Jazz Pharmaceuticals Inc.	Full Prescribing Information
Versacloz®	Clozapine, USP	Jazz Pharmaceuticals Inc.	Full Prescribing Information

Generic Products			
Trade Name	Generic Name	Company	Link
Clozapine	Clozapine Tablets, USP	Accord Healthcare Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Aurobindo Pharma USA Inc.	Full Prescribing Information
Clozapine	Clozapine, USP ODT	Jazz Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Mayne Pharma Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Mayne Pharma Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Mylan Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Orally Disintegrating Tablets	Mylan Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Mylan Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Orally Disintegrating Tablets	Mylan Pharmaceuticals Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Sun Pharmaceutical Industries Inc.	Full Prescribing Information
Clozapine	Clozapine Tablets, USP	Teva Pharmaceuticals USA Inc.	Full Prescribing Information
Clozapine	Clozapine, USP ODT	Teva Pharmaceuticals USA Inc.	Full Prescribing Information

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.14 Certification Lookup

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[FAQs >>](#)

Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Certification Lookup

To search for a pharmacy, please complete at least one field below and press **Search**. If an identifier is used for searching, no other fields need to be entered. Search results include contact information for pharmacies that are certified in the Clozapine REMS Program.

Pharmacy Information (at least one identifier is required):

or or and

and

or or

[Search](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

1.15 Certification Lookup Results



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Certification Lookup

To search for a pharmacy, please complete at least one field below and press **Search**. If an identifier is used for searching, no other fields need to be entered. Search results include contact information for pharmacies that are certified in the Clozapine REMS Program.

Pharmacy Information (at least one identifier is required):

or or and

and

or or

Pharmacy Name	Certification Id	Pharmacy Address	Pharmacy Phone	Pharmacy Type
Ikea Inc	FAC5413637605	4343 n scottsdale rd, PHOENIX, Arizona 85054	123-465-4687	Outpatient

Showing 1 to 1 of 1 entries

Navigation: < 1 > 10

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1.16 Site Map

FAQs >>

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Site Map

<u>Prescriber</u>	<u>Designee</u>	<u>Account</u>
Prescriber Certification Prescriber FAQs Prescriber Resources Prescriber Support	Prescriber Designee Certification Designee Support	Forgot Password Forgot Username Need an Account
<u>Pharmacy</u>	<u>Pharmacy Staff</u>	
Pharmacy Certification Pharmacy FAQs Pharmacy Resources Pharmacy Support	Pharmacy Staff Enrollment Pharmacy Staff Support	
<u>Patient</u>	<u>General</u>	
Patient FAQs Patient Information Patient Resources Patient Support	Contact Us General FAQs Prescribing Information Privacy Professional Societies Resources Technical Support FAQs Terms of Use Wholesaler/Distributor FAQs Wholesaler/Distributor Resources	

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1.17 FAQs

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Frequently Asked Questions (FAQs)

General	Prescriber	Prescriber Designee	Patient Mgmt	Pharmacy Mgmt	Pharmacy Auth Rep	Wholesaler/Distributor	Technical Support	Patient
<ul style="list-style-type: none">+ What is a REMS?+ What is the Clozapine REMS Program?+ What are the goals of the Clozapine REMS Program?+ Where can I obtain the Prescribing Information for clozapine?+ What are the different roles of healthcare staff in the Clozapine REMS Program?+ Can a Healthcare Provider fulfill multiple roles in the Clozapine REMS Program?+ How does a Healthcare Provider certify in more than one role in the Clozapine REMS Program (e.g., as a pharmacy staff and a prescriber designee)? Can the same email address be used for multiple roles in the Clozapine REMS Program?+ Why are white blood cell (WBC) counts no longer being collected?+ How frequently should a patient's ANC be monitored?+ When should I submit a patient's ANC to the Clozapine REMS Program?+ How do I contact the Clozapine REMS Program?+ How does a Healthcare Provider report an adverse event, product complaint, or obtain medical information about clozapine?+ What is the new certification deadline for prescribers and outpatient pharmacies?+ How is monitoring frequency determined in the Clozapine REMS Program?+ Why did established patients with monthly monitoring frequency get converted to weekly monitoring frequency?+ My existing clozapine patient was not migrated from the individual manufacturer registries and therefore the Clozapine REMS Program identifies this patient as new and has aligned this patient to a weekly monitoring frequency. How can I update the system so my patient is correctly returned to monthly monitoring frequency?								

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note:

Resources included under the other tabs are listed below:

- Prescriber
 - How can a prescriber become certified in the single shared Clozapine REMS Program?

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

- When do I need to complete certification?
- What are the changes for prescribers in an inpatient setting with the <MM/YYYY> Clozapine REMS Program Modification?
- If a prescriber is going to be out of the office for an extended period of time, can another prescriber cover during the absence?
- If a prescriber is going to be out of the office for a short period of time, can another prescriber write a prescription for the patient during the absence?
- Can a nurse practitioner, physician assistant, resident, or intern certify as a prescriber in the Clozapine REMS Program?
- Can a member of the prescriber's office staff help manage patients in the Clozapine REMS Program?
- How can a prescriber find a list of pharmacies that are certified in the Clozapine REMS Program?
- Where can I find the Patient ID for the Clozapine REMS ANC Lab Reporting Form?

- Prescriber Designee
 - What actions can a prescriber designee perform in the Clozapine REMS Program?

- Patient Management
 - Do patients need to be enrolled in the Clozapine REMS Program in order to receive clozapine?
 - How are patients enrolled into the Clozapine REMS Program?
 - Can a healthcare provider not certified in the Clozapine REMS Program submit an ANC?
 - Will the program send notices if the patient experiences a low ANC or substantial drop?
 - What is a Treatment Status?
 - What is a "Treatment Rationale"?
 - How can I provide a *Treatment Rationale*?
 - What happened to patients previously on the National Non-Rechallenge Master File (NNRMF)?
 - How are patient ANCs submitted to the Clozapine REMS Program?
 - Does the Clozapine REMS Program need to be advised when a patient is admitted to or discharged from an acute or long-term healthcare setting?
 - When discontinuing treatment, does the patient's ANC need to be monitored for 4 weeks?
 - If a patient is eligible to reduce their monitoring frequency does the Clozapine REMS Program need to be notified?
 - If the patient or caregiver will not provide the required information needed to complete Patient Enrollment (e.g., Name, Date of Birth) can they still receive clozapine?
 - How does a patient in an inpatient setting become enrolled if prescribers in this setting are not required to be certified in the Clozapine REMS Program?

- Pharmacy Management
 - What are the different pharmacy certification types in the Clozapine REMS Program?
 - What is a *Predispense Authorization (PDA)*?
 - What is an *Eligibility Check*?

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

- How is an *Eligibility Check* different from a *Predispense Authorization* (PDA)?
- What is a “Dispense Rationale?”
- How can I provide a *Dispense Rationale*?
- How does a pharmacy certify in the Clozapine REMS Program?
- How often must pharmacies *recertify*?
- How does a pharmacy recertify in the Clozapine REMS Program?
- What happens if a pharmacy does not recertify every 2 years?
- What happens if a pharmacy is deactivated?
- If my pharmacy is “deactivated,” what must be done?

- Wholesaler/Distributor
 - Does a distributor have to enroll in the Clozapine REMS Program?
 - How can a distributor enroll in the Clozapine REMS Program?
 - How can enrolled distributors access a list of pharmacies that participate in the Clozapine REMS Program?
 - A pharmacy has requested clozapine, but they are not yet certified in the Clozapine REMS Program. Can my company still distribute clozapine to them?
 - If a pharmacy has requested clozapine but is not eligible to receive clozapine, how do I notify them?

- Technical Support
 - What if I need help using the Clozapine REMS Program website?
 - What browser types and versions does the Clozapine REMS Program Website support?
 - How does the Clozapine REMS Program Website use cookies?
 - What do I do if I can't view a document on the Clozapine REMS Program Website?
 - How do I report a problem with the Clozapine REMS Program Website?
 - Why does the Clozapine REMS Program Website use Captcha?
 - How do I obtain a username and password for the Clozapine REMS Program Website?
 - What if I do not receive the verification email after I created my account?
 - What do I do if I forgot my password?
 - What do I do if I forgot my username?
 - What do I do if my user account is locked?
 - How do I change my username and/or password?
 - How does a healthcare provider create multiple accounts with the same email address?
 - How does a healthcare provider change a website username if they wish to create multiple accounts and have already used their email address as the username previously?
 - How does a healthcare provider change the email address on their REMS profile if they previously created an account with an email address they no longer wish to use?

- Patient
 - I am a clozapine patient. How do I know if I'm enrolled in the Clozapine REMS Program? If I'm not enrolled, how do I become enrolled in the Clozapine REMS Program?
 - Where do I find a list of local pharmacies that participate in the Clozapine REMS Program?

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1.18 FAQ – Pharmacy Authorized Representative

The screenshot shows the top navigation bar of the Clozapine REMS website. It includes the logo, a sign-in form with fields for Username and Password, and a 'Sign In' button. Below the navigation bar is a horizontal menu with links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. The main content area is titled 'Frequently Asked Questions (FAQs)' and features a tabbed interface. The 'Pharmacy Auth Rep' tab is selected, displaying a list of 15 questions related to pharmacy authorization, such as 'What is an authorized representative?' and 'Who should act as the authorized representative in the pharmacy?'. At the bottom of the page, there is a contact information line: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password Sign In
Forgot Username? Forgot Password? Need an Account?

Home Prescriber Pharmacy Patient Resources Support

Frequently Asked Questions (FAQs)

General	Prescriber	Prescriber Designee	Patient Mgmt	Pharmacy Mgmt	Pharmacy Auth Rep	Wholesaler/Distributor	Technical Support	Patient
---------	------------	---------------------	--------------	---------------	--------------------------	------------------------	-------------------	---------

- + What is an authorized representative?
- + Who should act as the authorized representative in the pharmacy?
- + When does certification need to be completed?
- + What is the difference between an inpatient pharmacy and an outpatient pharmacy?
- + What if I am in a pharmacy that dispenses clozapine for both inpatient and outpatient use?
- + What is "the switch"?
- + What happens to patients who try to fill a prescription at a pharmacy that is not certified?
- + Will pharmacies that are not certified be able to order and receive clozapine?
- + The pharmacy has been certified but the system is reporting that the pharmacy is not certified. What are the next steps?
- + Will patients still need to have blood draws?
- + Can clozapine be dispensed to a patient without bloodwork?
- + What actions are required if the prescribing physician isn't certified?
- + What should a pharmacist do with the patient's *ANC Lab Reporting Form*?
- + The pharmacy just certified and needs to order clozapine today. What are the next steps?
- + What if the authorized representative leaves the pharmacy?
- + If the patient's prescription is denied or the *Eligibility Check* indicates "do not dispense", will the Clozapine REMS Program system explain the reason?

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

1.19 Contact Us



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Contact Us

If you have any questions or require additional information, please contact the Clozapine REMS Program utilizing the information provided below.

Phone Number

844-267-8678

Fax Number

844-404-8876

Mailing Address

Clozapine REMS Program
PO BOX 29058
Phoenix, AZ 85038-9058

Program Manufacturers

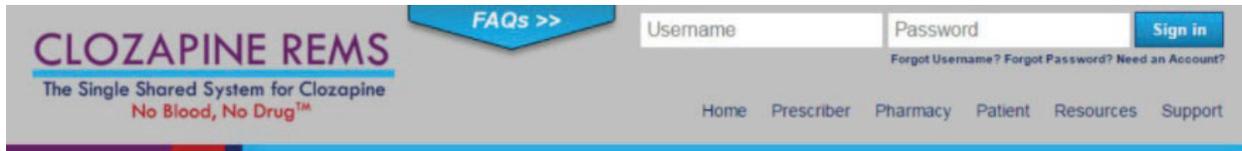
Company	Phone Number
Accord Healthcare Inc.	919-941-7878
Aurobindo Pharma USA Inc.	732-839-9400
HLS Therapeutics (USA) Inc.	844-457-8721
Jazz Pharmaceuticals Inc.	800-520-5568
Mayne Pharma Inc.	844-825-8500
Mylan Pharmaceuticals Inc.	800-796-9526
Sun Pharmaceuticals Industries Inc.	800-818-4555
Tasman Pharmaceuticals	257-317-4104
Teva Pharmaceuticals USA Inc.	800-292-4283

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

2. User Identification and Record Search

2.1 User Identification



User Identification

Please select the option below that **best** describes you and press **Next**.

What type of user are you? 

-- Please Select --
-- Please Select --
New User
Phone/Fax User
-- Please Select --

program role

New User - Users who are new to clozapine and have not previously submitted an enrollment form to the Clozapine REMS Program Contact Center.

Phone/Fax User - Users who submitted an enrollment form through the Clozapine REMS Program Contact Center via fax and have received an enrollment or certified ID.

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note:

Upon starting an enrollment or certification process the users are asked to identify what type of user they are and what their role is.

1 – The options for type of user are New User and Phone/Fax User. The tool-tip next to the field will include a definition of each for the user which are also below (Previous Registry User is now removed).

- New User – Users who are new to clozapine and have not previously submitted an enrollment form to the contact center clozapine registry
- Phone/Fax User – Users who submitted an enrollment form through the contact center via fax and have received an enrollment or certification ID.
 - When the system locates the user's record and creates a web account, the user's web account and their enrollment or certification record are linked.

2 – The options for role are Prescriber, authorized representative for pharmacy, Prescriber Designee, and Pharmacy Staff.

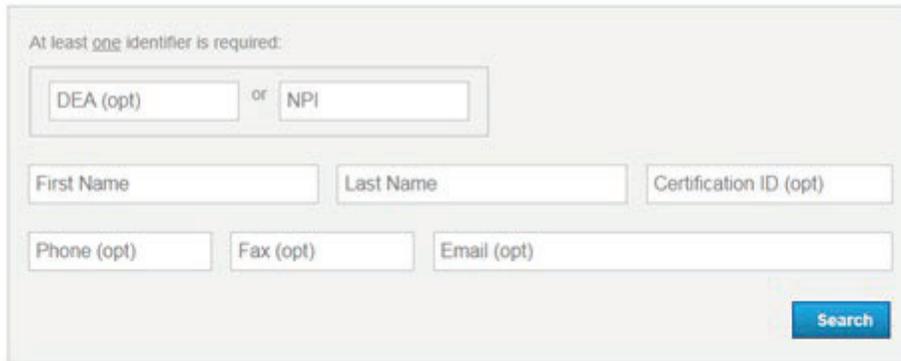
2.2 Phone/Fax User Prescriber Search



The header of the Clozapine REMS website. On the left is the logo: "CLOZAPINE REMS" in large blue letters, "The Single Shared System for Clozapine" in smaller blue letters, and "No Blood, No Drug™" in red. To the right of the logo is a login section with "Username:" and "Password:" labels, a "Sign in" button, and links for "Forgot Username?", "Forgot Password?", and "Need an Account?". Below the logo and login section is a navigation menu with links for "Home", "Prescriber", "Pharmacy", "Patient", "Resources", and "Support".

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.



A search form titled "Phone/Fax User". It contains the following fields and a search button:

- A note: "At least one identifier is required:"
- A group of two input fields: "DEA (opt)" and "NPI", separated by the word "or".
- Three input fields: "First Name", "Last Name", and "Certification ID (opt)".
- Three input fields: "Phone (opt)", "Fax (opt)", and "Email (opt)".
- A blue "Search" button.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

2.3 Phone/Fax User Prescriber Search with Results

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

At least one identifier below is required:

<input type="text" value="AB1234567"/>	<input type="text" value="NPI"/>	
<input type="text" value="Summer"/>	<input type="text" value="Hogan"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone
Summer	Hogan	555-555-5555

Showing 1 of 1 entries

[New User](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

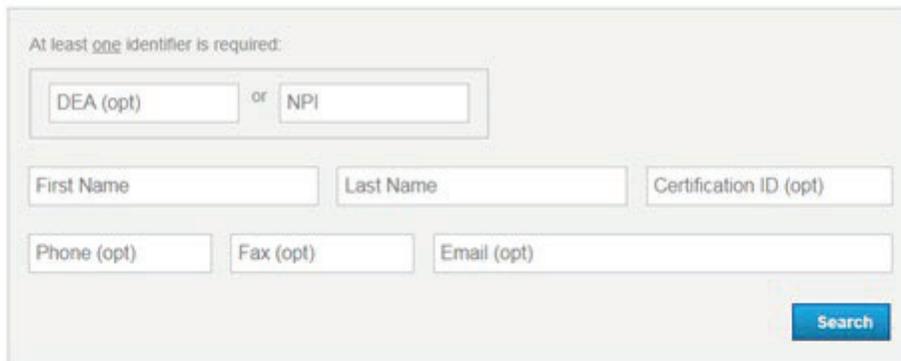
2.4 Phone/Fax User Prescriber Designee Search



The header of the Clozapine REMS website. On the left is the logo: "CLOZAPINE REMS" in large blue letters, "The Single Shared System for Clozapine" in smaller blue letters, and "No Blood, No Drug™" in red. To the right of the logo is a login section with "Username:" and "Password:" labels, a "Sign in" button, and links for "Forgot Username?", "Forgot Password?", and "Need an Account?". Below the logo and login section is a horizontal navigation menu with links for "Home", "Prescriber", "Pharmacy", "Patient", "Resources", and "Support".

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.



A search form titled "Phone/Fax User". It contains the following fields and a search button:

- A note: "At least one identifier is required:"
- A group of two input fields: "DEA (opt)" and "NPI", separated by the word "or".
- Three input fields: "First Name", "Last Name", and "Certification ID (opt)".
- Three input fields: "Phone (opt)", "Fax (opt)", and "Email (opt)".
- A blue "Search" button.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

2.5 Phone/Fax User Prescriber Designee Search with Results



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information

Designee Information

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone
Summer	Hogan	555-555-5555

Showing 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

2.6 Phone/Fax User Pharmacy Search

The screenshot shows the top portion of the Clozapine REMS website. On the left is the logo: "CLOZAPINE REMS" in large blue letters, with "The Single Shared System for Clozapine" and "No Blood, No Drug™" in smaller text below it. To the right of the logo are two input fields: "Username" and "Password", followed by a blue "Sign in" button. Below the password field are links: "Forgot Username? Forgot Password? Need an Account?". At the bottom of the header is a navigation menu with links: "Home", "Prescriber", "Pharmacy", "Patient", "Resources", and "Support".

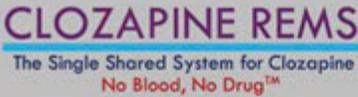
Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

The screenshot shows a search form with two main sections. The first section is titled "Pharmacy Information (at least one identifier is required):". It contains a "Zip Code" field followed by the word "and", and then three separate input fields for "DEA", "NPI", and "NCPDP". The second section is titled "Authorized Representative Information". It contains three input fields: "First Name", "Last Name", and "Certification ID (opt)". Below these are three more input fields: "Phone (opt)", "Fax (opt)", and "Email (opt)". A blue "Search" button is located at the bottom right of the form.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

2.7 Phone/Fax User Pharmacy Search with Results



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="AB1234567890"/>	<input type="text" value="NPI"/>	<input type="text" value="NCPDP"/>
------------------------------------	-----	---	----------------------------------	------------------------------------

Authorized Representative Information

<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Pharmacy Phone
Summer	Hogan	Joey's Apothecary	1 Main Street, New York, NY 10001	555-555-5555

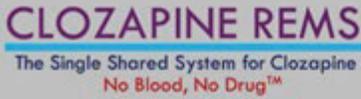
Showing 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

2.8 Phone/Fax User



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Authorized Representative Information

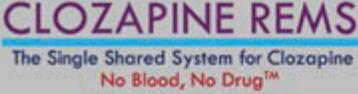
For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

2.9 Phone/Fax User with Results



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Authorized Representative Information

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or press the **New User** button to begin your enrollment process in the Clozapine REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Phone
Summer	Hogan	Joey's Apothecary	1234 W Nowhere Lane Tempe, AZ 85283	555-555-5555

Showing 1 of 1 entries 1 of 10

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

3. Web Account

3.1 Create Account

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Create Account

Please complete the form below and press **Submit**. The information you provide for your Username must be unique within the Clozapine REMS Program Website. Once you have submitted this form you will receive a verification email that includes a link. Please use the link to complete the activation process for your new web account. All fields below are required.

My Information

First Name

Last Name

Email Address

Confirm Email Address

Phone Number

Sign in

UserName

Use Email Address as Username [Suggest Username](#)

Password

Confirm Password

I'm not a robot  [Privacy](#) [Terms](#)

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

3.2 Account Verification

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Account Verification



A verification email has been sent to remsprogram@gmail.com.
Please use the link within the email to activate your web account for
the Clozapine REMS Program.

Account Summary

Name [Summer Hogan](#)
Email Address remsprogram@gmail.com
Phone Number [480-555-5555](tel:480-555-5555)
Username [summerhogan](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

3.3 Account Confirmation

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Account Confirmation



✔ Your web account has been successfully activated. Please sign in to your account using the fields in the upper right corner of this page.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

4. Prescriber Certification

4.1 Prescriber Intake

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Prescriber Intake

To certify as a prescriber in the Clozapine REMS Program, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Prescriber Information

First Name MI (opt)

Last Name

-- Credentials -- ▾

Email Address

Clinic / Practice Name

Address

Address 2 (opt)

City

-- State -- ▾ Zip Code

Phone Ext (opt)

Fax

-- Contact Preference -- ▾

Prescriber Identifiers

DEA

NPI

I do not have a DEA.

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

4.2 Prescriber Education Program

The screenshot shows the user interface for the Clozapine REMS Prescriber Education Program. At the top, the logo and tagline are repeated. A navigation bar includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A progress bar shows steps: Start, Intake, Education (active), Assessment, Review, Attestation, and Finish. The 'Education Program' section contains a paragraph of instructions. Below is a preview of the education material, which includes a disclaimer and a title: 'Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers'. A 'Next' button is visible at the bottom right of the preview. At the bottom of the page, there is a contact number: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a footer with links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Start Intake Education Assessment Review Attestation Finish

Education Program

Below is the education program for clozapine. Please review the program materials and press the **Next** button to continue. It is estimated that it will take 15-20 minutes to complete the Education Program and Clozapine REMS Knowledge Assessment for Healthcare Providers.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

This guide is intended to educate Healthcare Providers about clozapine and the Clozapine REMS Program. During the launch of the Clozapine REMS Program, there were challenges that required an extension of the phased implementation period. This guide is reflective of the full implementation of the Clozapine REMS Program, which is expected in 02/2019. For the current state of the Clozapine REMS Program, expected full implementation dates and important updates on the transition period, please see the *Clozapine REMS Frequently Asked Questions (FAQs)* on the Clozapine REMS Program Website at www.clozapinerems.com.

Clozapine and the Risk of Neutropenia:

A Guide for Healthcare Providers

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

4.3 Prescriber Education Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left, the logo reads "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". In the top right corner, the user name "Summer Hogan" is shown next to a "My Dashboard" button. A navigation menu below the logo includes "Home", "Prescriber" (highlighted), "Pharmacy", "Patient", "Resources", and "Support". A progress bar below the navigation menu shows steps: "Start", "Intake", "Education" (highlighted), "Assessment", "Review", "Attestation", and "Finish". The main heading is "Education Program Confirmation". Below this, a message states: "You have now completed the Education Program". A paragraph follows: "Please use the **Next** button below to continue with your certification process. The education program you just completed can always be reviewed again under your user profile in the top right corner of this site." A blue "Next" button is positioned below the text. At the bottom of the page, a footer contains the text: "For additional information about the Clozapine REMS Program, please call 844-267-8678." and a link menu: "Privacy | Terms of Use | Site Map | FAQs | Contact Us".

Note: Upon pressing the Next button on the Education Confirmation page, the user will be navigated through the *Clozapine REMS Knowledge Assessment for Healthcare Providers* (KA). KA is shown only once below for all stakeholders except for prescriber designees.

4.4 Prescriber Intake Review

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) **Prescriber** [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) **Review** [Attestation](#) [Finish](#)

Prescriber Intake Review

Please review the information for completeness and accuracy. You may make any changes as necessary. When your review is complete, please use the **Next** button to save your information below and proceed to the final step in your certification process.

Prescriber Information

First Name / MI (opt)

Last Name

Credentials ▾

Email Address

Clinic / Practice Name

Address

Address 2 (opt)

City

State / Zip Code ▾

Phone / Ext (opt)

Fax

Contact Preference ▾

Prescriber Identifiers

DEA

NPI

I do not have a DEA.

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

4.5 Prescriber Attestation

Summer Hogan My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education Assessment Review Attestation **Finish**

Prescriber Attestation

To complete the prescriber certification for **Summer Hogan** into the Clozapine REMS program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to Clozapine RDMS Program at 1-844-404-8876.

As a prescriber, I attest to the following Clozapine REMS Program requirements:

By signing this form, I attest that:

1. I understand that clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements to prescribe clozapine.
2. I have reviewed Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers, reviewed the clozapine Prescribing Information, and successfully completed the Clozapine REMS Knowledge Assessment for Healthcare Providers.
3. I understand the risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
4. Prior to initiating treatment, I agree to provide A Guide for Patients and Caregivers: What You Need to Know about Clozapine to each patient and/or his/her caregiver. I will review it with him/her to inform them about the risks associated with clozapine, including severe neutropenia and the Clozapine REMS Program requirements unless I determine that the patient's adherence to the treatment regimen will be negatively impacted by providing A Guide for Patients and Caregivers: What You Need to Know about Clozapine.
5. I will enroll all patients I treat with a clozapine product in the Clozapine REMS Program.
6. I understand the absolute neutrophil count (ANC) testing and monitoring requirements as described in the clozapine Prescribing Information.
7. I understand there is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN).
8. I will order ANC testing for each patient according to the clozapine Prescribing Information.
9. I will submit and verify the ANC according to each patient's monitoring frequency on file with the Clozapine REMS Program and I understand the ANC must be provided before clozapine can be dispensed:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date*Prescriber the lab draw date is day 0
10. I will verify the patient's monitoring frequency on file with the Clozapine REMS Program is aligned with the patient's monitoring frequency as described in the Prescribing Information.
11. I understand that, as described in Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers, I must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed.
12. I agree that personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
13. I understand that clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program.
14. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above) Signature Date

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

4.6 Prescriber Confirmation

The screenshot shows the Clozapine REMS website interface. At the top left, the logo reads "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". On the top right, the user name "Summer Hogan" and a "My Dashboard" button are visible. A navigation menu includes "Home", "Prescriber", "Pharmacy", "Patient", "Resources", and "Support". Below the navigation is a progress bar with steps: "Start", "Intake", "Education", "Assessment", "Review", "Attestation", and "Finish". The main heading is "Certification Confirmation" with a decorative graphic of colored squares. A green checkmark icon is followed by the text "You are now certified in the Clozapine REMS Program." Below this, a message states: "Below is your Clozapine REMS Program Certification ID. Please retain this information for your records." The "Certification ID" is displayed as "HCP123456789" with a copy icon. A final message says: "If you would like to enroll patients now, you can use [Enroll Patient](#). If you need to manage your patients, you can use [Manage Your Patients](#)." At the bottom, a call to action reads: "For additional information about the Clozapine REMS Program, please call 844-267-8678." The footer contains links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

5. Prescriber Designee Certification



The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Prescriber Designee Certification

Steps for Prescriber Designee Certification

The term designee refers to any person who has been designated or requested to perform some duty or function on behalf of a certified prescriber. Designees must be certified and approved in the Clozapine REMS Program before they can perform any duties or functions for their prescriber.

If you want to associate yourself to a pharmacy and have selected the Prescriber Designee Certification by accident, please go to [Pharmacy Staff Enrollment](#).

Prescriber Designee Certification in the Clozapine REMS Program includes the following three steps:

1. Enroll: Complete the Enrollment Form (name, address)

2. Educate: Review the REMS requirements

3. Confirm: Understanding of the requirements of the REMS

If the browser closes during certification, you can come back to the same point in the process

Please use the **Begin Now** button to start your certification today.

Begin Now!

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [Clozapine REMS Prescriber Designee Education Program](#)
-  [Clozapine REMS Prescriber Designee Enrollment Form](#)
-  [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
-  [Clozapine REMS Eligibility Check Fact Sheet](#)
-  [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

5.1 Prescriber Designee Intake

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) **[Intake](#)** [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Designee Intake

To certify as a designee in the Clozapine REMS Program, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Designee Information

First Name

Last Name

Email Address

Phone Ext (opt)

Fax (opt)

-- Contact Preference -- ▾

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

5.2 Prescriber Designee Education Program Page 1

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) **Prescriber** [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) **Education** [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

General Information

Certified prescribers may identify and associate designees to their Clozapine REMS Program certification record. This allows prescribers to approve responsible individual(s) to act on behalf of the certified prescriber for patients being treated with clozapine. Prescriber designees can submit absolute neutrophil count (ANC) test results, enroll, and manage patients with the following exceptions:

- Designees cannot categorize a patient as having benign ethnic neutropenia (BEN).
- Designees cannot authorize the continuation of clozapine treatment for patients with moderate to severe neutropenia (general population) or severe neutropenia (patients with documented BEN).
- Designees cannot categorize a patient as a hospice patient.

[1](#) [2](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

5.3 Prescriber Designee Education Program Page 2

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake **Education** Assessment Review Attestation Finish

Prescriber Designee Responsibilities

By signing this form, I acknowledge that I will act on behalf of the certified prescriber identified below to comply with the Clozapine REMS Program requirements.

I understand:

- Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements.
- There is a risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
- The ANC testing and monitoring requirements as described in the clozapine Prescribing Information
- **Outpatient Settings¹:** An ANC must be submitted to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed and per the Monitoring Schedule described in the Prescribing Information:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date
- *Assumes the lab draw date is day 0
- A certified prescriber must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed to a patient.
- Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program.
- Personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
- I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

¹Patients treated on an outpatient or chronic basis, includes but is not limited to those receiving clozapine only via retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

1 2

Back

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

5.4 Prescriber Designee Knowledge Assessment

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

Please select the **best** answer for the following question. This question must be answered correctly to become certified:

I have reviewed the requirements of the Clozapine REMS Program.

A. Yes

B. No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

5.5 Prescriber Designee Knowledge Assessment Confirmation – Success

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Knowledge Assessment Results

✔ **Congratulations! You have now completed the assessment.**

You answered the question correctly and have passed the assessment. Please press the **Next** button to complete your certification.

Knowledge Assessment Code: [KA-1652-A6F8-0BE7](#) 🖨

QUESTION 1

I have reviewed the requirements of the Clozapine REMS Program.

✔ A. Yes

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

5.6 Prescriber Designee Knowledge Assessment Confirmation – Not Successful

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Start Intake Education Assessment Review Attestation Finish

Knowledge Assessment Results

We're sorry, you did not pass the Knowledge Assessment.

Below is your response. Please use the **Retake Assessment** button below to begin your assessment again.

QUESTION 1

I have reviewed the requirements of the Clozapine REMS Program.

✘ B. No

ATTEMPT
1 2 3 4 5 6

Retake Assessment

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

5.7 Prescriber Designee Intake Review

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Designee Intake Review

Please review the information for completeness and accuracy. You may make any changes as necessary. When your review is complete, please use the **Next** button to save your information and proceed to the final step in your certification process.

Designee Information

First Name

Last Name

Email Address

Phone / Ext

Fax

Contact Preference

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

5.8 Prescriber Designee Attestation

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education Assessment Review **Attestation** Finish

Designee Attestation

To complete the designee certification for **Summer Hogan** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online certification form and fax it to Clozapine REMS Program at 844-404-8876. 

By signing this form, I acknowledge that I will act on behalf of the certified prescriber identified below to comply with the Clozapine REMS Program requirements.

I understand:

1. Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements.
2. There is a risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
3. **Outpatient¹ Settings:** An absolute neutrophil count (ANC) must be submitted to the Clozapine REMS Program for each patient according to the following monitoring frequency, and I understand these results must be provided before clozapine can be dispensed:
 - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
 - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
 - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date

*Assumes the lab draw date is day 0

4. A certified prescriber must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed to a patient.
5. Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program.
6. Personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
7. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.

¹Patients treated on an outpatient or chronic basis, includes but is not limited to those receiving clozapine only via retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

By checking this box, I hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above)

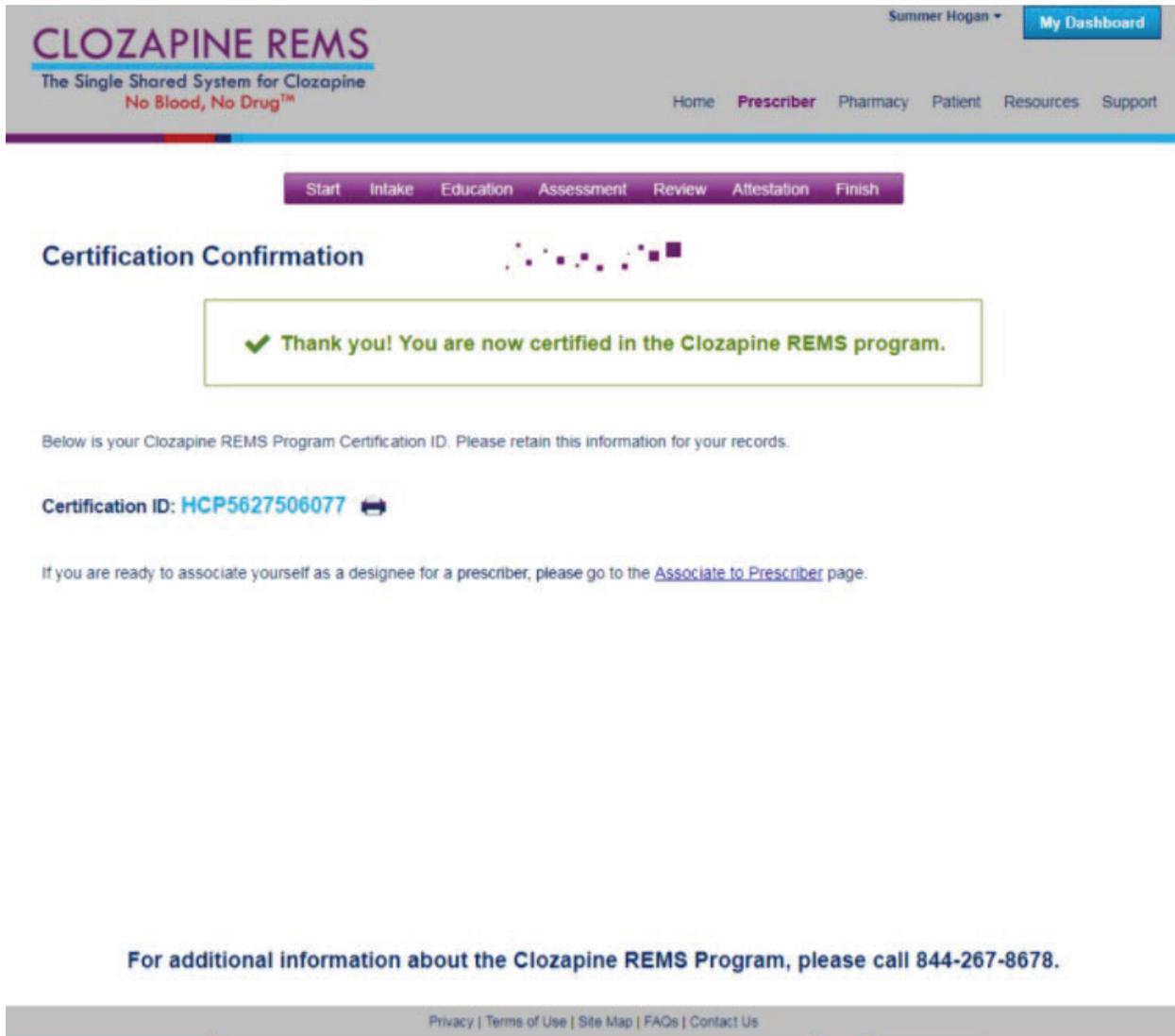
Signature Date

Back

Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

5.9 Prescriber Designee Confirmation



The screenshot shows the Clozapine REMS website interface. At the top, the logo and tagline are repeated. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A user profile for 'Summer Hogan' and a 'My Dashboard' button are visible. A progress bar below the navigation menu shows steps: Start, Intake, Education, Assessment, Review, Attestation, and Finish. The main content area is titled 'Certification Confirmation' and features a green checkmark icon and a message: 'Thank you! You are now certified in the Clozapine REMS program.' Below this, it states: 'Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.' The certification ID is 'HCP5627506077' with a copy icon. A final instruction reads: 'If you are ready to associate yourself as a designee for a prescriber, please go to the [Associate to Prescriber](#) page.' At the bottom, a call to action says: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Start Intake Education Assessment Review Attestation Finish

Certification Confirmation

✓ Thank you! You are now certified in the Clozapine REMS program.

Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.

Certification ID: **HCP5627506077** 📄

If you are ready to associate yourself as a designee for a prescriber, please go to the [Associate to Prescriber](#) page.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

6. Pharmacy Certification

6.1 Pharmacy Certification – Home Page

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[FAQs >>](#)

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

Pharmacy Certification

Steps for Pharmacy Certification

All inpatient and outpatient pharmacies must be certified in the Clozapine REMS Program in order to purchase and dispense clozapine. Certification requires the identification of an authorized representative for the pharmacy to complete the certification process. The authorized representative must ensure all pharmacists with privileges to dispense understand that clozapine is only available to certified pharmacies through the Clozapine REMS Program.

Pharmacy Staff must enroll in the Clozapine REMS Program to obtain a *Predispose Authorization (PDA)* from the Clozapine REMS Program Website, to enter absolute neutrophil count (ANC), verify the prescriber is certified, or verify the patient is enrolled. If the pharmacy is a non-switch pharmacy to comply with the REMS, the pharmacy staff will either need to obtain a PDA by calling the program or by signing in to the website. For more information on the Pharmacy Staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Certification in the Clozapine REMS Program includes the following four steps:

1. Enroll: Complete the Enrollment Form (name, address, NPI, DEA)

2. Educate: Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*

3. Assess: Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

4. Implement: Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

- [ANC Monitoring Table](#)
- [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
- [Clozapine REMS ANC Lab Reporting Form](#)
- [Clozapine REMS Chain Headquarters Pharmacy Enrollment Form](#)
- [Clozapine REMS Inpatient Pharmacy Enrollment Form](#)
- [Clozapine REMS Outpatient Pharmacy Enrollment Form](#)
- [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
- [Clozapine REMS Eligibility Check Fact Sheet](#)
- [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

6.2 Role Selection – New User

Note: User will be presented with this screen upon selecting 'New User' type on the User Identification screen.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

Program Role Selection

Please select the option below that **best** describes your role and press **Continue**.

- Authorized Representative of Outpatient Pharmacy** - An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual outpatient pharmacy. An authorized representative of an outpatient pharmacy cannot be affiliated with a chain pharmacy that is contracted with a pharmacy network provider.
 - Outpatient pharmacy: A pharmacy dispensing clozapine to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems
- Authorized Representative of Inpatient Pharmacy** - An authorized representative of an inpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within a pharmacy where the patient's treatment is coordinated at a site of care and pharmacy claims are submitted as a medical benefit.
 - Inpatient pharmacy: A pharmacy within a facility dispensing clozapine to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short term illness or condition)
- Authorized Representative of Chain Headquarters Pharmacy** - An authorized representative of a chain headquarters pharmacy is responsible for ensuring certification and training in the Clozapine REMS Program for a corporate pharmacy contracted to participate with a pharmacy network provider. Corporate pharmacies are retail or mail outpatient pharmacy headquarters.
 - The Chain Headquarters Pharmacy certification process requires a **single** authorized representative to review the [Education Program](#), complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*, and the [Chain Headquarters Pharmacy Enrollment](#) form
 - Once completed, please contact your switch provider Account Manager for further instructions on submission of the *Clozapine REMS Knowledge Assessment for Healthcare Providers & Enrollment Form* for certification processing
 - A contract with your switch provider is required for a Chain Headquarters Pharmacy certification to be complete
 - Please review this [important communication to Chain Pharmacies](#)

[Continue](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

6.3 Role Selection – Phone/Fax User

Note: User will be presented with this screen upon selecting 'Phone/Fax User' type on the User Identification screen.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password Sign in
Forgot Username? Forgot Password? Need an Account?

Home Prescriber Pharmacy Patient Resources Support

Program Role Selection

Please select the option below that **best** describes your role and press **Continue**.

- Authorized Representative of Outpatient Pharmacy** - An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual outpatient pharmacy. An authorized representative of an outpatient pharmacy cannot be affiliated with a chain pharmacy that is contracted with a pharmacy network provider.
 - Outpatient pharmacy: A pharmacy dispensing clozapine to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems
- Authorized Representative of Inpatient Pharmacy** - An authorized representative of an inpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within a pharmacy where the patient's treatment is coordinated at a site of care and pharmacy claims are submitted as a medical benefit.
 - Inpatient pharmacy: A pharmacy within a facility dispensing clozapine to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short term illness or condition)
- Authorized Representative of Chain Headquarters Pharmacy** - An authorized representative of a chain headquarters pharmacy is responsible for ensuring certification and training in the Clozapine REMS Program for a corporate pharmacy contracted to participate with a pharmacy network provider. Corporate pharmacies are retail or mail outpatient pharmacy headquarters.

Continue

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

6.4 Role Selection Confirmation – Inpatient Pharmacy

Note: This pop-up message is common to both New Users and Phone/Fax users.

The screenshot shows the Clozapine REMS website interface. At the top, there is a navigation bar with the logo and tagline, a login section with 'Username' and 'Password' fields and a 'Sign in' button, and a menu with 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. The main content area is titled 'Program Role Selection' and contains a list of radio button options. A modal pop-up window is centered on the screen, titled 'Authorized Representative of Inpatient Pharmacy'. The pop-up text reads: 'Based on the response selected, please confirm you are certifying as an Inpatient Pharmacy. An inpatient pharmacy dispenses clozapine only to patients treated receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short term illness or condition). If the pharmacy you are certifying does not meet this definition of an Inpatient Pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.' At the bottom of the pop-up are 'Cancel' and 'Confirm' buttons. Below the pop-up, a 'Continue' button is visible. At the bottom of the page, there is a footer with the text 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a link to 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password Sign in
Forgot Username? Forgot Password? Need an Account?

Home Prescriber **Pharmacy** Patient Resources Support

Program Role Selection

Please select the option below that **best** describes your role and press **Continue**.

- Authorized Representative of Outpatient Pharmacy**
certification and training. This pharmacy cannot be used for inpatient care. This includes, but is not limited to, retail drug-stores, ambulatory care centers, and long-term care facilities.
- Authorized Representative of Inpatient Pharmacy**
certification and training. Claims are submitted to the payer. This pharmacy dispenses clozapine only to patients treated receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short term illness or condition). If the pharmacy you are certifying does not meet this definition of an Inpatient Pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.
- Authorized Representative of Pharmacy Network**
responsible for ensuring that the pharmacy network is certified to participate with a pharmacy headquarters is contracted to participate with a

Cancel Confirm

Continue

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

6.5 Role Selection Confirmation – Outpatient Pharmacy

Note: This pop-up message is common to both New Users and Phone/Fax users.

The screenshot shows the Clozapine REMS website interface. At the top, there is a navigation bar with the logo and tagline, a search bar, and a 'Sign in' button. Below the navigation bar, there are links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. The main content area is titled 'Program Role Selection' and contains a list of radio button options for selecting a role. A pop-up window is overlaid on the 'Authorized Representative of Independent Outpatient Pharmacy' option. The pop-up contains the following text:

Authorized Representative of Independent Outpatient Pharmacy

Based on the response selected, please confirm you are certifying as an Independent Outpatient Pharmacy.

An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems. As an independent outpatient pharmacy, you agree that your pharmacy is a retail, mail order or institutional outpatient pharmacy enrolling as a single pharmacy location with its own authorized representative (i.e., not a location covered by a central headquarters for enrollment or training).

If the pharmacy you are certifying does not meet this definition of an Outpatient Independent Pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

At the bottom of the pop-up are two buttons: 'Cancel' and 'Confirm'.

Below the pop-up, there is a 'Continue' button and a footer with the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' At the very bottom, there are links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

6.6 Role Selection Confirmation – Chain Headquarters Pharmacy

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Program Role Selection

Please select the option below that **best** describes your role and press **Continue**.

- Authorized Representative of Outpatient Pharmacy** - An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual outpatient pharmacy. An authorized representative of an outpatient pharmacy cannot be:
 - Outpatient pharmacy limited to, retail drug stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems
- Authorized Representative of Chain Headquarters Pharmacy** - An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems. As a Chain Headquarters Pharmacy, you agree that you are acting on behalf of a group of outpatient pharmacies as a corporate headquarters enrolling in the Clozapine REMS Program for multiple pharmacy locations (i.e., chain stores or a group of pharmacies owned/operated as a single entity); and, whose enrollment and certification activities will be handled centrally by one authorized representative acting on behalf of all the locations in the "chain".

If the pharmacies you are certifying do not meet this definition of requiring enrollment by a Chain Headquarters Pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.
- Authorized Representative of Inpatient Pharmacy** - An authorized representative of an inpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual inpatient pharmacy. Inpatient pharmacy claims are submitted to the pharmacy network provider.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

6.7 Authorized Representative Intake

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

Authorized Representative Intake

To begin the process as an authorized representative in the Clozapine REMS Program, please complete the form below and press **Next**. All fields listed below are required unless otherwise indicated.

Authorized Representative Information

First Name

Last Name

Credentials

Email Address

Phone Ext (opt)

Fax (opt)

-- Contact Preference --

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

6.8 Authorized Representative Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left, the logo 'CLOZAPINE REMS' is shown with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The top right corner features the user name 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation, a purple bar contains the steps: 'Intake', 'Education', 'Assessment', and 'Confirmation', with 'Confirmation' being the active step. The main content area is titled 'Confirmation' and features a green-bordered box with the message: 'You have successfully completed the required authorized representative training.' Below this, a paragraph of text provides instructions: 'If you are ready to certify your pharmacy now, please use [Certify Pharmacy](#). To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page. If you have completed your session today, simply close your browser.' At the bottom of the main content area, there is a call to action: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

6.9 Pharmacy Intake

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

[Intake](#) [Attestation](#) [Confirmation](#)

Pharmacy Intake

⚠ Note: Your pharmacy type has been updated. Click [here](#) to change.

To certify your Pharmacy, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the contact preference you selected during your Authorized Representative Intake. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Name

-- Select Type --  **1**

Address

Address 2 (opt)

City

--State-- Zip

Phone Ext (opt)

Fax (opt)

Pharmacy Identifiers

Please provide at least one identifier.

NCPDP (opt)

DEA (opt)

NPI (opt) **2**

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note:

1 – The options for type of Pharmacies are Inpatient and Outpatient. The tool-tip next to this field will include definition of inpatient and outpatient pharmacies, which are as below:

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

- Inpatient pharmacy: A pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).
- Outpatient pharmacy: A pharmacy dispensing clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

2 – Adjudicate claims online question – This question will be displayed only if the Pharmacy Type selected on this page is 'Outpatient Pharmacy'.

6.10 Pharmacy Re-classification

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1

Does your pharmacy management system support electronic communication with the Clozapine REMS Program using established telecommunications standards?

Yes
 No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1A

Is your pharmacy affiliated with a chain pharmacy that is contracted with a pharmacy network provider?

- Yes
 No

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1B

Is your pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)?

- Yes
 No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 2

Does your pharmacy dispense clozapine only to patients treated on an outpatient or chronic basis? This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

- Yes
- No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please contact your chain headquarters pharmacy authorized representative for assistance. If you are the authorized representative, or if you do not know who the authorized representative is, please call the Clozapine REMS Program at 844-267-8678.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

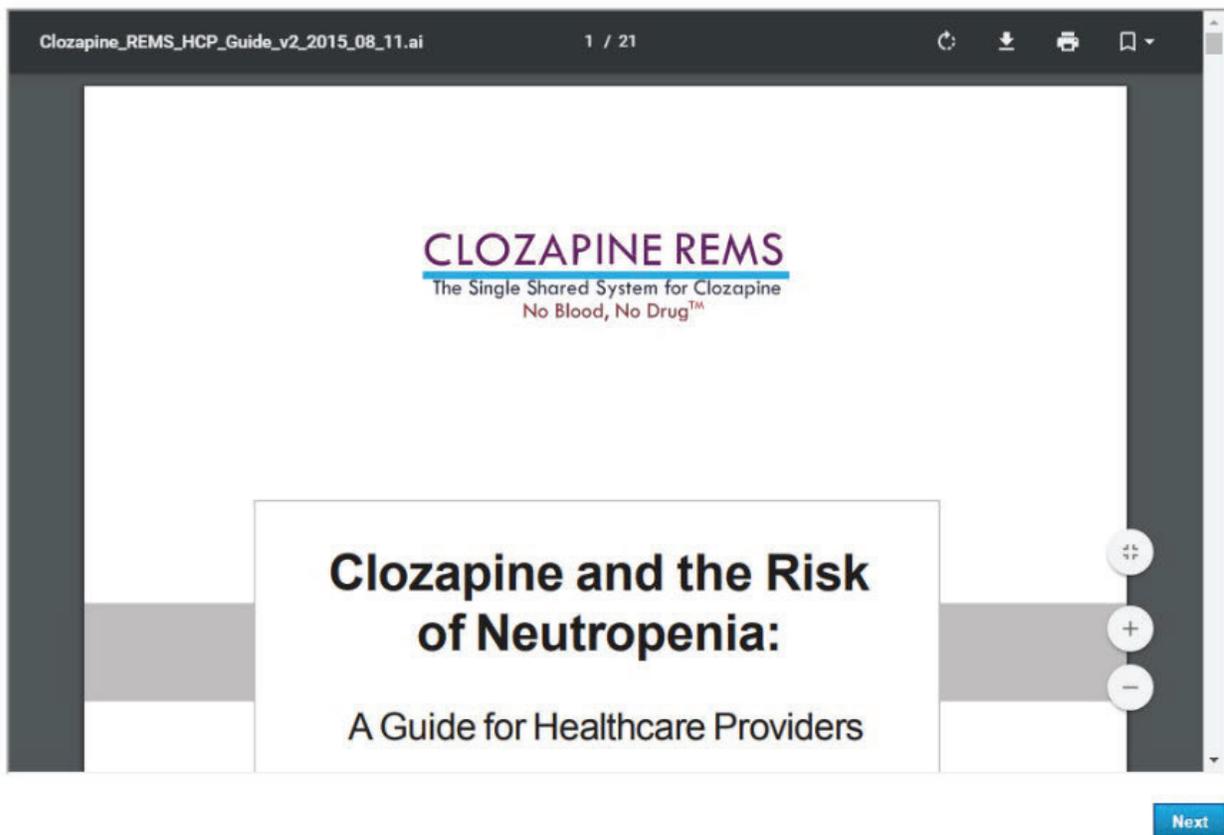
6.11 Pharmacy Education Program



Intake Education Assessment Confirmation

Education Program

Below is the education program for clozapine. Please review the program materials and press the **Next** button to continue. It is estimated that it will take 15-20 minutes to complete the Education Program and *Clozapine REMS Knowledge Assessment for Healthcare Providers*.



For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

6.12 Pharmacy Education Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left, the logo 'CLOZAPINE REMS' is shown with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. In the top right corner, the user 'Summer Hogan' is logged in, with a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy' (highlighted), 'Patient', 'Resources', and 'Support'. Below the navigation is a progress bar with four steps: 'Intake', 'Education' (active), 'Assessment', and 'Confirmation'. The main heading is 'Education Program Confirmation'. The text states: 'You have now completed the Education Program'. Below this, it says: 'Please use the **Next** button below to continue with your certification process. The education program you just completed can always be reviewed again under your user profile in the top right corner of this site.' A blue 'Next' button is visible. At the bottom, a footer contains the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a secondary navigation menu with 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

Note: Upon pressing the Next button on the Education Confirmation page, the user will be navigated through the *Clozapine REMS Knowledge Assessment for Healthcare Providers*. KA is shown only once below for all stakeholders except for prescriber designees.

6.13 Pharmacy Attestation – Inpatient Pharmacy

Note: This page includes only the attestation text for the Inpatient Pharmacy from the *Clozapine REMS Inpatient Pharmacy Enrollment Form*.

Summer Hogan [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber **Pharmacy** Patient Resources Support

Intake Attestation Confirmation

Pharmacy Attestation

To complete the certification for **ABC Pharmacy** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to Clozapine REMS Program at 1-844-404-8876. 

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers and the Prescribing Information* and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. Establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - b. Verify the patient is enrolled in the Clozapine REMS Program by:
 - Signing in to the Clozapine REMS Program Website at www.clozapinerems.com to complete an "Eligibility Check", or
 - Calling the Clozapine REMS Program Contact Center at 844-267-8678
 - c. Verify the ANC is current based on the patient's monitoring frequency (within 7 days of the *Eligibility Check* date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
 - d. Verify the last ANC is acceptable or verify the certified prescriber's authorization for clozapine treatment if the ANC is low indicating moderate or severe neutropenia
 - e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact my pharmacists to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. Inpatient pharmacies must complete an *Eligibility Check* and verify ANC/prescriber authorization before dispensing clozapine products to a patient to ensure compliance with the required safe-use conditions
7. Provide dispensing location information to the Clozapine REMS Program
8. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials
9. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program.

Note: Inpatient pharmacies are not required to obtain a "Predispense Authorization™" (PDA) prior to dispensing clozapine.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above) Signature Date

[Back](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

Clozapine REMS Program_Website_Screen_Captures

November 2018

Page 78 of 238

Reference ID: 4376730

6.14 Pharmacy Attestation – Outpatient Pharmacy

Note: This page includes only the attestation text for the Outpatient Pharmacy from the *Clozapine REMS Outpatient Pharmacy Enrollment Form*.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Support

Intake Attestation Confirmation

Pharmacy Attestation

To complete the certification for **ABC Pharmacy** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to Clozapine REMS Program at 1-844-404-8876. 🖨️

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers and the Prescribing Information* and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. My pharmacy will establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - b. Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
 - c. Verify the ANC is current based on the patient's monitoring frequency (within 7 days of the "Predispense Authorization" (PDA) transaction date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
 - d. Verify the last ANC is acceptable or verify the certified prescriber's authorization for continuing clozapine treatment if the ANC is low indicating moderate or severe neutropenia
 - e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy, institution, or prescriber who is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact my pharmacists to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. Provide dispensing location information to the Clozapine REMS Program
7. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials
8. Outpatient pharmacies must obtain a PDA each time before dispensing clozapine products to a patient to ensure compliance with the required safe-use conditions
9. Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program.
10. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

6.15 Pharmacy Confirmation

Note: This page will be available for:

1. Inpatient Pharmacies
2. Outpatient Pharmacies who cannot adjudicate claims online



Intake Attestation Confirmation

Certification Confirmation



✓ Your pharmacy is now certified in the Clozapine REMS Program.

Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.

Certification ID: [FAC7771640309](#) 🖨️

To add additional pharmacies or manage your pharmacies, please use the **My Dashboard** button at the top of the page.

Please download the Education Program, Knowledge Assessment for Healthcare Providers, and Knowledge Assessment Answer Guide from your Profile page. These tools should be used to train all pharmacists and relevant staff involved in dispensing clozapine. A record of the training must be maintained for future review by the Clozapine REMS Program.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

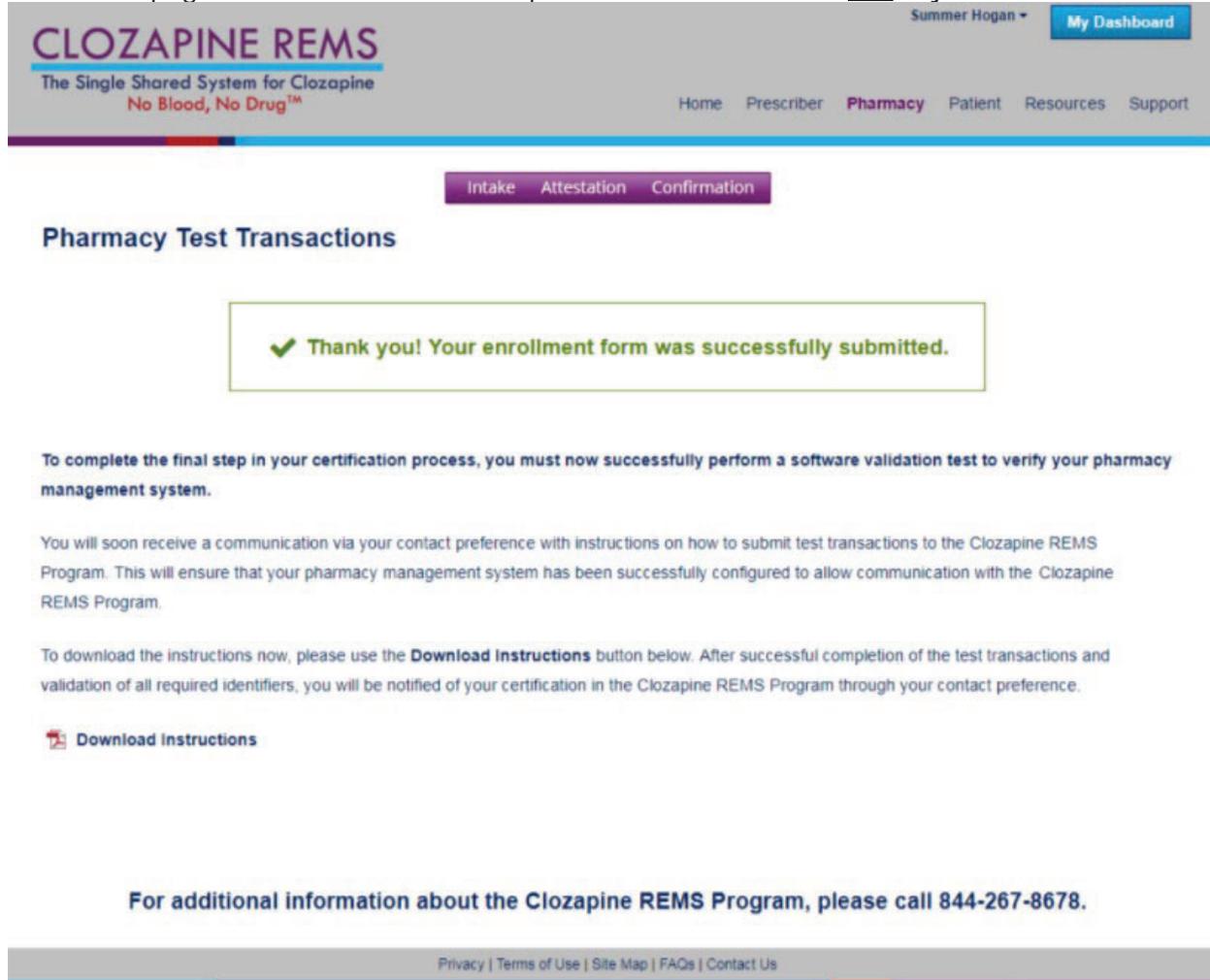
[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

6.16 Pharmacy Test Transactions

Note: This page will be available for Outpatient Pharmacies who can adjudicate claims online



The screenshot shows the Clozapine REMS website interface. At the top, the logo and tagline are visible. A navigation bar includes links for Home, Prescriber, Pharmacy (highlighted), Patient, Resources, and Support. A user profile for Summer Hogan is shown with a My Dashboard button. Below the navigation, a purple bar contains buttons for Intake, Attestation, and Confirmation. The main heading is "Pharmacy Test Transactions". A green-bordered box contains a success message: "✓ Thank you! Your enrollment form was successfully submitted." Below this, a paragraph states: "To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system." Another paragraph explains that the user will receive communication via their contact preference with instructions on how to submit test transactions. A final paragraph instructs the user to click the "Download Instructions" button. At the bottom, a call to action says: "For additional information about the Clozapine REMS Program, please call 844-267-8678." The footer contains links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

[Intake](#) [Attestation](#) [Confirmation](#)

Pharmacy Test Transactions

✓ Thank you! Your enrollment form was successfully submitted.

To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system.

You will soon receive a communication via your contact preference with instructions on how to submit test transactions to the Clozapine REMS Program. This will ensure that your pharmacy management system has been successfully configured to allow communication with the Clozapine REMS Program.

To download the instructions now, please use the **Download Instructions** button below. After successful completion of the test transactions and validation of all required identifiers, you will be notified of your certification in the Clozapine REMS Program through your contact preference.

 [Download Instructions](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

7. Chain Pharmacy Certification

7.1 Chain Pharmacy Store Intake

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

Pharmacy Intake

To certify your chain pharmacy store, please complete the form below and press **Next**. Once the store is certified, you will receive a certification confirmation via the contact preference you selected during your authorized representative intake. All fields below are required unless otherwise indicated.

Pharmacy Information

Pharmacy Identifiers

Please provide at least one:

For additional information about the Clozapine REMS Program, please call 844-267-8678.

7.2 Chain Pharmacy Store Confirmation

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

Chain Store Confirmation

✓ The chain pharmacy store has been successfully added.

To add another store, please use the **Add Store** button below.

[Add Store](#)

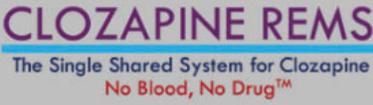
[My Dashboard](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

8. Pharmacy Staff Enrollment

8.1 Enrollment Home Page



The Single Shared System for Clozapine
No Blood, No Drug™

FAQs >>

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

Pharmacy Staff Enrollment

Steps for Pharmacy Staff Enrollment

Pharmacy staff may include pharmacists or other individuals who assist in dispensing medication in a pharmacy. If your pharmacy is certified to dispense clozapine, pharmacy staff can enroll in the Clozapine REMS Program to have access to the Clozapine REMS Program Website. Pharmacy staff can link to multiple REMS-certified pharmacy locations.

Pharmacy staff enroll by creating an online account. Education is not required for enrollment but will be available after your enrollment is complete through your authorized representative.

For Outpatient Pharmacies: Pharmacy staff must enroll in the Clozapine REMS Program to obtain a *Predispose Authorization* (PDA) before dispensing each clozapine prescription. Pharmacy staff who are enrolled can obtain a PDA by calling the Clozapine REMS Program Contact Center or through electronic claim adjudication if your pharmacy has set up that process. Talk to your authorized representative if you are not sure how your pharmacy must obtain a PDA. Pharmacy staff must enroll to obtain a PDA through the Clozapine REMS Program Website.

For Inpatient Pharmacies: Pharmacy Staff must enroll to perform *Eligibility Checks* through the Clozapine REMS Program Website or the Clozapine REMS Program Contact Center.

Pharmacy staff enrollment in the Clozapine REMS Program includes the following two steps:

1. Enroll: Complete the Enrollment Form (name, address)

2. Attest: Complete and sign the Pharmacy Staff Attestation

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia](#)
-  [Clozapine REMS Eligibility Check Fact Sheet](#)
-  [Clozapine REMS PDA Fact Sheet](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

8.2 Pharmacy Search

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

Pharmacy Search

To identify the pharmacy you represent, please complete the fields below and press **Search**. Once you are able to access your dashboard, you will be able to associate to additional pharmacies. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

and

[Search](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

8.3 Pharmacy Search Results

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

Pharmacy Search

To identify the pharmacy you represent, please complete the fields below and press **Search**. Once you are able to access your dashboard, you will be able to associate to additional pharmacies. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="3456789"/>
------------------------------------	-----	----------------------------------	----------------------------------	--------------------------------------

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Clozapine REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
CVS	423 Main Street, Tampa FL 33614	555-555-5555

Showing 1 of 1 entries

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

8.4 Pharmacy Staff Intake

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

Pharmacy Staff Intake

To enroll as a pharmacy staff in the Clozapine REMS Program, please complete the form below and press **Next**. Once enrolled, you will receive an enrollment confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Pharmacy Staff Information

First Name

Last Name

Email Address

Phone Ext (opt)

Fax (opt)

-- Contact Preference -- ▾

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

8.5 Pharmacy Staff Attestation

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Support

Start Intake Attestation Finish

Pharmacy Staff Attestation

To complete the pharmacy staff enrollment for **Summer Hogan** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

As a pharmacy staff, I attest to the following Clozapine REMS Program requirements:

Pharmacy Staff can access the Clozapine REMS Program online at www.clozapinerems.com to complete the following:

- Enter an absolute neutrophil count (ANC) result for a patient
- Verify a patient is enrolled in the Clozapine REMS Program
- In an outpatient pharmacy:
 - Obtain a "Predispense Authorization" (PDA)^{1,2} or
 - Provide a "Dispense Rationale"
- In an inpatient pharmacy:
 - Complete an "Eligibility Check"

For online access to perform the above tasks, you must enroll by creating an account.

¹Inpatient pharmacies do not need to obtain a PDA.

²Outpatient pharmacies with a pharmacy management system that supports electronic communication with the Clozapine REMS Program using established telecommunications standards do not obtain a PDA via the Clozapine REMS Program Website.

By enrolling, you agree not to share your credentials for the Clozapine REMS Program Website or allow others to sign in to the website using your credentials.

As part of your enrollment, you must select the certified pharmacy location(s) where you fill and/or dispense clozapine. It is your responsibility to update this information as necessary.

By checking this box, I hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above)

Signature Date

Back

Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

8.6 Pharmacy Staff Confirmation

The screenshot shows the 'Enrollment Confirmation' page for a pharmacy staff member. At the top, the user is identified as 'Summer Hogan' with a 'My Dashboard' button. The navigation menu includes 'Home', 'Prescriber', 'Pharmacy' (highlighted), 'Patient', 'Resources', and 'Support'. A progress bar at the top indicates the current step is 'Enrollment Confirmation', with other steps being 'Start', 'Intake', 'Attestation', and 'Finish'. The main heading is 'Enrollment Confirmation' with a decorative graphic of colored squares. A green-bordered box contains a checkmark and the text: 'You have now enrolled in the Clozapine REMS Program.' Below this, a message states: 'Below is your Clozapine REMS Program Enrollment ID. Please retain this information for your records.' The enrollment ID is displayed as 'HCP123456789'. A final instruction reads: 'To return to your dashboard for other activities, please use the My Dashboard button at the top of the page. If you have completed your session for today, simply close your browser.' At the bottom, a call to action says: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber **Pharmacy** Patient Resources Support

Start Intake Attestation Finish

Enrollment Confirmation

✓ You have now enrolled in the Clozapine REMS Program.

Below is your Clozapine REMS Program Enrollment ID. Please retain this information for your records.

Enrollment ID: [HCP123456789](#)

To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page. If you have completed your session for today, simply close your browser.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

9. Knowledge Assessment for Healthcare Providers

Note: The *Clozapine REMS Knowledge Assessment for Healthcare Providers* pages below are for prescribers, prescriber designees, and authorized representatives.

9.1 Knowledge Assessment for Healthcare Providers Landing Page

The screenshot shows the landing page for the Clozapine REMS Knowledge Assessment for Healthcare Providers. The page features a header with the Clozapine REMS logo and tagline, a user profile for Summer Hogan, and a navigation menu. A progress bar indicates the current step is 'Assessment'. The main content area includes a title, instructions for the assessment, and a 'Start Assessment' button. A footer contains contact information for more details.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Clozapine REMS Knowledge Assessment for Healthcare Providers

You are now going to review questions that will test your knowledge of appropriate use and administration of clozapine. To be certified in the Clozapine REMS Program you will need to answer ALL questions correctly. Please select the **best** option for each question.

You will have a maximum of six attempts to pass the assessment. After three unsuccessful attempts, the education program is required to be reviewed again before retaking the knowledge assessment. After six unsuccessful attempts, your access to retake the knowledge assessment will be suspended and you will need to contact the Clozapine REMS Program to reinstate your ability to complete the knowledge assessment.

[Start Assessment](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

9.2 Knowledge Assessment Question 1

The screenshot shows the top portion of the Clozapine REMS website. On the left, the logo 'CLOZAPINE REMS' is displayed in purple, with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™' below it. On the right, the user name 'Summer Hogan' is shown next to a dropdown arrow, and a 'My Dashboard' button is visible. A navigation menu includes links for 'Home', 'Prescriber', 'Pharmacy' (highlighted in red), 'Patient', 'Resources', and 'Support'.

Intake Education Assessment Confirmation

Knowledge Assessment

QUESTION 1

All clozapine products are only available under the single shared Clozapine REMS Program.

- A. True
- B. False

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

9.3 Knowledge Assessment Question 2

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Support

Intake Education Assessment Confirmation

Knowledge Assessment

QUESTION 2

Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

- A. True
- B. False

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

9.4 Knowledge Assessment Question 3

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Support

Intake Education Assessment Confirmation

Knowledge Assessment

QUESTION 3

Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ μ L
- B. An absolute neutrophil count (ANC) less than 1000/ μ L
- C. An absolute neutrophil count (ANC) less than 500/ μ L
- D. None of the above

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

9.5 Knowledge Assessment Question 4

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

QUESTION 4

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ μ L for a patient with documented benign ethnic neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ μ L for a patient who is part of the general population (i.e., the patient does not have documented BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

9.6 Knowledge Assessment Question 5

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) **Prescriber** [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Intake](#) [Education](#) **Assessment** [Confirmation](#)

Knowledge Assessment

QUESTION 5

Before clozapine is dispensed to a patient, a certified prescriber must:

- A. Determine if the patient has documented BEN
- B. Enroll the patient in Clozapine REMS Program
- C. Counsel the patient/caregiver about the risk of severe neutropenia
- D. Order blood work to obtain an ANC
- E. Review the ANC and submit it to the Clozapine REMS Program
- F. All of the above

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

9.7 Knowledge Assessment Question 6

The screenshot displays the Clozapine REMS Program website interface. At the top, the logo 'CLOZAPINE REMS' is followed by the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The user 'Summer Hogan' is logged in, with a 'My Dashboard' link. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A progress bar shows the current step is 'Assessment', with other steps being 'Start', 'Intake', 'Education', 'Review', 'Attestation', and 'Finish'. The main heading is 'Knowledge Assessment'. Below it, 'QUESTION 6' is highlighted. The question text reads: 'In the outpatient setting, prescribers must submit the ANC to the single shared Clozapine REMS Program before the patient can be dispensed clozapine.' Two radio button options are provided: 'A. True' and 'B. False'. A 'Next' button is located below the options. At the bottom of the content area, a message states: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

QUESTION 6

In the outpatient setting, prescribers must submit the ANC to the single shared Clozapine REMS Program before the patient can be dispensed clozapine.

A. True
 B. False

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

9.8 Knowledge Assessment Question 7

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Intake Education **Assessment** Confirmation

Knowledge Assessment

QUESTION 7

Before clozapine can be dispensed, a pharmacist in an outpatient pharmacy must:

- A. Verify the patient is enrolled in the single shared Clozapine REMS Program
- B. Verify the prescriber is certified in the single shared Clozapine REMS Program
- C. Verify the ANC is acceptable or verify the prescriber has authorized continuing treatment if the ANC is abnormal
- D. Obtain a "Predispose Authorization" each time from the Clozapine REMS Program
- E. All of the above

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

9.9 Knowledge Assessment Question 8

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are repeated. A navigation bar includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. A user profile for 'Summer Hogan' and a 'My Dashboard' link are visible. A progress bar shows the current step is 'Assessment'. The main content area is titled 'Knowledge Assessment' and features a 'QUESTION 8' header. The question asks 'How much clozapine can be dispensed?' with four radio button options. A 'Next' button is located below the options. At the bottom, a footer contains contact information and a call to action: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' A final footer bar lists 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

QUESTION 8

How much clozapine can be dispensed?

- A. A 30-day supply
- B. A 90-day supply
- C. As much as the patient wants or the insurance will pay for
- D. It depends when the patient's next blood draw is according to the monitoring requirements. Dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

9.10 Knowledge Assessment Question 9

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Intake Education Assessment **Confirmation**

Knowledge Assessment

QUESTION 9

Regarding patients with documented BEN, which of the following statements are true?

- A. Patients with BEN have a different clozapine treatment algorithm and monitoring requirements
- B. Patients with BEN are healthy and do not suffer from repeated severe infections
- C. Patients with BEN are NOT at increased risk for developing clozapine-induced neutropenia
- D. Before starting clozapine, additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Hematology consultation may be necessary
- E. All of the above statements are true

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

9.11 Knowledge Assessment Question 10

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

QUESTION 10

If a new patient's baseline ANC is within the normal range, how should the ANC monitoring schedule proceed?

- A. Weekly from initiation to discontinuation of therapy
- B. Weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- C. Monthly from initiation to discontinuation of therapy
- D. No additional ANC monitoring is required if the patient's baseline ANC is within the normal range

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

9.12 Knowledge Assessment Question 11

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

QUESTION 11

If a patient's ANC indicates mild neutropenia, which of the following statements is true?

- A. ANC monitoring should be conducted three times weekly until ANC \geq 1500/ μ L if the patient is part of the general population (i.e., if the patient does not have documented BEN)
- B. Mild neutropenia is within the normal range for a patient with documented BEN
- C. If the patient has documented BEN, ANC monitoring should be conducted: weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- D. All of the above

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

9.13 Knowledge Assessment Question 12

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

QUESTION 12

If a patient's ANC indicates moderate neutropenia, which of the following statements is true?

- A. Treatment should be continued regardless of whether the patient is part of the general population or has documented BEN
- B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt therapy and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the general population or has BEN
- D. None of the above

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

9.14 Knowledge Assessment Question 13

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) **[Prescriber](#)** [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Education](#) **[Assessment](#)** [Review](#) [Attestation](#) [Finish](#)

Knowledge Assessment

QUESTION 13

If a patient's ANC indicates severe neutropenia, which of the following statements is true?

- A. Treatment should be interrupted regardless of whether the patient is part of the general population or has BEN and a hematology consultation should be considered; resume treatment only if the prescriber determines that the benefits of clozapine therapy outweigh the risks
- B. If the patient is part of the general population (i.e. if the patient does not have documented BEN), interrupt treatment and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
- D. All of the above

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

9.15 Knowledge Assessment Confirmation – Success

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment Results

✓ **Congratulations! You have now completed the assessment.**

You answered all the questions correctly and have passed the assessment. Please press the **Next** button to complete your certification.

Knowledge Assessment Code: [KA-1636-D098-1E12](#) ↗

QUESTION 1

All clozapine products are only available under the single shared Clozapine REMS Program.

✓ A. True

QUESTION 2

Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

✓ A. True

QUESTION 3

Severe neutropenia is defined as:

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

9.16 Knowledge Assessment Confirmation – Not Successful

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are present. A navigation bar includes links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. A secondary navigation bar shows a progress indicator with buttons for Intake, Education, Assessment, and Confirmation. The main heading is "Knowledge Assessment Results". A red-bordered box contains the message: "We're sorry, you did not pass the Knowledge Assessment." Below this, a paragraph explains that the user should review the "Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers" before retaking the assessment. A scrollable window shows three questions: Question 1 (All clozapine products are only available under the single shared Clozapine REMS Program. A. True), Question 2 (Clozapine is associated with severe neutropenia, which can lead to serious infection and death. B. False), and Question 3 (Severe neutropenia is defined as:). Below the questions is an "ATTEMPT" counter showing 1 out of 6 attempts, and a "Retake Assessment" button. At the bottom, a contact number is provided: "For additional information about the Clozapine REMS Program, please call 844-267-8678." The footer contains links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Support

Intake Education Assessment Confirmation

Knowledge Assessment Results

We're sorry, you did not pass the Knowledge Assessment.

Below is a summary of your responses. We recommend you review the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* again before you attempt to retake the Knowledge Assessment. Once you feel your review is complete, please use the **Retake Assessment** button below to begin your assessment again.

QUESTION 1
All clozapine products are only available under the single shared Clozapine REMS Program.
✓ A. True

QUESTION 2
Clozapine is associated with severe neutropenia, which can lead to serious infection and death.
✗ B. False

QUESTION 3
Severe neutropenia is defined as:

ATTEMPT
1 2 3 4 5 6

Retake Assessment

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

10. Patient Enrollment

10.1 Patient Intake

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Start](#) [Intake](#) [Lab Info](#) [Finish](#)

Patient Intake

To enroll your patient in the Clozapine REMS Program, please complete the form below and press **Next**. Once the patient enrollment is complete, you will receive an enrollment confirmation via your contact preference. All fields listed below are required.

Patient Information

First Name

Last Name

Date of Birth (MM/DD/YYYY)

Zip Code

-- Gender -- ▾

-- Race -- ▾

-- Patient Group -- ▾ ? Groups can be used to categorize your patients.

Does the patient have Benign Ethnic Neutropenia (BEN)?

-- Please Select -- ▾

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

10.2 Patient Lab Intake

Start Intake Lab Info Finish

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values, you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

Jackie Collins

Lab Entry

ANC Value (per μ L)
If you don't have an ANC Value, but want to calculate an ANC Value based on WBC, please click on the calculator button.

Blood DrawDate

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per μ L)	None	None	None

Treatment Status
 1

Monitoring Frequency

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The Add Lab page allows the user to enter Patient Lab Information. Options available for *Treatment Status* include:

- 1 – Active
- 1 – Interrupted
- 1 – Discontinued

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

10.3 Patient Lab Intake with *Treatment Rationale*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy **Patient** Resources Support

Start Intake Lab Info Finish

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values, you may do so in the fields provided below. Additionally, if you have lab information you may enter it now, otherwise, please press **Next** to continue.

Jackie Collins

Lab Entry

Lab	Current	Highest	Lowest
Blood Draw date	None	None	None
ANC Level (per μ L) ?	None	None	None

ANC Value (per μ L)
If you don't have an ANC Value, but want to calculate an ANC Value based on WBC, please click on the calculator button.

600

Blood Draw Date
12/06/2017

Modify Lab

Treatment Status
Active ▾

Treatment Rationale 1 --Please Select-- ▾

Treatment Rationale Duration 2 --Please Select-- ▾

Monitoring Frequency
Weekly ▾

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

Cancel Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The Add Lab page allows the user to enter Patient Lab Information.

1 – Options available for *Treatment Status* include:

- Benign Ethnic Neutropenia (BEN) Patient
- Benefit Outweighs Risk

2 – Treatment Rationale Duration

- Until next ANC Lab
- Until (MM/DD/YYYY)

10.4 ANC Calculator

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

ANC Calculator

WBC count (x10 ⁹ /mm ³)	Segs (%)	Bands (%)	ANC value (per μ L)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

WBC count (x10 ⁹ /mm ³)	Neutrophils (%)	ANC value (per μ L)
<input type="text"/>	<input type="text"/>	<input type="text"/>

NOTE:
For WBC count, data should be entered in decimal format (a value of 4,300 should be entered as 4.3).
For Segs, Bands, or Neutrophils, data should be entered without percent sign (20% should be entered as 20).
If the ANC value is populated with a value, the same value is populated in the ANC value field on the form.

Source: Mosby's Diagnostic and Laboratory Test Reference, 6th ed. 2003. White blood cell count and differential, page 942.

Cancel Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

11. Stakeholder Profiles

Note: Stakeholder profiles are accessed via the drop-down next to the signed-in user's name at the top of every page.

11.1 Prescriber Profile

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

My Profile

My Information

[Edit](#)

First Name / MI:

Last Name:

Credentials: ▾

Clinic / Practice Name:

Address:

Address 2:

City:

State / Zip Code: ▾

Phone / Ext:

Fax:

Contact Preference: ▾

DEA:

NPI:

My Certification

Certification ID: [HCP123456789](#) ↗

Education Program

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

11.2 Prescriber Designee Profile

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

My Profile

My Information Edit

First Name

Last Name

Phone / Ext

Fax

Contact Preference

My Certification

Certification ID: [HCP123456789](#)

Education Program

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

11.3 Authorized Representative Profile

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

My Profile

My Information Edit

First Name

Last Name

Position/Title

Phone / Ext

Fax

Contact Preference

Education Program

Clozapine REMS Knowledge Assessment for Healthcare Providers

Knowledge Assessment Answer Guide

Cancel Save

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

11.4 Chain Headquarters Pharmacy Authorized Representative Profile

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

My Profile

My Information [Edit](#)

First Name

Last Name

Position / Title

Phone / Ext

Fax

Contact Preference

Education Program

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

11.5 Chain Headquarters Pharmacy Profile

Note: The chain headquarters pharmacy authorized representative will have two options via the drop-down next to the signed-in user's name at the top of every page; one for My Profile (authorized representative profile above) and Chain Headquarters Pharmacy Profile (below).

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Chain Headquarters Pharmacy Profile

Chain Headquarters Pharmacy Information

[Edit](#)

Chain Name:

Address:

Address 2:

City:

State / Zip:

Phone / Ext:

Fax:

Chain ID: **CS5123**

Chain Headquarters Pharmacy Certification

Certification ID: **FAC5471595906**

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

11.6 Pharmacy Staff Profile

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

My Profile

My Information Edit

First Name

Last Name

Phone / Ext

Fax ▾

Contact Preference

My Enrollment

Enrollment ID: [HCP123456789](#) ↗

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

12. My Account

Note: My Account pages are accessed via the drop-down next to the signed-in user's name at the top of every page.

12.1 Forgot Username

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Forgot Username

Please enter your credentials in the spaces provided below. Your username will be sent to the email you registered on file with the Clozapine REMS Program.

First Name

Last Name

Email Address

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.2 Change Username

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Username

To change your username, please provide your new username below. The information you provide for your username must be unique within the Clozapine REMS Program Website.

Use Email Address as Username
[Change Password](#)
[Change Email Address](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

12.3 Change Username Confirmation

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are visible, along with a user profile for 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. The main content area is titled 'Change Username' and features a green confirmation message: 'Your username has been successfully saved.' Below this, a text block explains that the new username must be unique. A form contains a 'Username' input field, a checkbox for 'Use Email Address as Username', and a 'Suggest Username' button. There are also links for 'Change Password' and 'Change Email Address'. At the bottom of the form are 'Cancel' and 'Save' buttons. A footer note provides a phone number for more information, and a bottom-most footer contains links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Change Username

✓ Your username has been successfully saved.

To change your username, please provide your new username below. The information you provide for your username must be unique within the Clozapine REMS Program Website.

Username

Use Email Address as Username [Suggest Username](#)

[Change Password](#)
[Change Email Address](#)

Cancel Save

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

12.4 Change Password

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Password

To change your password, please complete the fields below.

[Change Username](#)
[Change Email Address](#)

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

12.5 Change Password Notification

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Change Password

⚠ Your Password needs to be changed.

To change your password, please complete the fields below.

[Change Username](#)
[Change Email Address](#)

Cancel

Save

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.6 Change Password Confirmation

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Change Password

✔ Your password has been successfully saved.

To change your password, please complete the fields below.

Old Password

New Password

Confirm Password

[Change Username](#)
[Change Email Address](#)

Cancel Save

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.7 Change Email Address

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Email Address

To change your email address, please complete the fields below.

[Change Username](#)
[Change Password](#)

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.8 Change Email Address Confirmation

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Email Address

✔ Your email address has been successfully updated. A verification email has been sent to <email address>. Please use the link within the email to confirm this change.

To change your email address, please complete the fields below.

[Change Username](#)
[Change Password](#)

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

13. Patient Groups

13.1 Manage Groups

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications ⁵ Patients Designees **Manage Groups**

The table below contains all of your patient groups. If you need to add a new patient group, please use the **Add Group** button.

Add Group Search

Group Name	Actions
Group A	-- Please Select -- <input type="button" value="Go"/>
Group B	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 2 of 2 entries

« 1 » 10 ▾

My Dashboard

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The Manage Groups page will include a list of all groups the prescriber or designee has created for themselves. The actions the prescriber and designee can take are:

- 1 – Add Group – will take the user to the Add Group page
- 2 – Change Group Name – will take the user to the Edit Group page
- 2 – Remove Group – will take the user to the Remove Group page

13.2 Add Group

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Add Group

To add a new group, please specify the group name below and press **Submit**. You can add a patient to the group by accessing the patient's profile.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

13.3 Change Group Name

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Change Group Name

To change the group, simply edit the group name in the field below and press **Submit**.

Group Name

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

13.4 Remove Group

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Remove Group

To remove the group below simply press **Remove**; otherwise, press **Cancel** to return to Manage Groups.

Group Name: **Group A**

[Cancel](#) [Remove](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

13.5 Remove Group Warning

The screenshot displays the Clozapine REMS website interface. At the top left, the logo 'CLOZAPINE REMS' is shown with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The top right corner features the user name 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. The main content area is titled 'Remove Group' and contains the text 'To remove the group below simply click the Remove button below.' Below this, a form field shows 'Group Name: Group A'. A modal dialog box is centered on the screen, titled 'Warning' with a red triangle icon. The dialog text reads: 'Patients are currently assigned to the group you are removing. Would you like to reassign all the patients to a new group?' It features two buttons: a red 'No' button and a green 'Yes' button. Below the dialog, the main page has 'Cancel' and 'Remove' buttons. At the bottom, a footer contains the text 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a link menu: 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

13.6 Reassign Patients

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Reassign Patients

Please select the new group below and press **Submit**.

Search

Group Name:

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

14. Dashboard

14.1 Dashboard Alerts and Notifications

14.1.1 Dashboard Alerts

Note: Alerts will be displayed for all stakeholders. The Alerts and Notifications tabs are common across all stakeholders.

The screenshot shows the 'Alerts' tab selected in the dashboard. The header includes the Clozapine REMS logo and navigation links. Below the tabs, a message states: 'All program alerts are listed below. Please use the link within the alert to take the necessary action to satisfy the alert.' A search bar is present. A table displays one alert entry with columns for Alert Date, Alert Category, Alert Reference Name, and Alert Subject. The alert is dated 09/10/2018, categorized as 'Designee/Pharmacy Staff', and references 'Hogan, Summer' with a subject of 'Designee Determination'. A pagination control shows 'Showing 1 to 1 of 1 entries' and a page number of 1.

Alert Date	Alert Category	Alert Reference Name	Alert Subject
09/10/2018	Designee/Pharmacy Staff	Hogan, Summer	Designee Determination

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.1.2 Dashboard Notifications

Note: Notifications will be displayed for all stakeholders. The Alerts and Notifications tabs are common across all stakeholders.

The screenshot shows the Clozapine REMS dashboard interface. At the top, the logo and tagline are repeated. The user is identified as Summer Hogan, and there is a 'My Dashboard' button. A navigation menu includes Home, Prescriber, Pharmacy, Patient, Resources, and Support. Below this is a tabbed interface with 'Alerts' and 'Notifications' (both showing 1 notification), along with 'Patients', 'Designees', and 'Manage Groups'. The 'Notifications' tab is active, displaying a message: 'All program notifications are listed below. Please select a notification and use the Acknowledge button to clear the notification.' A search bar is present. A table lists the notification details:

	Notification Date	Notification Category	Notification Reference Name	Notification Subject
<input type="checkbox"/>	09/10/2018	Certification/Enrollment	Hogan, Summer	Certification Confirmation

Below the table, it says 'Showing 1 to 6 of 6 entries' and includes pagination controls for 1 of 10 items. An 'Acknowledge' button is located at the bottom right of the notification area.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

14.2 Prescriber Dashboard

14.2.1 Prescriber Dashboard Patient Tab Collapsed

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications ¹ **Patients** Designees Manage Groups

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, please use the **Enroll Patient** button to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.

Enroll Patient Search

	First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
	Mike	Brown	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>
	John	Smith	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 10 of 18 entries « 1 » 10 ▾

 = NNRMF (National Non-Rechallenge Master File) patient

For definitions of terms used on this page, click [here](#).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.2 Prescriber Dashboard Patient Tab Expanded

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, please use the **Enroll Patient** button to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.

First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
Mike	Brown	05/01/2000	Enrolled		Active	-- Please Select --
John	Smith	05/01/2000	Enrolled		Active	-- Please Select --

Showing 1 to 10 of 18 entries

Legend: ■ = NNRMF (National Non-Rechallenge Master File) patient

For definitions of terms used on this page, click [here](#).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The dashboard for the prescriber will include a list of all patients the prescriber is managing. The actions the prescriber can take are:

For patients with an enrollment status of "Incomplete", the prescriber can "Resume Patient Enrollment"

1 – Enroll Patient – will take users to the Patient Intake page and through the patient enrollment process

For patients with an enrollment status of "Enrolled", the prescriber can take the following actions:

2 – Add Lab – will take the user to the Lab Information page

2 – Change Treatment Status – will take the user to the Lab Information page

2 – Change *Treatment Rationale* – will take the user to the Lab Information page

2 – View Patient History – will take the user to the Patient History page

2 – View Patient Profile – will take the user to the Patient Profile page

2 – Remove from Program – will remove the patient from the program

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

3 – Options available for *Dispense Rationale* status include:

- a. Active
- b. Expired
- c. Limit Reached
- d. Not on File

4 – For definitions of terms used on this page – will pop-up the definitions on the page (see next mockup)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.3 Definitions of Terms Pop-up

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline are visible. The navigation bar includes links for Home, Prescriber, Pharmacy, Patient, Resources, and Support. Below the navigation, there are tabs for Alerts, Notifications (with a red badge), Patients, Designees, and Manage Groups. The main content area features a table of patients with a search bar and an 'Enroll Patient' button. A pop-up window titled 'Definition of Terms' is overlaid on the table, providing definitions for various terms used in the program.

Definition of Terms

Treatment Status

- Pretreatment** - new patient with no baseline ANC submitted who has not started clozapine
- Active** - receiving clozapine at regular intervals consistent with their monitoring frequency
- Interrupted** - clozapine usage has stopped temporarily pending next actions before resuming therapy or being permanently discontinued
- Discontinued** - clozapine usage has stopped

Enrollment Status

- Enrolled (patients and pharmacy staff)** - All enrollment requirements have been met
- Certified (for all other stakeholders)** - All certification requirements have been met
- Incomplete** - Requirements for enrollment or certification have not been met and must be continued
- BEN Patient** - Benign Ethnic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANCs are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine
- NNRMF** - Patients were listed in the National Non-Rechallenge Master File (NNRMF) if a patient had a WBC less than 2,000/ μ L or an ANC less than 1000/ μ L. All patients who were listed in the NNRMF and all their lab data were transferred into the Clozapine REMS Program

Showing 1 to 10 of 16 entries

☒ = NNRMF (National Non-Rechallenge Master File) patients.

For definitions of terms used on this page, click [here](#).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.4 Add Lab, Change Treatment Status, and Change Monitoring Frequency for Prescribers

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values, you may do so in the fields provided below.

Joe M

Lab Entry

ANC Value (per μ L)
If you don't have an ANC Value, but want to calculate an ANC Value based on WBC, please click on the calculator button.

Blood Draw Date
MM/DD/YYYY

Treatment Status
Active ▾ **1**

Monitoring Frequency
Weekly ▾

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

I attest that all ANC results for this patient in the past year were within normal limits per label and this patient has been on clozapine therapy continuously for one year making them eligible for **monthly monitoring**.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note:

The Add Lab page allows the user to enter Patient Lab Information. Options available for *Treatment Status* include:

- 1 – Active
- 1 – Interrupted
- 1 – Discontinued

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.5 View Patient History Lab History Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History Monitoring Frequency History Dispense Rationale

Name: **Varsha Bhatia** Display WBC

DOB: **05/01/2000**

Gender: **Female**

Entry Date	Blood Draw Date	ANC
05/08/2017	05/08/2017	1500
05/09/2017	05/09/2017	500

Showing 1 to 2 of 2 entries  << 1 >> 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

14.2.6 View Patient History Treatment Status Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History Monitoring Frequency History Dispense Rationale

Name: **Varsha Bhatia**
DOB: **05/01/2000**
Gender: **Female**

Entry Date	Treatment Status	Rationale	Duration
05/08/2017	Active		
05/09/2017	Active	Benefit Outweighs Risk	

Showing 1 to 2 of 2 entries

« 1 » 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

14.2.7 View Patient History Monitoring Frequency Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Patient History

[Lab History](#) [Treatment Status History](#) **[Monitoring Frequency History](#)** [Dispense Rationale](#)

Name: [Varsha Bhatia](#)
DOB: [05/01/2000](#)
Gender: [Female](#)

Entry Date	Monitoring Frequency
05/08/2017	Weekly

Showing 1 to 1 of 1 entries

« 1 » 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.8 View Patient History *Dispense Rationale* Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Patient History

[Lab History](#) [Treatment Status History](#) [Monitoring Frequency History](#) **[Dispense Rationale](#)**

Name: [Jeff Bradley](#)
DOB: [02/16/1910](#)
Gender: [Male](#)

Pharmacy Name	Date Issued	Expiration Date
First Care Pharmacy	03/24/2015	03/26/2015
Scottsdale Pharmacy	05/15/2015	05/17/2015

Showing 1 to 2 of 2 entries

< 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.9 View Patient Profile

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Patient Profile

Patient Information [Edit](#)

First Name

Last Name

DOB

Zip Code

Gender ▾

Race ▾

Group ▾

BEN Patient **No**

NNRMF Patient **No**

Patient Enrollment Information

Enrollment ID: **PAT132456789**

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.10 Prescriber Dashboard Designees Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Ether Thomas ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts Notifications ¹ Patients **Designees** Manage Groups

The table below contains all the designees that are currently assigned or requesting approval from you. If you need to add a new designee to your list, please use the **Add Designee** button.

Add Designee Search

First Name	Last Name	Certification ID	Approval Status	Actions
Don	Herve	HCP5414002422	Approved	-- Please Select -- -- Please Select -- Remove Designee

Showing 1 to 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Alerts ¹ Notifications ¹⁰ Patients **Designees** Manage Groups

The table below contains all the designees that are currently assigned or requesting approval from you. If you need to add a new designee to your list, please use the **Add Designee** button.

Add Designee Search

First Name	Last Name	Certification ID	Approval Status	Actions
John	Smith	HCP5415021792	Approved	-- Please Select -- Go
Mark	Brown	HCP5414002422	Approved	-- Please Select -- Go
Scott	Abbot	HCP5627729840	Pending	-- Please Select -- -- Please Select -- Approve Designee

Showing 1 to 3 of 3 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note: The dashboard for the prescriber will include a list of all designees the prescriber is associated to. The actions the prescriber can take are:

- 1 – Add Designee – will take the user to the Add Designee page
- 2 – Remove Designee – will take the user to the Remove Designee page
- 3 – Approve Designee – will take the user to the Approve Designee page

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.11 Add Designee with Results

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Add Designee

To add a designee, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Designee Information

<input type="text" value="Terry"/>	<input type="text" value="White"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

[Search](#)

If the search results have returned the designee you want to associate to, please select the row and press **Submit**. If you do not see the designee you are looking for, please try your search again or contact the designee to ensure they are certified in the program.

First Name	Last Name	Phone
Terry	White	555-555-5555

Showing 1 of 1 entries

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.12 Remove Designee

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Remove Designee

Removing this designee will revoke their ability to perform actions on your behalf. To continue, please check the box below and press **Submit**.

Designee Name: [Anantharaman Manickavasagam](#)

Certification ID: [HCP123456](#)

I hereby remove this designee's ability to perform actions on my behalf in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.2.13 Approve Designee

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Designee Determination

This designee will act on my behalf in fulfilling the requirements for the Clozapine REMS Program.

Designee Name: [Jane Brown](#)

Certification ID: [HCP055254](#)

[Decline](#)

[Approve](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3 Prescriber Designee Dashboard

14.3.1 Prescriber Designee Dashboard Patient Tab Collapsed

The screenshot displays the Clozapine REMS Prescriber Designee Dashboard. At the top, the logo and tagline 'The Single Shared System for Clozapine No Blood, No Drug™' are visible. The user is logged in as 'Summer Hogan' and is on the 'My Dashboard' page. The navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below the navigation, there are tabs for 'Alerts', 'Notifications', 'Patients', 'Prescribers', and 'Manage Groups'. The 'Patients' tab is selected. A search bar is located on the right side of the patient list area. The text below the search bar states: 'The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, select a prescriber from the Prescribers tab and use the **Add Patient Action** to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.' The table below shows two patients: Mike Brown and John Smith. Both are enrolled and active. The table has columns for First Name, Last Name, DOB, Enrollment, Group, Relationship, and Actions. The Actions column contains a dropdown menu and a 'Go' button. Below the table, it says 'Showing 1 to 10 of 16 entries' and '1' is selected in a dropdown menu. A legend indicates that a red flag icon represents an NNRMF patient. A link for definitions of terms is provided at the bottom.

First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
Mike	Brown	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>
John	Smith	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 10 of 16 entries

= NNRMF (National Non-Rechallenge Master File) patient

For definitions of terms used on this page, click [here](#).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.2 Prescriber Designee Dashboard Patient Tab Expanded

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, select a prescriber from the Prescribers tab and use the **Add Patient Action** to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.

First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
Mike	Brown	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>
Gender: Female NNRMF: No BEN: No		View ANC Monitoring Table			Enrollment ID: PAT5414000800	
		Blood Draw date	10/04/2017	05/08/2017	10/04/2017	
		ANC Level (per µL)	400	1500	400	
John	Smith	05/01/2000	Enrolled		Active	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 10 of 18 entries

= NNRMF (National Non-Rechallenge Master File) patient

For definitions of terms used on this page, click [here](#).

1

2

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The dashboard for the prescriber designee will include a list of all patients the designee's prescriber is managing. The actions the prescriber designee can take are:

For patients with an enrollment status of "Incomplete", the prescriber designee can "Resume Patient Enrollment".

For patients with an enrollment status of "Enrolled", the prescriber can take the following actions:

- 1 – Add Lab – will take the user to the Lab Information page
- 1 – Change Treatment Status – will take the user to the Lab Information page
- 1 – Change *Treatment Rationale* – will take the user to the Lab Information page
- 1 – View Patient History – will take the user to the Patient History page
- 1 – View Patient Profile – will take the user to the Patient Profile page
- 1 – Remove from Program – will remove the patient from the program
- 2 – For definitions of terms used on this page – the definitions will pop-up when "here" is clicked (see next mockup)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.3 Definitions of Terms Pop-up

The screenshot shows a web browser window with a 'Definition of Terms' pop-up. The background website header includes 'CLOZAPINE REMS', 'Summer Hogan', and 'My Dashboard'. The pop-up window has a purple header and lists the following definitions:

Treatment Status

- Pretreatment** - new patient with no baseline ANC submitted who has not started clozapine
- Active** - receiving clozapine at regular intervals consistent with their monitoring frequency
- Interrupted** - clozapine usage has stopped temporarily pending next actions before resuming therapy or being permanently discontinued
- Discontinued** - clozapine usage has stopped

Enrollment Status

- Enrolled (patients and pharmacy staff)** - All enrollment requirements have been met
- Certified (for all other stakeholders)** - All certification requirements have been met
- Incomplete** - Requirements for enrollment or certification have not been met and must be continued

BEN Patient - Benign Ethnic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANC's are lower than "standard" laboratory ranges from neutrophils. Because of this condition, patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine.

NNRMF - Patients were listed in the National Non-Rechallenge Master File (NNRMF) if a patient had a WBC less than 2,000/ μ L or an ANC less than 1000/ μ L. All patients who were listed in the NNRMF and all their lab data were transferred into the Clozapine REMS Program.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

At the bottom of the page, there are links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.4 Add Lab and Change Treatment Status for Prescriber Designees

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values, you may do so in the fields provided below.

Joe M

Lab Entry

ANC Value (per μ L)
If you don't have an ANC Value, but want to calculate an ANC Value based on WBC, please click on the calculator button.

Blood Draw Date

[Verify Lab](#)

Treatment Status
Active ▾ 1

Monitoring Frequency
Weekly ▾

I attest that the patient is terminally ill/in hospice care and monitoring can be reduced per the label.

I attest that all ANC results for this patient in the past year were within normal limits per label and this patient has been on clozapine therapy continuously for one year making them eligible for monthly monitoring.

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note:

The Add Lab page allows the user to enter Patient Lab Information. Options available for *Treatment Status* include:

- 1 – Active
- 1 – Interrupted
- 1 – Discontinued

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.5 View Patient History: Lab History Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History Monitoring Frequency History Dispense Rationale

Name: [Varsha Bhatia](#) Display WBC

DOB: [05/01/2000](#)

Gender: [Female](#)

Entry Date	Blood Draw Date	ANC
05/08/2017	05/08/2017	1500
05/09/2017	05/09/2017	500

Showing 1 to 2 of 2 entries  << 1 >> 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

14.3.6 View Patient History: Treatment Status Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History Monitoring Frequency History Dispense Rationale

Name: **Varsha Bhatia**
DOB: **05/01/2000**
Gender: **Female**

Entry Date	Treatment Status	Rationale	Duration
05/08/2017	Active		
05/09/2017	Active	Benefit Outweighs Risk	

Showing 1 to 2 of 2 entries

« 1 » 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

14.3.7 View Patient History: Monitoring Frequency Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History **Monitoring Frequency History** Dispense Rationale

Name: [Varsha Bhatia](#)
DOB: [05/01/2000](#)
Gender: [Female](#)

Entry Date	Monitoring Frequency
05/08/2017	Weekly

Showing 1 to 1 of 1 entries

« 1 » 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.8 View Patient History: *Dispense Rationale* Tab

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Patient History

Lab History Treatment Status History Monitoring Frequency History **Dispense Rationale**

Name: [Jeff Bradley](#)
DOB: [02/16/1910](#)
Gender: [Male](#)

Pharmacy Name	Date Issued	Expiration Date
First Care Pharmacy	03/24/2015	03/26/2015
Scottsdale Pharmacy	05/15/2015	05/17/2015

Showing 1 to 2 of 2 entries

< 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.9 View Patient Profile

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Patient Profile

Patient Information [Edit](#)

First Name

Last Name

DOB

Zip Code

Gender

Race

Group

BEN Patient No

NNRMF Patient No

Patient Enrollment Information

Enrollment ID: **PAT132456789** [↔](#)

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.10 Prescriber Designee Dashboard Prescribers Tab

Don Herve ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications ¹ Patients **Prescribers** Manage Groups

The table below contains all the prescribers that you are currently a designee for. If you need to be a designee for a prescriber not in your list, please use the **Associate to Prescriber** button.

Associate to Prescriber Search

First Name	Last Name	Certification ID	Approval Status	Actions
Ether	Thomas	HCP5414006589	Approved	-- Please Select -- -- Please Select -- Remove Designee Relationship Add Patient

Showing 1 to 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications ¹ Patients **Prescribers** Manage Groups

The table below contains all the prescribers that you are currently a designee for. If you need to be a designee for a prescriber not in your list, please use the **Associate to Prescriber** button.

Associate to Prescriber Search

First Name	Last Name	Certification ID	Approval Status	Actions
Hetal	Diwan	HCP5405480914	Pending	-- Please Select -- -- Please Select -- Cancel Designee Request

Showing 1 to 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

Note: The dashboard for the prescriber designee will include a list of all prescribers the designee is acting on behalf of. The actions the prescriber designee can take are:

- 1 – Associate to Prescriber – will take the user to the Associate to Prescriber page
- 2 – Remove Designee Relationship – will take the user to the Remove Designee Relationship page
- 2 – Add Patient – user can add a patient using this option
- 3 – Cancel Designee Request – will take the user to the Cancel Designee Request page

14.3.11 Associate to Prescriber

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Associate to Prescriber

To associate a prescriber, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	and	<input type="text" value="DEA"/>	or	<input type="text" value="NPI"/>
<input type="text" value="Phone (opt)"/>					
<input type="button" value="Search"/>					

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.12 Remove Designee Relationship

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Remove Designee Relationship

To remove your relationship with this prescriber, please check the box below and press **Submit**.

Prescriber Name: [Summer Hogan](#)

Relationship Status: [Approved](#)

I hereby remove my relationship with this prescriber and understand that I will no longer have the ability to perform actions on their behalf in the Clozapine REMS Program.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.3.13 Cancel Designee Request

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Cancel Designee Request

To cancel the approval request to act on behalf of this prescriber, please check the box below and press **Submit**.

Prescriber Name: [Summer Hogan](#)

Relationship Status: [Pending](#)

I hereby cancel my request to act on behalf of this prescriber in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.4 Pharmacy Dashboard – Inpatient Pharmacies

14.4.1 Inpatient Pharmacy Dashboard Pharmacies Tab

The screenshot displays the 'Pharmacies' tab of the Clozapine REMS dashboard. At the top, there are navigation tabs for Alerts, Notifications, Pharmacies (selected), and Pharmacy Staff. A search bar and an 'Add Pharmacy' button are located above the table. The table lists seven pharmacies with columns for Name, Address, Type, Certification ID, Status, and Actions. A dropdown menu is open for the 'Test Pharma' entry, showing options like 'Remove Pharmacy', 'View/Update Pharmacy Profile', 'Add Lab', 'Eligibility Check', and 'Recertify Pharmacy'. A footer message provides contact information for the program.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- Go
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- -- Please Select -- Remove Pharmacy View/Update Pharmacy Profile Add Lab Eligibility Check Recertify Pharmacy Go
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	Go
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- Go
Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	-- Please Select -- Go
Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	-- Please Select -- Go
Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- Go

Showing 1 to 7 of 7 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note: The dashboard for the authorized representative of inpatient pharmacy will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:

- 1 – Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:

- 2 – Remove Pharmacy – will take the user to the Remove Pharmacy page
- 2 – View/Update Pharmacy Profile – will take the user to the Pharmacy Profile page
- 2 – Add Lab – will take the user to the Add Lab
- 2 – *Eligibility Check* – will take the user to the *Eligibility Check* page.
- 2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
- 3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.4.2 Add Lab

Note: This Add Lab page is displayed for both Inpatient, Outpatient pharmacies on- and off-switch.

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Add Lab

To add lab information for your patient, please complete the fields below and **Submit**. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab

ANC value per microlitre

Blood Draw Date

Dispensation Information (optional)

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.4.3 Add Lab – Successful

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Add Lab

To add lab information for your patient, please complete the fields below and **Submit**. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

Add Patient Lab

ANC value per microlitre

Blood Draw Date

Dispensation Information (optional)

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Patient's lab results were successfully saved.

[Ok](#)

Clozapine REMS Program_Website_Screen_Captures
Reference ID: 4376730

November 2018

Page 162 of 238

14.4.4 Add Lab – Unsuccessful

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Add Lab

To add lab information for your patient, please complete the fields below and **Submit**. All fields listed below are required unless otherwise indicated.

Patient Information

 [?](#)

Add Patient Lab

Dispensation Information (optional)

 [?](#)

At least one identifier is required

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.4.5 Eligibility Check

Note: This *Eligibility Check* page displayed is for Inpatient Pharmacies.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Eligibility Check

To determine if the safe-use conditions have been met for your inpatient to receive clozapine, please complete the *Eligibility Check* information below and **Submit**. If you have lab information for your patient, you may enter it here. The result of the *Eligibility Check* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information (optional)

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

Cancel Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.4.6 Eligibility Check Result – Successful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾

[My Dashboard](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	Lab Status Lab was Saved
DOB	For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

14.4.7 Eligibility Check Result – Successful with warning message

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Lab Status **Lab was Saved**

A *Treatment Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.4.8 Eligibility Check Result – Unsuccessful

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

1

Name **Summer H**

DOB

✘ The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

2

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note:

- 1 – The tool-tip next to this field will display this Monitoring Frequency text:
 - For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the *Eligibility Check* date.
 - For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the *Eligibility Check* date.
 - For monthly monitoring frequency, the ANC submitted to the Clozapine REMS must be drawn* within 31 days prior to the *Eligibility Check* date.

*Assumes lab draw date is day 0

- 2 – Patient's Lab History – This button will take the user to the Patient's Lab History page

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

3

14.5 Pharmacy Dashboard – Outpatient Pharmacies

The screenshot shows the 'Pharmacies' tab selected in the dashboard. A search bar is present with the text 'Please search for your pharmacy in the table below and take the appropriate action. If you do not see your pharmacy listed, please use **Add Pharmacy** button to add the pharmacy to the list.' Below the search bar is a table with 7 entries. The table columns are Pharmacy Name, Address, Pharmacy Type, Certification ID, Certification Status, and Actions. The 'Actions' column contains dropdown menus and 'Go' buttons. A callout box labeled '2' highlights the dropdown menu for the 'Ikea Inc' entry, which includes options like 'Remove Pharmacy', 'View/Update Pharmacy Profile', 'Add Lab', 'Dispense Rationale', and 'Recertify Pharmacy'. A callout box labeled '3' highlights the 'Go' button for the 'Tata Pharma' entry. A callout box labeled '1' highlights the 'Add Pharmacy' button. The footer of the dashboard shows 'Showing 1 to 7 of 7 entries' and pagination controls.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- Go
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- Go
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- -- Please Select -- Remove Pharmacy View/Update Pharmacy Profile Add Lab Dispense Rationale Recertify Pharmacy Go
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	Go
Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	-- Please Select -- Go
Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119640	Incomplete	-- Please Select -- Go
Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- Go

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

The dashboard for the authorized representative of outpatient pharmacy types will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:

- 1 – Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:

- 2 – Remove Pharmacy – will take the user to the Remove Pharmacy page
- 2 – View/Update Pharmacy Profile – will take the user to the Pharmacy Profile page
- 2 – Add Lab – will take the user to the Add Lab
- 2 – *Dispense Rationale* – will take the user to *Dispense Rationale* page
- 2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
- 3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.5.1 Dispense Rationale

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Dispense Rationale

To request a *Dispense Rationale* for your patient, please complete the information below and **Submit**. If you have lab information for your patient, you can enter it here. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer --

-- NDC# Number --

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note: This *Dispense Rationale* page is displayed for outpatient pharmacies on- & off-switch.

14.5.2 Dispense Rationale Result Screen – Success

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.5.3 Dispense Rationale Result Screen – Success (After DR is issued)

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

14.5.4 Dispense Rationale Result Screen – Unsuccessful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p> 
DOB	
Authorization Number	

[Patient's Lab History](#)

Provide *Dispense Rationale* for this patient.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6 Pharmacy Dashboard – Outpatient Pharmacies on switch

The screenshot shows the 'Pharmacies' tab in the Clozapine REMS dashboard. At the top, there is a navigation bar with 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. Below this is a search bar and an 'Add Pharmacy' button. The main content is a table with columns: Pharmacy Name, Address, Pharmacy Type, Certification ID, Certification Status, and Actions. The table lists seven pharmacies, including 'aks shay ku', 'Test Pharma', 'Ikea Inc', 'JC Penny', 'Tata Pharma', 'Sharma Pharma', and 'Inpatient'. The 'Actions' column for each pharmacy contains a dropdown menu with options like 'Remove Pharmacy', 'View/Update Pharmacy Profile', 'Add Lab', 'Predispose Authorization', 'Dispense Rationale', and 'Recertify Pharmacy'. A 'Go' button is next to each dropdown. A search bar is located at the top right of the table area. A '1' is placed in a box above the search bar. A '2' is placed in a box next to the dropdown menu for 'JC Penny'. A '3' is placed in a box next to the dropdown menu for 'Sharma Pharma'. The page shows 'Showing 1 to 7 of 7 entries' at the bottom left and a pagination control at the bottom right.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- Go
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- Go
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- Go
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- Go
Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	-- Please Select -- Go
Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	-- Please Select -- Go
Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- Go

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note: The dashboard for the authorized representative of the on-switch outpatient pharmacy will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:

- 1 – Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:

- 2 – Remove Pharmacy – will take the user to the Remove Pharmacy page
- 2 – View/Update Pharmacy Profile – will take the user to the Pharmacy Profile page
- 2 – Add Lab – will take the user to the Add Lab
- 2 – *Predispense Authorization* – will take the user to the *Predispense Authorization* page
- 2 – *Dispense Rationale* – will take the user to *Dispense Rationale* page
- 2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
- 3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.1 Predispose Authorization

Summer Hogan • My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Predispose Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the *Predispose Authorization* information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the *Predispose Authorization* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispose Authorization Request

Date of Service ?

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

14.6.2 Predispose Authorization Result – Successful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispose Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name **Summer H**

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

14.6.3 *Predispense Authorization* Result – Unsuccessful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name **Summer H**
DOB
Authorization Number

✖ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

⚠ Current ANC is not on file.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



2

[Patient's Lab History](#)

3

Provide *Dispense Rationale* for this patient.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

- 1 – The tool-tip next to this field will display this text:
 - For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the *Eligibility Check* date.
 - For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the *Eligibility Check* date.
 - For monthly monitoring frequency, the ANC submitted to the Clozapine REMS must be drawn* within 31 days prior to the *Eligibility Check* date.

*Assumes lab draw date is day 0

- 2 – Patient's Lab History – This button will take the user to the Patient's Lab History page.
- 3 – Provide "Dispense Rationale" for this patient – This check box will take the user to the *Dispense Rationale* screen.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.4 *Predispense Authorization* Result – Success (After DR is issued)

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

View Pharmacy Profile

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Pharmacy Profile

Pharmacy Information Edit

Pharmacy Name:

Pharmacy Type: **Outpatient**

Address:

Address 2:

City:

State / Zip Code:

Phone / Ext:

Fax:

NCPDP:

DEA:

NPI:

Pharmacy Certification Information

Certification ID: **HCP123456789** ↔

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.5 Remove Pharmacy

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press **Submit**.

Pharmacy Name: **Joey's Apothecary**

Certification ID: **PRS123456789**

I hereby remove this pharmacy from the Clozapine REMS Program.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.6 Recertify Pharmacy

Note: This Recertify Pharmacy page is displayed for Inpatient, Outpatient on- and off-switch Pharmacies.

14.6.6.1 Pharmacy Recertification Wizard

Note: Users will be presented with a set of questions to recertify a pharmacy

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Username Password Sign in

Forgot Username? Forgot Password? Need an Account?

Home Prescriber Pharmacy Patient Resources Support

Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1

Does your pharmacy management system support electronic communication with the Clozapine REMS Program using established telecommunications standards?

- Yes
- No

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1A

Is your pharmacy affiliated with a chain pharmacy that is contracted with a pharmacy network provider?

- Yes
- No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1B

Is your pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)?

- Yes
 No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 2

Does your pharmacy dispense clozapine only to patients treated on an outpatient or chronic basis? This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

- Yes
- No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please contact your chain headquarters pharmacy authorized representative for assistance. If you are the authorized representative, or if you do not know who the authorized representative is, please call the Clozapine REMS Program at 844-267-8678.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

[Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Clozapine REMS Pharmacy Classification

Please call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.6.2 Pharmacy Recertification – Intake

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan • My Dashboard

Home Prescriber **Pharmacy** Patient Resources Support

Intake Attestation Confirmation

Pharmacy Intake

2

⚠ Note: Your pharmacy type has been updated. Click [here](#) to change.

To certify your Pharmacy, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the contact preference you selected during your Authorized Representative Intake. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Name

-- Select Type -- **1**

Address

Address 2 (opt)

City

--State-- * Zip

Phone Ext (opt)

Fax (opt)

Pharmacy Identifiers

Please provide at least one identifier.

NCPDP (opt)

DEA (opt)

NPI (opt)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

Note:

- 1 – After the user attempts all the questions during pharmacy recertification, the user will be presented with the Pharmacy Intake page where the Pharmacy Type field will be disabled.
- 2 – If the user wishes to change the pharmacy type, then the user can click on the link and he will have to re-take the recertification wizard.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.6.3 Pharmacy Reactivation: Non-Chain Pharmacy

Note: If a pharmacy does not recertify within the certification window, the pharmacy will be deactivated from the program. In order to return to the program, the pharmacy will be presented with the screen below upon logging in to their dashboard. This screen applies to Non-Chain Pharmacy only.

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, there is a user profile 'Summer Hogan' with a dropdown arrow and a 'My Dashboard' button. Below the navigation bar is a horizontal menu with links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', and 'Support'. The main content area contains a message: 'Based on the information provided, we have determined that your certification was deactivated. Please use the **Reactivate** button to start your re-certification.' Below this message is a blue button labeled 'Reactivate'.

Based on the information provided, we have determined that your certification was deactivated. Please use the **Reactivate** button to start your re-certification.

[Reactivate](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.6.4 Pharmacy Reactivation: Chain Pharmacy

Note: If a pharmacy does not recertify with the certification window, the pharmacy will be deactivated from the program. In order to return to the program, the pharmacy will be presented with the screen below upon logging in to their Dashboard. This screen applies to Chain Pharmacy only.

The screenshot displays the Clozapine REMS Program website interface. At the top left, the logo reads "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". On the top right, the user name "Summer Hogan" is shown next to a "My Dashboard" button. A navigation menu includes links for "Home", "Prescriber", "Pharmacy", "Patient", "Resources", and "Support". The main content area features a message: "Pharmacies are required to renew their certification in the Clozapine REMS Program every two years. Our records indicate your pharmacy has not recertified and therefore your certification in the Clozapine REMS Program is no longer active. To recertify your pharmacy, please call the Clozapine REMS Program Contact Center at 844-267-8678." Below this message, a call to action states: "For additional information about the Clozapine REMS Program, please call 844-267-8678." The footer contains links for "Privacy | Terms of Use | Site Map | FAQs | Contact Us".

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.7 Pharmacy Dashboard Pharmacy Staff Tab

The table below contains all the pharmacy staff that are currently assigned to you.

First Name	Last Name	Pharmacy Name	Address	Enrollment ID	Enrollment Status	Actions
Sally	Smith	Joey's Apothecary	1 East Main Street, New York NY 10001	HCP123456789	Enrolled	<ul style="list-style-type: none">Remove Pharmacy Staff

Showing 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note: The dashboard for the authorized representative of inpatient and outpatient pharmacy types will include a list of all pharmacy staff that is representing the authorized representative. The actions the authorized representative can take are:

1 – Remove Pharmacy Staff – will take the user to the Remove Pharmacy Staff page

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.6.8 Remove Pharmacy Staff

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press **Submit**.

Staff Member: [Sally Smith](#)

Pharmacy Name: [Joey's Apothecary](#)

Enrollment ID: [HCP123456789](#)

I hereby remove this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

14.7 Chain Pharmacy Dashboard

14.7.1 Chain Pharmacy Dashboard Pharmacies Tab

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts ³ Notifications ¹ Pharmacies Pharmacy Staff

To certify a store that has been trained on all program requirements, select the store(s) and use the **Certify Store** button.
To add a store not in your list, use the **Add Chain Store** button. For all other activities, use the Actions list for the store.

Add Chain Store Search

<input type="checkbox"/>	Store Name	Address	Certification ID	Certification Status	Actions
<input type="checkbox"/>	Joey's Apothecary	1 East Main Street, New York NY 10001	FAC1002345831	Certified	-- Please Select -- Go View Pharmacy Profile Remove Pharmacy
<input type="checkbox"/>	Hogan RX	2 Park Avenue, New York NY 10201	FAC2234583304	Certified	-- Please Select -- Go
<input checked="" type="checkbox"/>	Apollo Pharmacy	311 Bell Road, Anaheim CA 92805	FAC0057124807	Incomplete	-- Please Select -- Go
<input type="checkbox"/>	Life Pharmacy	423 Main Street, Tampa FL 33614	FAC0057124807	Certified	-- Please Select -- Go
<input type="checkbox"/>	Mercury Drug	52 Milky Way Dr, Anchorage, AK 99508	FAC2585234583	Certified	-- Please Select -- Go

Showing 10 of 10 entries

Certify Store

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note: The dashboard for the authorized representative of chain headquarters pharmacy will include a list of all chain store pharmacies the authorized representative is managing. The actions the authorized representative can take are:

1 – Add Chain Store – will take the users to the Chain Pharmacy Store Intake page and through the chain store certification process

For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:

2 – View Pharmacy Profile – will take the user to the Pharmacy Profile page
2 – Remove Pharmacy – will take the user to the Remove Pharmacy page

3 – Certify Store button – for pharmacies with a certification status of “Incomplete,” the authorized representative can check one, numerous, or all checkboxes (located on the left side of the data grid) and press the button to certify the store once the staff is trained.

14.7.2 View Pharmacy Profile

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Pharmacy Profile

Pharmacy Information Edit

Pharmacy Name

Pharmacy Type

Address

Address 2

City

State / Zip Code

Phone / Ext

Fax

NCPDP

DEA

NPI

Pharmacy Certification Information

Certification ID: **HCP123456789**

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

14.7.3 Remove Pharmacy

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press **Submit**.

Pharmacy Name: [Joey's Apothecary](#)

Certification ID: [PRS123456789](#)

I hereby remove this pharmacy from the Clozapine REMS Program.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.7.4 Chain Pharmacy Dashboard Pharmacy Staff Tab

The table below contains all the pharmacy staff that are currently assigned to you.

First Name	Last Name	Pharmacy Name	Address	Enrollment ID	Enrollment Status	Actions
Sally	Smith	Joey's Apothecary	1 East Main Street, New York NY 10001	HCP123456789	Enrolled	<ul style="list-style-type: none">-- Please Select --GoRemove Pharmacy Staff

Showing 10 of 10 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note: The dashboard for the authorized representative of chain headquarters pharmacy will include a list of all pharmacy staff that is representing the authorized representative. The actions the authorized representative can take are:

- 1 – Remove Pharmacy Staff – will take the user to the Remove Pharmacy Staff page

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.7.5 Remove Pharmacy Staff

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press **Submit**.

Staff Member: [Sally Smith](#)

Pharmacy Name: [Joey's Apothecary](#)

Enrollment ID: [HCP123456789](#)

I hereby remove this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.8 Pharmacy Staff Dashboard

14.8.1 Pharmacy Staff Dashboard Pharmacies Tab

The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the **Associate Pharmacy** button. For pharmacy actions, use the Actions list below.

▲ Pharmacies in the list below that are in red text will be deactivated within seven (7) calendar days if the Authorized Representative does not recertify the pharmacy within that timeframe. Please contact your pharmacy Authorized Representative to remind them to recertify the pharmacy. If the pharmacy is deactivated, Pharmacy Staff will not have access to perform Actions for the pharmacy on the website until recertification occurs. Call the Contact Center for additional assistance.

Pharmacy Name	Address	Certification Status	Actions
Barro Pharma	4343 scottsdale rd, SAN JOSE, California 95128	Certified	-- Please Select -- <input type="button" value="Go"/>
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	-- Please Select -- <input type="button" value="Go"/>
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	Certified	-- Please Select -- <input type="button" value="Go"/>
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	Certified	-- Please Select -- <input type="button" value="Go"/>
Pharma co	4343 scottsdale rd, BALTIMORE, Maryland 21215	Certified	-- Please Select -- <input type="button" value="Go"/> -- Please Select -- Add Lab <input type="button" value="Go"/> Eligibility Check <input type="button" value="Go"/> Remove Pharmacy Relationship <input type="button" value="Go"/> -- Please Select -- <input type="button" value="Go"/>

Showing 1 to 5 of 5 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Note: The dashboard for the pharmacy staff will include a list of all pharmacies the pharmacy staff is representing. The actions the pharmacy staff member can take are:

- 1 – Associate to Pharmacy – will take the user to the Associate to Pharmacy page.
- 2 - Add Lab- will take the user to the Add Lab page
- 3 - *Eligibility Check* – will take the user to the *Eligibility Check* page.
- 4 –*Predispense Authorization* – will take the user to the *Predispense Authorization* page.
- 5 – *Dispense Rationale*- will take the user to the *Dispense Rationale* page.
- 6 – Remove Pharmacy Relationship- will take the user to Remove Pharmacy page.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.8.2 Associate to Pharmacy

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Associate to Pharmacy

To identify the pharmacy you represent, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="3456789"/>
------------------------------------	-----	----------------------------------	----------------------------------	--------------------------------------

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Clozapine REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
CVS	423 Main Street, Tampa FL 33614	555-555-5555

Showing 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.8.3 Eligibility Check

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check

To determine if the safe-use conditions have been met for your inpatient to receive clozapine, please complete the *Eligibility Check* information below and **Submit**. If you have lab information for your patient, you may enter it here. The result of the *Eligibility Check* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

Dispensation Information

?

At least one identifier is required

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.8.4 Eligibility Check Result – Unsuccessful

Note: This result is displayed for the *Eligibility Check* when the result is unsuccessful.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

⚠ The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.8.5 Predispose Authorization

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Predispose Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the *Predispose Authorization* information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the *Predispose Authorization* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispose Authorization Request

Date of Service ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

14.8.6 *Predispense Authorization* Result – Unsuccessful

Note: This result is displayed for the *Predispense Authorization* when the result is unsuccessful.

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

⚠ Current ANC is not on file.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

Provide *Dispense Rationale* for this patient.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

15. Dispense Rationale – Static Pages

15.1 Home Page

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[FAQs >>](#)

Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Prescriber

All prescribers of clozapine products must certify in the Clozapine REMS Program. Certification requires prescribers to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

The <MM/YYYY> Clozapine REMS Program Modification went live on <MM/DD/YYYY>. Prescribers are required to certify in the Clozapine REMS Program as soon as possible to continue patient therapy. If prescribers are not certified at the time of the <MM/YYYY> Clozapine REMS Program Modification, a dispense of clozapine will not be authorized for patients under their care. Click on the [Important Program Update \(IPU\)](#) button for more information.

[Start Prescriber Certification](#)

Pharmacy

All pharmacies dispensing clozapine products must certify in the Clozapine REMS Program. Certification requires pharmacies to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
- **Implement:** Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

The <MM/YYYY> Clozapine REMS Program Modification went live on <MM/DD/YYYY>. Pharmacies are required to certify in the Clozapine REMS Program. If pharmacies are not certified at the time of the <MM/YYYY> Clozapine REMS Program Modification, a dispense of clozapine will not be authorized for patients under their care. Click on the [Important Program Update \(IPU\)](#) button for more information.

[Start Pharmacy Certification](#)

***** Important Program Update (as of MM/DD/YYYY) *****
Please click to open the IPU

What is the Clozapine REMS Program?

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/uL), which can lead to serious and fatal infections. The requirements to prescribe, dispense and receive clozapine are incorporated into a single shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the Food and Drug Administration (FDA) for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

16. Dispense Rationale – Pharmacy Authorized Representative (Non-Switch)

16.1 Pharmacy – Authorized Representative Dashboard

Please search for your pharmacy in the table below and take the appropriate action. If you do not see your pharmacy listed, please use **Add Pharmacy** button to add the pharmacy to the list.

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
Hogan Rx	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- <input type="button" value="Go"/>
Test Pharma	2101 E. Dunlap Selma, Alabama 35848 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- <input type="button" value="Go"/>
Mercury Drug Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- <input type="button" value="Go"/>
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	-- Please Select -- <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	-- Please Select -- <input type="button" value="Go"/> <ul style="list-style-type: none">Remove PharmacyView/Update Pharmacy ProfileAdd LabPredispense AuthorizationDispense RationaleRecertify Pharmacy
<input checked="" type="checkbox"/> Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119840	Incomplete	-- Please Select -- <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 7 of 7 entries

Navigation: < 1 > 10

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

16.2 Pharmacy – Authorized Representative *Predispense Authorization*

Summer Hogan • [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the *Predispense Authorization* information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the *Predispense Authorization* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispense Authorization Request

Date of Service ?

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required.

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

16.3 Pharmacy – Authorized Representative *Predispose Authorization Result- Successful*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispose Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

16.4 Pharmacy – Authorized Representative *Predispense Authorization Result- Unsuccessful*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Predispense Authorization Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name **Summer H**

DOB

Authorization Number

✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

⚠ Current ANC is not on file.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



Patient's Lab History

Provide *Dispense Rationale* for this patient.

Cancel

Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16.5 Pharmacy – Authorized Representative *Predispense Authorization* Result – Successful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

✓ **The *Dispense Rationale* has been provided.**
Please resubmit the request to receive the authorization to dispense clozapine to the patient.

[Resubmit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16.6 Pharmacy – Authorized Representative *Predispense Authorization Result- Successful (After the Dispense Rationale is issued)*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

16.7 Pharmacy – Authorized Representative *Predispense Authorization* Result – Unsuccessful

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right is a 'My Dashboard' button. Below the logo is a horizontal menu with links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. The user's name 'test testat' is visible in the top right corner.

Predispense Authorization Result

 The maximum number of allowable *Dispense Rationales* has been reached for this patient.
For further assistance with this patient's eligibility, please contact the prescriber.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

17. Dispense Rationale – Pharmacy Staff (Non-Switch)

Pharmacy Staff Dashboard

Trish Kay ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications ¹ Pharmacies

The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the **Associate Pharmacy** button. For pharmacy actions, use the Actions list below.

Associate Pharmacy

⚠ Pharmacies in the list below that are in red text will be deactivated within seven (7) calendar days if the Authorized Representative does not recertify the pharmacy within that timeframe. Please contact your pharmacy Authorized Representative to remind them to recertify the pharmacy. If the pharmacy is deactivated, Pharmacy Staff will not have access to perform Actions for the pharmacy on the website until recertification occurs. Please call the Contact Center for additional assistance.

Pharmacy Name	Address	Certification Status	Actions
Barro Pharma	4343 scottsdale rd, SAN JOSE, California 95128	Certified	-- Please Select -- <input type="button" value="Go"/>
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	-- Please Select -- Add Lab <input type="button" value="Go"/> Predispense Authorization <input type="button" value="Go"/> Dispense Rationale Remove Pharmacy Relationship
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	Certified	-- Please Select -- <input type="button" value="Go"/>
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	Certified	-- Please Select -- <input type="button" value="Go"/>
Trader Joes	4343 scottsdale rd, BALTIMORE, Maryland 21215	Certified	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 5 of 5 entries < 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

17.1 Pharmacy Staff *Predispense Authorization*

Summer Hogan ▾ My Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Home Prescriber Pharmacy Patient Resources Support

Predispense Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the *Predispense Authorization* information below and **Submit**. If you have lab information for your patient, you may enter it here. The results of the *Predispense Authorization* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Predispense Authorization Request

Date of Service ?

-- Manufacturer --

-- NDC# Number --

Days Supply

Quantity

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

17.2 Pharmacy Staff *Predispense Authorization Result*- Successful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

17.3 Pharmacy Staff *Predispense Authorization Result*- Unsuccessful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μL) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
DOB	
Authorization Number	

[Patient's Lab History](#)

Provide *Dispense Rationale* for this patient.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

17.4 Pharmacy Staff *Predispense Authorization* Result – Successful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

✓ **The *Dispense Rationale* has been provided.**
Please resubmit the request to receive the authorization to dispense clozapine to the patient.

[Resubmit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

17.5 Pharmacy Staff *Predispense Authorization Result*- Successful (After the *Dispense Rationale* is issued)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Predispense Authorization Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

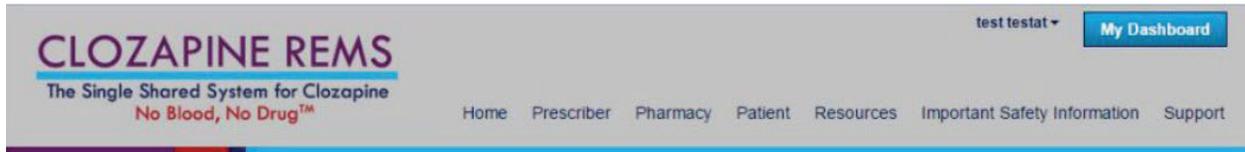
A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

17.6 Pharmacy Staff *Predispense Authorization* Result – Unsuccessful



The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the text 'CLOZAPINE REMS' and 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right is a 'test testat' dropdown menu and a 'My Dashboard' button. Below the logo is a horizontal navigation menu with links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

Predispense Authorization Result

 The maximum number of allowable *Dispense Rationales* has been reached for this patient.
For further assistance with this patient's eligibility, please contact the prescriber.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

18. Dispense Rationale – Pharmacy Authorized Representative (Switch)

18.1 Pharmacy – Authorized Representative Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Alerts Notifications **Pharmacies** Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you do not see your pharmacy listed, please use **Add Pharmacy** button to add the pharmacy to the list.

Add Pharmacy Search

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
aks shay ku	4343 n scottsdale rd, BURKEVILLE, Virginia 23922	Inpatient	FAC5413173502	Certified	-- Please Select -- <input type="button" value="Go"/>
Test Pharma	4343 n scottsdale rd, PHOENIX, Arizona 85054	Inpatient	FAC5413316247	Certified	-- Please Select -- <input type="button" value="Go"/>
Ikea Inc	4343 n scottsdale rd, PHOENIX, Arizona 85054	Outpatient	FAC5413637605	Certified	-- Please Select -- <input type="button" value="Go"/> -- Please Select -- Remove Pharmacy View/Update Pharmacy Profile Add Lab Dispense Rationale Recertify Pharmacy
JC Penny	4343 north scottsdale, PHOENIX, Arizona 85054	Outpatient	FAC5413634942	Certified	<input type="button" value="Go"/>
<input checked="" type="checkbox"/> Tata Pharma	4343 n scottsdale rd, LANSING, Michigan 48915	Outpatient	FAC5414118715	Incomplete	-- Please Select -- <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Sharma Pharma	4343 N scottsdale rd, LANSING, Michigan 48912	Outpatient	FAC5414119640	Incomplete	-- Please Select -- <input type="button" value="Go"/>
<input checked="" type="checkbox"/> Inpatient	Address, SCOTTSDALE, Arizona 85250	Inpatient	FAC5414782350	Incomplete	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 7 of 7 entries < 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Privacy | Terms of Use | Site Map | FAQs | Contact Us

18.2 Pharmacy – Authorized Representative *Dispense Rationale*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Dispense Rationale

To request a *Dispense Rationale* for your patient, please complete the information below and **Submit**. If you have lab information for your patient, you can enter it here. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer --

-- NDC# Number --

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note: This *Dispense Rationale* page is displayed for outpatient pharmacies on- & off-switch.

18.3 Pharmacy – Authorized Representative *Dispense Rationale* Result Screen- Success

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

18.4 Pharmacy – Authorized Representative *Dispense Rationale* Result Screen- Success (After DR is issued)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

18.5 Pharmacy – Authorized Representative *Dispense Rationale* Result Screen- Unsuccessful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name Summer H	<p>✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.</p> <p>⚠ Current ANC is not on file.</p> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p>
DOB	
Authorization Number	

[Patient's Lab History](#)

Provide *Dispense Rationale* for this patient.

[Cancel](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

18.6 Pharmacy – Authorized Representative *Eligibility Check Result- Successful*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Lab Status [Lab was Saved](#)

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

18.7 Pharmacy – Authorized Representative *Eligibility Check Result- Unsuccessful*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name **Summer H**

DOB

⚠ The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

19. Dispense Rationale – Pharmacy Staff (Inpatient Pharmacy) 19.1 Pharmacy Staff Dashboard

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Trish Kay ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Alerts](#) [Notifications ¹](#) [Pharmacies](#)

The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the **Associate Pharmacy** button. For pharmacy actions, use the Actions list below.

Associate Pharmacy

⚠ Pharmacies in the list below that are in red text will be deactivated within seven (7) calendar days if the Authorized Representative does not recertify the pharmacy within that timeframe. Please contact your pharmacy Authorized Representative to remind them to recertify the pharmacy. If the pharmacy is deactivated, Pharmacy Staff will not have access to perform Actions for the pharmacy on the website until recertification occurs. Please call the Contact Center for additional assistance.

Pharmacy Name	Address	Certification Status	Actions
Barro Pharma	4343 scottsdale rd, SAN JOSE, California 95128	Certified	-- Please Select -- <input type="button" value="Go"/>
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	-- Please Select -- <input type="button" value="Go"/>
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	Certified	-- Please Select -- <input type="button" value="Go"/>
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	Certified	-- Please Select -- <input type="button" value="Go"/> Add Lab <input type="button" value="Go"/> Eligibility Check <input type="button" value="Go"/> Remove Pharmacy Relationship <input type="button" value="Go"/>
Trader Joes	4343 scottsdale rd, BALTIMORE, Maryland 21215	Certified	-- Please Select -- <input type="button" value="Go"/>

Showing 1 to 5 of 5 entries < 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

19.2 Pharmacy Staff *Eligibility Check*

Summer Hogan ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check

To determine if the safe-use conditions have been met for your inpatient to receive clozapine, please complete the *Eligibility Check* information below and **Submit**. If you have lab information for your patient, you may enter it here. The result of the *Eligibility Check* will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer --

-- NDC# Number --

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

19.3 Pharmacy Staff *Eligibility Check Result*- Successful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Eligibility Check Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Lab Status [Lab was Saved](#)

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

19.4 Pharmacy Staff *Eligibility Check Result*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Eligibility Check Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per µL) ?	1500	None

Current Monitoring Frequency: Weekly

Name **Summer H**

DOB

⚠ The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

For further assistance with this patient's eligibility, please contact the patient's prescriber.

[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note: If an authorized representative or pharmacy staff using the pharmacy network (switch) receives a rejection message due to "prescriber not certified", the following message will appear on their screen:

REMS Clozapine REMS – Prescriber must be certified or you can request a *Dispense Rationale* through www.clozapinerems.com or by calling 844-267-8678.

Once this message is received, the authorized representative or Pharmacy Staff can either call the Clozapine REMS Program contact center to obtain a *Dispense Rationale* or they can access the website and follow the above screens to obtain the *Dispense Rationale*. Once they receive confirmation of the *Dispense Rationale*, the authorized representative or Pharmacy Staff will need to re-run the claim to allow the authorization of the dispense.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

20. Dispense Rationale – Pharmacy Staff (Switch) 20.1 Pharmacy Staff Dashboard

Trish Kay ▾ [My Dashboard](#)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

[Alerts](#) [Notifications](#) **Pharmacies**

The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the **Associate Pharmacy** button. For pharmacy actions, use the Actions list below.

Associate Pharmacy

⚠ Pharmacies in the list below that are in red text will be deactivated within seven (7) calendar days if the Authorized Representative does not recertify the pharmacy within that timeframe. Please contact your pharmacy Authorized Representative to remind them to recertify the pharmacy. If the pharmacy is deactivated, Pharmacy Staff will not have access to perform Actions for the pharmacy on the website until recertification occurs. Please call the Contact Center for additional assistance.

Pharmacy Name	Address	Certification Status	Actions
Barro Pharma	4343 scottsdale rd, SAN JOSE, California 95128	Certified	-- Please Select -- <input type="button" value="Go"/>
Orlando Pharma	4343 scottsdale rd, BENTON HARBOR, Michigan 49022	Deactivated	-- Please Select -- <input type="button" value="Go"/>
tata reliance	4343 scottsdale rd, PHOENIX, Arizona 85016	Certified	-- Please Select -- <input type="button" value="Go"/>
Tomas Pharma	4343 scottsdale rd, OMAHA, Nebraska 68117	Certified	-- Please Select -- <input type="button" value="Go"/>
Trader Joes	4343 scottsdale rd, BALTIMORE, Maryland 21215	Certified	-- Please Select -- Add Lab Dispense Rationale Remove Pharmacy Relationship <input type="button" value="Go"/>

Showing 1 to 5 of 5 entries < 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

20.2 Pharmacy Staff *Dispense Rationale*

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Dispense Rationale

To request a *Dispense Rationale* for your patient, please complete the information below and **Submit**. If you have lab information for your patient, you can enter it here. All fields listed below are required unless otherwise indicated.

Patient Information

First Name

Last Name

Date of Birth

Zip Code ?

If a patient's zip code is unknown, enter the pharmacy's zip code instead.

Add Patient Lab (optional)

ANC value per microlitre (opt)

Blood Draw Date (opt)

Dispensation Information

Date of Service (opt) ?

-- Manufacturer -- ▾

-- NDC# Number -- ▾

Days Supply (opt)

Quantity (opt)

At least one identifier is required

Prescriber DEA

Prescriber NPI

Cancel

Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

20.3 Pharmacy Staff *Dispense Rationale* Result- Success

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Support

Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

Lab Status **Lab was Saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

20.4 Pharmacy Staff *Dispense Rationale* Result- Success (After DR is issued)

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

✓ The below patient is eligible to receive clozapine.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name [Summer H](#)

DOB

Authorization Number

▲ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

▲ Current ANC is not on file.

A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

20.5 Pharmacy Staff *Dispense Rationale* Result- Unsuccessful

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Dispense Rationale Result

⚠ Do not dispense clozapine to this patient.
Please call the Clozapine REMS Program at 844-267-8678 for more information.

Lab ?	Current	Previous
Blood Draw date	04/20/2017	None
ANC Level (per μ L) ?	1500	None

Current Monitoring Frequency: Weekly

Name **Summer H**

DOB

Authorization Number

✘ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.

⚠ Current ANC is not on file.

For further assistance with this patient's eligibility, please contact the patient's prescriber.



[Patient's Lab History](#)

Provide *Dispense Rationale* for this patient.

[Cancel](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

21. Dispense Rationale – Prescriber and Prescriber Designee

21.1 Prescriber and Prescriber Designee Dashboard

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, please use the **Enroll Patient** button to add the patient. A flagged row indicates an NNRMF patient.

First Name	Last Name	DOB	Enrollment	Group	Relationship	Actions
John	Abraham	01/19/1982	Enrolled		Transferred	- Please Select 1 <input type="button" value="Go"/>
tammy	baker	10/18/2000	Incomplete		Active	- Please Select <input type="button" value="Go"/>
Jeff	Bradley	02/16/1910	Enrolled		Active	- Please Select - <input type="button" value="Go"/>

2 Gender: Male
NNRMF: No
BEN: Yes

View ANC Monitoring Table	Current	Highest	Lowest
Blood Draw date	05/24/2016	03/14/2016	05/15/2016
ANC Level (per µL)	340	9000	290

3 Enrollment Id: PAT71
Dispense Rationale: Active

chola	chelan	10/10/1965	Enrolled		Active	- Please Select - <input type="button" value="Go"/>
chola	chelan	04/10/2016	Enrolled		Active	- Please Select - <input type="button" value="Go"/>
Patient	contactsingh	01/01/1934	Enrolled		Active	- Please Select - <input type="button" value="Go"/>
Patient	Contactsingh	07/21/2016	Enrolled		Active	- Please Select - <input type="button" value="Go"/>
Chris	Cruise	02/16/1990	Enrolled		Active	- Please Select - <input type="button" value="Go"/>
John	Davidson	02/25/2016	Enrolled		Active	- Please Select - <input type="button" value="Go"/>
John	Davidson	02/25/2016	Enrolled		Active	- Please Select - <input type="button" value="Go"/>

Showing 1 to 10 of 49 entries

■ = NNRMF patient

For definitions of terms used on this page, click [here](#).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

Note:

1. Prescriber and Prescriber Designees can also view the *Dispense Rationale* history by clicking on the drop-down menu and selecting '*Dispense Rationale History*'.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

2. This expandable section is functionality that will be on both the Prescriber and Prescriber Designee dashboard. This section provides information about the status of the *Dispense Rationale*.
3. Options available for *Dispense Rationale* status include:
 - a. Active
 - b. Expired
 - c. Limit Reached
 - d. Not on File

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

21.2 Prescriber and Prescriber Designee *Dispense Rationale* History

CLOZAPINE REMS
The Single Shared System for Clozapine
No Blood, No Drug™

Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Support](#)

Patient History

[Lab History](#) [Treatment Status History](#) [Monitoring Frequency History](#) **[Dispense Rationale](#)**

Name: [Jeff Bradley](#)
DOB: [02/16/1910](#)
Gender: [Male](#)

Pharmacy Name	Date Issued	Expiration Date
First Care Pharmacy	03/24/2015	03/26/2015
Scottsdale Pharmacy	05/15/2015	05/17/2015

Showing 1 to 2 of 2 entries

< 1 > 10 ▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

[Privacy](#) | [Terms of Use](#) | [Site Map](#) | [FAQs](#) | [Contact Us](#)

Instructions

Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. This form must be completed and returned to the Clozapine REMS Program before clozapine products may be shipped to certified pharmacy locations. This form applies to all distributors who wish to purchase any clozapine product.

In order to distribute clozapine, the distributor must designate an authorized representative.

The authorized representative for the distributor must:

- Review and agree to the responsibilities below.
- Complete and submit this one-time *Clozapine REMS Distributor Enrollment Form*.
- Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements.

Please complete the requested information below and submit this form to info@clozapinedistributor.com. If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

Distributor Responsibilities

I am the authorized representative designated to coordinate the activities to comply with the Clozapine REMS Program distribution requirements. I understand:

- Distributors must enroll in the Clozapine REMS Program to distribute clozapine
- Distributors will have access to a secure daily pharmacy certification file from the Clozapine REMS Program

On behalf of the distributor, I agree to establish procedures that are subject to audit to help ensure compliance with the following program requirements:

- Train relevant staff involved in distributing clozapine on the distribution requirements of the Clozapine REMS Program
- Provide clozapine only to certified pharmacies and enrolled distributors in the Clozapine REMS Program
- Provide complete, unblinded and unblocked data to individual sponsors, including information on shipments to pharmacies
- Cooperate with periodic audits, REMS Assessments, or noncompliance investigations to ensure that clozapine products are distributed in accordance with the Clozapine REMS Program requirements

Distributor Information (All Fields Required)

Name:

Address:

City:

State:

Zip Code:

Phone:

Fax:

DEA:

Authorized Representative Information (All Fields Required)

First Name:

Last Name:

Phone:

Fax:

Email:

Contact Preference (please select one):

Email

Fax

Authorized Representative Signature:

Date (MM/DD/YYYY):

Dear Clozapine Prescriber:

On October 12, 2015, the single shared Clozapine REMS Program replaced all individual clozapine registries. Our records indicate you have not certified in the Clozapine REMS Program. As a reminder, one of the key requirements of the Clozapine REMS Program is that any Healthcare Provider who prescribes or dispenses clozapine must certify in the program.

Since you have not certified, your account with the Clozapine REMS Program has been deactivated and interruption of patient therapy is imminent.

If you wish to treat patients using clozapine products, you must certify online through the Clozapine REMS Program Website at www.clozapinerems.com; by completing the *Clozapine REMS Prescriber Enrollment Form*, training, and the *Clozapine REMS Knowledge Assessment for Healthcare Providers* and faxing the completed documents to 844-404-8876; or, by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If you have any questions, or if you believe that you have received this letter in error, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Regards,

The Clozapine REMS Program

Please review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* available at www.clozapinerems.com for more detailed information about the Clozapine REMS Program requirements and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit www.clozapinerems.com to review the complete Prescribing Information.

Dear Pharmacy Manager:

On October 12, 2015, the single shared Clozapine REMS Program replaced all individual clozapine registries. Our records indicate your pharmacy dispenses clozapine and is not yet certified in the Clozapine REMS Program.

Because you are not yet certified, on <Deactivation Date> your account with the Clozapine REMS Program will be deactivated and you will no longer be able to receive and dispense clozapine.

You must certify in the Clozapine REMS Program to avoid interruption in your ability to receive and dispense clozapine products, and to avoid potential interruption in a patient's clozapine therapy.

Pharmacies can certify online through the Clozapine REMS Program Website at www.clozapinerems.com; by completing the appropriate *Clozapine REMS Enrollment Form*, training, and *Clozapine REMS Knowledge Assessment for Healthcare Providers*, and faxing the completed documents to 844-404-8876; or, by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If you have any questions, or believe that you have received this letter in error, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Regards,

The Clozapine REMS Program

Please review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* available at www.clozapinerems.com for more detailed information about the Clozapine REMS Program requirements and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit www.clozapinerems.com to review the complete Prescribing Information.

> The products covered under the Clozapine REMS Program are: Clozaril® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension

Fazaclo® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products

Dear Pharmacy Manager:

This letter is intended to inform outpatient pharmacies who must obtain a "Predispense Authorization" (PDA) via the Clozapine REMS Program Website or who obtain a PDA by calling the Clozapine REMS Program Contact Center of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program occurring in the February, 2019 REMS Modification. If your pharmacy is part of a pharmacy chain, contact your chain's authorized representative to complete enrollment and certification. If you need assistance, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Changes to the Clozapine REMS Program in February, 2019 may affect your ability to dispense clozapine.

1. **Only pharmacies certified in the Clozapine REMS Program will be able to receive and dispense clozapine.**

- All pharmacies that dispense clozapine must be certified in the Clozapine REMS Program to purchase or receive clozapine from a wholesaler or distributor.
- If your pharmacy dispenses clozapine and *is not yet* certified in the Clozapine REMS Program, certify online at www.clozapinerems.com or download the *Clozapine REMS Outpatient Pharmacy Enrollment Form* and fax the completed form to 844-404-8876.

2. **Pharmacy Classification and program requirements may have changed.**

Pharmacies previously certified in the Clozapine REMS Program may be reclassified using the following definitions:

- **Inpatient pharmacy:** a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)
- **Outpatient pharmacy:** a facility that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems

This pharmacy reclassification, if necessary, will occur at your next scheduled pharmacy recertification. Requirements of pharmacy types differ so if you were an inpatient pharmacy now reclassified as an outpatient pharmacy, please review additional information on outpatient pharmacy requirements available in the *Clozapine REMS PDA Fact Sheet* attached to this letter; in the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, in the *Clozapine REMS Frequently Asked Questions (FAQ's)* available at www.clozapinerems.com; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

You may call the Clozapine REMS Program Contact Center at 844-267-8678 if you are unsure whether your pharmacy type is inpatient or outpatient (based on the definitions above) or if your pharmacy provides both inpatient and outpatient pharmacy services to patients being treated with clozapine.

3. **Prescribing clozapine for patients in an outpatient setting¹ requires certification in the Clozapine REMS Program.**

If the prescriber is not certified in the Clozapine REMS Program, an outpatient pharmacy will not receive authorization to dispense clozapine.

4. **Certified pharmacies may apply clinical judgment and continue to dispense clozapine to enrolled patients if the prescriber is not certified in the Clozapine REMS Program by utilizing a new function, the "Dispense Rationale."**

The use of a *Dispense Rationale* is limited. Refer to the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or the *Clozapine REMS FAQ's* available at www.clozapinerems.com; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

¹An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

What is a *Dispense Rationale*?

- The Clozapine REMS Program will alert the pharmacy when the prescriber is not certified in the Clozapine REMS Program via a reject message of the PDA request. The pharmacy may then exercise clinical judgement to provide a *Dispense Rationale* to authorize the dispense **if**:
 - The patient is enrolled in the Clozapine REMS Program; and,
 - Has an acceptable absolute neutrophil count (ANC) value on file; or,
 - If the last ANC on file indicates moderate or severe neutropenia, has a “Treatment Rationale” on file.
- *Dispense Rationales* are valid for 72 hours (3 calendar days) and limited to no more than three (3) occurrences for an individual patient within a rolling six (6) month period.

How can I provide a *Dispense Rationale*?

- Certified pharmacies can provide a *Dispense Rationale*:
 - Via the Clozapine REMS Program Website at www.clozapinerems.com, or
 - By calling the Clozapine REMS Program Contact Center at 844-267-8678, or
 - By following the step-by-step instructions provided in the enclosed *Clozapine REMS Predispense Authorization Fact Sheet*.

Patient dispensing

- A PDA will be issued if the patient meets the following program Elements to Assure Safe Use:
 - The patient must be enrolled in the Clozapine REMS Program; and,
 - An acceptable ANC value is on file; or,
 - Has a *Treatment Rationale* on file if the last ANC submitted to the Clozapine REMS Program indicates moderate or severe neutropenia.
- Pharmacies should dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.
- All PDA responses will provide the dispensing pharmacy with the most recent ANC value and the associated blood draw date, and patient’s monitoring frequency (MF) on file with the Clozapine REMS Program.

Pharmacies are encouraged to submit the ANC to the Clozapine REMS Program when:

- The pharmacist is made aware of a more current ANC than the most recent lab value reported in the PDA response.
- The most recent ANC indicates moderate or severe neutropenia. The prescriber must provide a *Treatment Rationale* to the Clozapine REMS Program to allow the pharmacy to receive a PDA and dispense clozapine to the patient. The pharmacy may contact the prescriber to remind them of the need for a *Treatment Rationale*.
- Pharmacies may submit ANCs to the Clozapine REMS Program at www.clozapinerems.com, by calling the Clozapine REMS Program Contact Center at 844-267-8678; or, faxing a completed *Clozapine REMS ANC Lab Reporting Form* (available from the website) to the Clozapine REMS Program.
- If the ANC result on file with the Clozapine REMS Program is not current according to the patient’s MF (within 7 days of the PDA transaction date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring), a PDA will still be issued, but the pharmacist will receive a warning message regarding the need to ensure the ANC is current.

The pharmacy’s authorized representative must ensure that all pharmacy staff are aware of these modifications to the Clozapine REMS Program effective February 2019.

For additional information related to the Clozapine REMS Program, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Sincerely,

The Clozapine REMS Program

Enclosures: *Clozapine REMS Predispense Authorization Fact Sheet*
How to Start Clozapine and Monitor Patients Fact Sheet

Dear Pharmacy Manager:

This letter is intended to inform outpatient pharmacies who must obtain a "Predispense Authorization" (PDA) electronically via their pharmacy management system (i.e., "the switch") of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program that will occur in the February 2019 REMS Modification.

Changes to the Clozapine REMS Program in February 2019 may affect your ability to dispense clozapine.

- Only pharmacies certified in the Clozapine REMS Program will be able to receive and dispense clozapine.**
 - Only pharmacies certified in the Clozapine REMS Program will be able to purchase or receive clozapine from a wholesaler or distributor.
 - If your pharmacy dispenses clozapine and *is not yet* certified in the Clozapine REMS Program, certify online at www.clozapinerems.com or download the *Clozapine REMS Outpatient Pharmacy Enrollment Form* and fax the completed form to 844-404-8876.
 - If your pharmacy is part of a pharmacy chain, contact your chain's authorized representative to complete enrollment and certification. If you need assistance, call the Clozapine REMS Program Contact Center at 844-267-8678.
- Prescribing clozapine for patients in an outpatient setting¹ requires certification in the Clozapine REMS Program.**

If the prescriber is not certified in the Clozapine REMS Program, the outpatient pharmacy will not receive authorization to dispense clozapine.
- Certified pharmacies may apply clinical judgment and continue to dispense clozapine to enrolled patients if the prescriber is not certified in the Clozapine REMS Program by utilizing a new function, the "Dispense Rationale."**

The use of a *Dispense Rationale* is limited. Refer to information provided below, the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or *Clozapine REMS Frequently Asked Questions (FAQ's)* available at www.clozapinerems.com; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

What is a *Dispense Rationale*?

- The Clozapine REMS Program will alert the pharmacy when the prescriber is not certified in the Clozapine REMS Program via a reject message of the PDA request. The pharmacy may then exercise clinical judgement to provide a *Dispense Rationale* to authorize the dispense *if*:
 - The patient is enrolled in the Clozapine REMS Program; and
 - Has an acceptable absolute neutrophil count (ANC) value on file; or
 - The last ANC on file indicates moderate or severe neutropenia, and has a "Treatment Rationale" on file.
- Dispense Rationales* are valid for 72 hours (3 calendar days) and are limited to no more than three (3) occurrences for an individual patient within a rolling six (6) month period.

¹ An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

How can I provide a *Dispense Rationale*?

- Certified pharmacies can provide a *Dispense Rationale*:
 - Via the Clozapine REMS Program Website at www.clozapinerems.com, or
 - By calling the Clozapine REMS Program Contact Center at 844-267-8678, or
 - By following the step-by-step web instructions provided in the enclosed *Clozapine REMS Predispense Authorization Fact Sheet*.

Patient dispensing

- A PDA will be issued if the patient meets the following program Elements to Assure Safe Use:
 - The patient must be enrolled in the Clozapine REMS Program; and,
 - An acceptable ANC value is on file;
 - A *Treatment Rationale* is on file if the last ANC submitted to the Clozapine REMS Program indicates moderate to severe neutropenia.
- Pharmacies should dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.
- All PDA responses will provide the dispensing pharmacy with the most recent ANC value, the associated blood draw date, and patient's monitoring frequency (MF) on file with the Clozapine REMS Program.

Pharmacies are encouraged to submit the ANC to the Clozapine REMS Program when:

- The pharmacist is made aware of a more current ANC than the most recent lab value reported in the PDA response.
- The most recent ANC indicates moderate or severe neutropenia. The prescriber must provide a *Treatment Rationale* to the Clozapine REMS Program to allow the pharmacy to receive a PDA and dispense clozapine to the patient. The pharmacy may contact the prescriber to remind them of the need for a *Treatment Rationale*.
- Pharmacies may submit ANCs to the Clozapine REMS Program at www.clozapinerems.com, by calling the Clozapine REMS Program Contact Center at 844-267-8678 or faxing a completed *Clozapine REMS ANC Lab Reporting Form* (available from the website) to the Clozapine REMS Program.
- If the last ANC result on file with the Clozapine REMS Program is not current according to the patient's MF (within 7 days of the PDA transaction date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring), a PDA will still be issued, but the pharmacist will receive a warning message regarding the need to ensure that the ANC is current.

The pharmacy's authorized representative must ensure that all pharmacy staff are aware of these modifications to the Clozapine REMS Program effective February 2019.

For additional information related to the Clozapine REMS Program or use of the REMS Pharmacy Network, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Sincerely,

The Clozapine REMS Program

Enclosures: *Clozapine REMS Predispense Authorization Fact Sheet*
How to Start Clozapine and Monitor Patients Fact Sheet

Dear Inpatient Pharmacy Personnel:

This letter is intended to inform inpatient pharmacies of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program that will occur in the 02/2019 REMS Modification.

Changes to the Clozapine REMS Program in 02/2019 may affect your ability to dispense clozapine.

1. Only pharmacies certified in the Clozapine REMS Program will be able to receive and dispense clozapine.

- Only pharmacies certified in the Clozapine REMS Program will be able to purchase or receive clozapine from a wholesaler or distributor.
- If your pharmacy dispenses clozapine and *is not yet* certified in the Clozapine REMS Program, certify online at www.clozapinerems.com or download the *Clozapine REMS Inpatient Pharmacy Enrollment Form* and fax the completed form to 844-404-8876.

2. Pharmacy classification and program requirements may have changed.

Inpatient pharmacies previously certified in the Clozapine REMS Program may be reclassified using the following definitions:

- **Inpatient pharmacy**: a pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions, or injuries (usually for a short-term illness or condition).
- **Outpatient pharmacy**: a pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

This pharmacy reclassification, if necessary, will occur during the next scheduled pharmacy recertification. If an inpatient pharmacy is reclassified as an outpatient pharmacy, the requirements for dispensing clozapine are different. Please review the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* available on the Clozapine REMS Program Website at www.clozapinerems.com for more information.

You may call the Clozapine REMS Program Contact Center at 844-267-8678 if you are unsure whether your pharmacy type is inpatient or outpatient (based on the definitions above) or if your pharmacy provides both inpatient and outpatient pharmacy services to patients being treated with clozapine.

3. Certification is not required to prescribe clozapine for patients receiving inpatient care if the patient is enrolled in the Clozapine REMS Program.

Prescribers who continue clozapine for patients during inpatient medical care and other related services for surgery, acute medical conditions, or injuries (usually for a short-term illness or condition) *will not* be required to become certified in the Clozapine REMS Program if the patient is already enrolled in the Clozapine REMS Program.

- A patient being initiated on clozapine while in an inpatient setting who is not enrolled in the Clozapine REMS Program must be enrolled by a certified prescriber.

4. Dispense a temporary supply of clozapine to an enrolled patient upon discharge from a healthcare facility that is not more than:

- A 7-day supply, or
- An amount sufficient to supply the patient until their next blood draw date per the monitoring frequency (MF) on file with the Clozapine REMS Program; or
- The amount authorized by the prescriber.

The “Eligibility Check” (EC) process for inpatient pharmacies is also changing as outlined below:

The Eligibility Check for Inpatient Pharmacies will evaluate:

- **Patient Enrollment Status:** The patient **must** be enrolled in the Clozapine REMS Program to receive clozapine.
 - If the patient **is** enrolled, you will receive an authorization to dispense clozapine.
 - If the patient **is not** enrolled, a certified prescriber must enroll the patient before the patient becomes eligible to receive clozapine.
- **Absolute Neutrophil Count (ANC):** Inpatient pharmacies can determine if the patient ANC is on file with the Clozapine REMS Program, if it’s current, and if it’s within the normal range. Abnormalities or an absence of this information will not prevent dispensing of clozapine.
 - All EC responses will provide inpatient pharmacies with the patient’s most recent ANC value and the associated blood draw date, and his/her MF on file with the Clozapine REMS Program.
 - The pharmacy may access the inpatient medical record system to verify:
 - The ANC is current based on the patient’s MF (i.e., within 7 days of the EC date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring)
 - ANC is within the acceptable range described in the Prescribing Information or the certified prescriber has authorized clozapine treatment if the patient’s ANC falls below the acceptable range when the prescriber determines the benefits exceed the risks of developing severe neutropenia.
 - If the patient’s ANC is low and there is no “Treatment Rationale” on file, the inpatient pharmacy will receive a warning message. Inpatient prescribers should use clinical judgment to determine if benefits of receiving clozapine outweigh its risks if a patient has an ANC indicating moderate or severe neutropenia.
 - If the patient has an ANC that is more current than the ANC draw date on file with the Clozapine REMS Program as received in the EC response, the pharmacy is encouraged to submit the ANC to the Clozapine REMS Program utilizing the step-by-step instructions provided in the enclosed *Clozapine REMS Eligibility Check Fact Sheet*.

The pharmacy’s authorized representative must ensure that all pharmacy staff are aware of these modifications to the Clozapine REMS Program effective 02/2019.

For additional information related to the Clozapine REMS Program, visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

Sincerely,

The Clozapine REMS Program

Enclosures: *Clozapine REMS Eligibility Check Fact Sheet*
How to Start Clozapine and Monitor Patients Fact Sheet

Dear Prescriber and/or Prescriber Designee:

This letter is intended to notify prescribers and prescriber designees of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program that will occur in the 02/2019 REMS Modification.

Changes to the Clozapine REMS Program in 02/2019 may affect your ability to prescribe clozapine.

1. Only prescribers certified in the Clozapine REMS Program will be able to prescribe clozapine to patients for outpatient use.

If you need to prescribe clozapine but are **not yet** certified in the Clozapine REMS Program, go immediately to www.clozapinerems.com to certify online. You may also download the *Clozapine REMS Prescriber Enrollment Form* and *Clozapine REMS Knowledge Assessment for Healthcare Providers*, and fax the completed forms to 844-404-8876. Once a prescriber is certified, his/her designees must enroll online at www.clozapinerems.com.

2. Prescribing clozapine for patients receiving inpatient care does not require prescriber certification in the Clozapine REMS Program if the patient is already enrolled in the program. If the patient is to be initiated on clozapine while admitted to an inpatient setting, a certified prescriber must enroll the patient in the Clozapine REMS Program prior to receiving their first dose of clozapine.

Prescribers in an inpatient setting should use clinical judgment to determine if the benefits of receiving clozapine outweigh its risks if a patient has an absolute neutrophil count (ANC) indicating moderate or severe neutropenia. For more information on patient access to clozapine in the inpatient setting, please review the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* available on the Clozapine REMS Program Website at www.clozapinerems.com.

3. Pharmacies that dispense clozapine must be certified in the Clozapine REMS Program.

A list of certified pharmacies is available on the Clozapine REMS Program Website at www.clozapinerems.com.

Prescribers, once certified, must:

- Enroll all patients in the Clozapine REMS Program prior to their first dose of clozapine.
- Order ANC lab work according to the monitoring frequency (MF) described in the Prescribing Information.
- Submit ANC according to the patient's MF on file with the Clozapine REMS Program:
 - For weekly MF, ANC must be submitted within 7 days of the lab draw* date
 - For every two weeks MF, ANC must be submitted within 15 days of the lab draw* date
 - For monthly MF, ANC must be submitted within 31 days of the lab draw* date

*Assumes the lab draw date is day 0.

- Patient ANC's may be submitted by:
 - By logging in to the Clozapine REMS Program Website at www.clozapinerems.com,
 - By calling the Clozapine REMS Program Contact Center at 844-267-8678; or
 - By using the *Clozapine REMS ANC Lab Reporting Form* (available at www.clozapinerems.com) and faxing it to 844-404-8876. Labs submitted via the Clozapine REMS Program Website are available immediately; however, allow up to 48 hours to process ANC labs submitted by fax.

- Provide a "Treatment Rationale" to authorize dispensing via an outpatient pharmacy for patients who have an ANC indicating moderate or severe neutropenia. *Treatment Rationales* may be provided online or on the *Clozapine REMS ANC Lab Reporting Form* (available at www.clozapinerems.com) and faxed to 844-404-8876.

For additional information related to the Clozapine REMS Program, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Sincerely,

The Clozapine REMS Program

Enclosure: *How to Start Clozapine and Monitor Patients Fact Sheet*

Dear <Prescriber FirstName LastName>:

On October 12, 2015, the single shared Clozapine Risk Evaluation Mitigation Strategy (REMS) Program replaced all individual clozapine registries. Our records indicate you prescribe clozapine to patients and that you currently have <Enrolled Patient Count> enrolled patients affiliated and under your care within the Clozapine REMS Program. Our records also indicate that you have not yet certified in the Clozapine REMS Program.

You must certify in the Clozapine REMS Program to avoid interruption in your ability to continue prescribing clozapine products, and to avoid potential delays to your patient's clozapine therapy. As a reminder, one of the key requirements of the Clozapine REMS Program is that any Healthcare Provider who prescribes clozapine must certify in the program.

If you have not completed certification by <Certification Deadline>, your account with the Clozapine REMS Program will be deactivated.

If you wish to continue to treat patients using clozapine products, you must certify online through the Clozapine REMS Program Website at www.clozapinerems.com; or by completing the *Clozapine REMS Prescriber Enrollment Form*, training, and the *Clozapine REMS Knowledge Assessment for Healthcare Providers* and faxing the completed documents to 844-404-8876; or, by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If you have any questions, or if you believe that you have received this letter in error, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Regards,

The Clozapine REMS Program

Please review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* available at www.clozapinerems.com for more detailed information about the Clozapine REMS Program requirements and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit www.clozapinerems.com to review the complete Prescribing Information.

Dear <Prescriber FirstName LastName>:

On October 12, 2015, the single shared Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program replaced all individual clozapine registries. Your prescriber information was migrated from an existing registry to the Clozapine REMS Program. Our records indicate that you may not be currently prescribing clozapine and do not currently have enrolled patients affiliated under your care within the Clozapine REMS Program. Our records also indicate that you have not certified in the Clozapine REMS Program.

On <Deactivation Date>, your account with the Clozapine REMS Program will be deactivated.

If you prescribe clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, you must certify in the Clozapine REMS Program to avoid interruption in your ability to prescribe clozapine products, and to avoid potential delays to a patient's clozapine therapy. As a reminder, one of the key requirements of the Clozapine REMS Program is that any Healthcare Provider who prescribes clozapine for outpatient use must certify in the program.

If you wish to treat patients using clozapine products, you must certify online through the Clozapine REMS Program Website at www.clozapinerems.com; by completing the *Clozapine REMS Prescriber Enrollment Form*, training, and *Clozapine REMS Knowledge Assessment for Healthcare Providers*; and faxing the completed documents to 844-404-8876; or, by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If you have any questions, or believe that you have received this letter in error, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Regards,

The Clozapine REMS Program

Please review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* available at www.clozapinerems.com for more detailed information about the Clozapine REMS Program requirements and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit www.clozapinerems.com to review the complete Prescribing Information.

The products covered under the Clozapine REMS Program are: Clozaril® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension

Fazaclor® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products

Dear <Professional Society>:

The Clozapine REMS Program is pleased to announce a program modification slated to become effective February 2019. A summary of changes is provided below:

- A pharmacy cannot dispense clozapine to patients if the pharmacy is not certified in the Clozapine REMS Program.
- Reclassification of certain inpatient and outpatient pharmacies may be needed at recertification with related updates to enrollment forms.
- Patients in inpatient settings no longer require a program-certified prescriber *unless the patient has never been enrolled into the Clozapine REMS Program*.
- A “Treatment Rationale” is required prior to dispensing in outpatient settings if the patient’s absolute neutrophil count (ANC) indicates moderate or severe neutropenia.
- In an outpatient setting, a “Dispense Rationale” may be provided to allow dispensing of clozapine for a limited time when a prescriber is not certified.

Please assist the Clozapine REMS Program in notifying pharmacies of these important program modifications by distributing this letter to your membership. You may direct them to contact the Clozapine REMS Program with any questions or for additional information.

Sincerely,

The Clozapine REMS Program

Enclosures:

- *Dear Inpatient Pharmacy Letter*
- *Dear Outpatient Pharmacy Using Switch Letter*
- *Dear Outpatient Pharmacy Using Web PDA Letter*
- *Clozapine REMS PDA Fact Sheet*
- *Clozapine REMS Eligibility Check Fact Sheet*
- *How to Start Clozapine and Monitor Patients Fact Sheet*

Dear <Professional Society>:

The Clozapine REMS Program is pleased to announce a program modification slated to become effective 02/2019. A summary of the changes is provided below:

- If patients in inpatient settings are already enrolled in the Clozapine REMS Program, they no longer require a program-certified prescriber to prescribe clozapine for inpatient use.
- In order to be considered current, patient's absolute neutrophil count (ANC) values must be on file and within 7 days of the lab draw date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring.
- A "Treatment Rationale" is required prior to dispensing in outpatient settings if the patient's ANC level indicates moderate or severe neutropenia.
- Only a certified prescriber can provide a valid *Treatment Rationale* to continue clozapine treatment in a patient whose ANC indicates moderate or severe neutropenia.

Please assist the Clozapine REMS Program in notifying prescribers of these important program modifications by distributing this letter to your membership. You may direct them to contact the Clozapine REMS Program with any questions or for additional information.

Sincerely,

The Clozapine REMS Program

Enclosures:

- *Dear Prescriber Letter*
- *How to Start Clozapine and Monitor Patients Fact Sheet*