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.

<table>
<thead>
<tr>
<th>Role</th>
<th>Certify or Enroll?</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber</td>
<td>Certify</td>
<td>Prescriber Certification Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Complete the Clozapine REMS Prescriber Enrollment Form online at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pass the Clozapine REMS Knowledge Assessment for Healthcare Providers via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center</td>
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<tr>
<td>Prescriber Designee</td>
<td>Enroll</td>
<td>Prescriber Designee Enrollment Process</td>
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<tr>
<td></td>
<td></td>
<td>• Complete the Clozapine REMS Prescriber Designee Enrollment Form online at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876</td>
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<td>• Become associated in the system with a certified prescriber</td>
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<td>• Be approved by a certified prescriber</td>
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<tr>
<td>Role</td>
<td>Certify or Enroll?</td>
<td>Description</td>
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<tr>
<td>------------------------------------------</td>
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<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tbody>
</table>
| Authorized Representative (Non-chain Pharmacy) | Certify            | **Authorized Representative Certification Process**  
|                                           |                    | - Complete the *Clozapine REMS Outpatient Pharmacy Enrollment Form* or the *Clozapine REMS Inpatient Pharmacy Enrollment Form* online at [www.clozapinerems.com](http://www.clozapinerems.com) or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876  
|                                           |                    | - Pass the *Clozapine REMS Knowledge Assessment for Healthcare Providers* 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            | **Chain Pharmacy Authorized Representative Certification Process**  
|                                           |                    | - Work with an account manager from your pharmacy network system (i.e., the “switch”) provider to complete the certification process  
|                                           |                    | - Pass the *Clozapine REMS Knowledge Assessment for Healthcare Providers* 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             | **Pharmacy Staff Enrollment Process**  
|                                           |                    | - Enroll online as pharmacy staff at [www.clozapinerems.com](http://www.clozapinerems.com)  
|                                           |                    | - Become associated in the system with a pharmacy
<table>
<thead>
<tr>
<th>Definition</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A prescriber is any healthcare professional who prescribes clozapine to a patient.</strong></td>
<td><strong>Certification Process</strong></td>
</tr>
<tr>
<td></td>
<td>• A prescriber must certify in the Clozapine REMS Program:</td>
</tr>
<tr>
<td></td>
<td>o Review the Prescribing Information for clozapine</td>
</tr>
<tr>
<td></td>
<td>o Complete the Clozapine REMS Prescriber Enrollment Form</td>
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<tr>
<td></td>
<td>o Pass the Clozapine REMS Knowledge Assessment for Healthcare Providers</td>
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<tr>
<td><strong>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).</strong></td>
<td>• Prescribers who order clozapine to be dispensed from an inpatient pharmacy** are not required to become certified in the Clozapine REMS Program</td>
</tr>
<tr>
<td><strong>Responsibilities</strong></td>
<td>• 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:</td>
</tr>
<tr>
<td></td>
<td>o Enroll every new patient in the Clozapine REMS Program</td>
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<tr>
<td></td>
<td>o Counsel each patient (or their caregiver) about the risk of severe neutropenia which can lead to serious infection and death</td>
</tr>
<tr>
<td></td>
<td>o Check the ANC for each patient according to the monitoring requirements</td>
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<tr>
<td></td>
<td>o Submit and verify ANC according to the patient’s monitoring frequency on file with the Clozapine REMS Program:</td>
</tr>
<tr>
<td></td>
<td>• For weekly monitoring frequency, ANC must be submitted within 7 days of the lab draw* date</td>
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<tr>
<td></td>
<td>• For every two weeks monitoring frequency, ANC must be submitted within 15 days of the lab draw* date</td>
</tr>
<tr>
<td></td>
<td>• For monthly monitoring frequency, ANC must be submitted within 31 days of the lab draw* date</td>
</tr>
<tr>
<td></td>
<td>*Assumes the lab draw date is day 0</td>
</tr>
</tbody>
</table>

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.
Definition
Responsibilities

• Provide a “Treatment Rationale” to authorize the continuation of clozapine therapy for patients with moderate or severe neutropenia if it is determined that:
  • The benefits of clozapine therapy outweigh the risks
  • The patient has documented benign ethnic neutropenia (BEN)

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.

Prescriber Designee

Definition
Responsibilities

A Healthcare Provider, office staff member, or pharmacist designated by a certified prescriber to act on their behalf

Enrollment Process
• Complete the Clozapine REMS Prescriber Designee Enrollment Form 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

Responsibilities
• A prescriber designee can:
  • 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:
  • Enroll a patient with benign ethnic neutropenia (BEN)
  • Provide a Treatment Rationale for a patient
  • Designate a patient as a hospice patient
## Authorized Representative for Outpatient Pharmacy

<table>
<thead>
<tr>
<th>Definition</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>For outpatient pharmacies with a single location, the authorized representative may be a:</td>
<td>Certification Process</td>
</tr>
<tr>
<td>• Pharmacy Manager, or</td>
<td>• An authorized representative for an outpatient pharmacy must certify in the Clozapine REMS Program by:</td>
</tr>
<tr>
<td>• Staff Pharmacist</td>
<td>o Reviewing the Prescribing Information for clozapine</td>
</tr>
<tr>
<td>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:</td>
<td>o Certifying their pharmacy in the Clozapine REMS Program by:</td>
</tr>
<tr>
<td>• Director of Pharmacy Services, or</td>
<td>• Reviewing <em>Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</em></td>
</tr>
<tr>
<td>• Corporate Executive overseeing Pharmacy Service</td>
<td>• Completing the <em>Clozapine REMS Outpatient Pharmacy Enrollment Form</em></td>
</tr>
<tr>
<td>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</td>
<td>• Passing the <em>Clozapine REMS Knowledge Assessment for Healthcare Providers</em></td>
</tr>
<tr>
<td></td>
<td>o Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements</td>
</tr>
<tr>
<td></td>
<td>o Putting processes and procedures in place to verify:</td>
</tr>
<tr>
<td></td>
<td>• The prescriber is certified in the Clozapine REMS Program prior to dispensing clozapine</td>
</tr>
<tr>
<td></td>
<td>• The patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine</td>
</tr>
<tr>
<td></td>
<td>• The ANC result is current according to the patient’s monitoring frequency:</td>
</tr>
<tr>
<td></td>
<td>▪ For weekly monitoring frequency, the submitted ANC result must have been drawn* within 7 days prior to the “Predispense Authorization” (PDA) transaction date</td>
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<tr>
<td></td>
<td>▪ For every two weeks monitoring frequency, the submitted ANC result must have been drawn* within 15 days prior to the PDA transaction date</td>
</tr>
<tr>
<td></td>
<td>▪ For monthly monitoring frequency, the submitted ANC result must have been drawn* within 31 days prior to the PDA transaction date</td>
</tr>
<tr>
<td></td>
<td>*Assumes the lab draw date is day 0</td>
</tr>
<tr>
<td></td>
<td>▪ The submitted ANC is within acceptable range or a certified prescriber has provided a <em>Treatment Rationale</em> to authorize the continuation of clozapine treatment</td>
</tr>
<tr>
<td>Definition</td>
<td>Responsibilities</td>
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<tr>
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</tr>
<tr>
<td></td>
<td>o Renewing certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment</td>
</tr>
</tbody>
</table>
| Responsibilities | • 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

<table>
<thead>
<tr>
<th>Definition</th>
<th>Responsibilities</th>
</tr>
</thead>
</table>
| For inpatient pharmacies with a single location, the authorized representative may be a:  
- Pharmacy Manager, or  
- Staff Pharmacist | Certification Process  
- An authorized representative for a pharmacy must certify in the Clozapine REMS Program by:  
- Reviewing the Prescribing Information for clozapine  
- Certifying their pharmacy in the Clozapine REMS Program by:  
  • Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*  
  • Completing the *Clozapine REMS Inpatient Pharmacy Enrollment Form*  
  • Passing the *Clozapine REMS Knowledge Assessment for Healthcare Providers*  
- 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  

| Responsibilities | • 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 |
### REMS Program Requirements

**Definition**

Before dispensing clozapine, inpatient pharmacies can:

- 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 *Treatment Rationale* 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

**Definition**

Any pharmacist or pharmacy employee may assume the role of pharmacy staff member associated with a pharmacy to conduct basic program functions.

**Enrollment Process**

- Enroll online as pharmacy staff
- Associate with a pharmacy

**Responsibilities**

- **Outpatient pharmacy staff must:**
  - 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:**
  - Verify a patient is enrolled in the Clozapine REMS Program using the *Eligibility Check*
  - Verify patient has an ANC on file and the ANC is current and within acceptable range via an *Eligibility Check* 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:

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

*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](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.
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:
   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 enroll 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.

<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Definition</th>
</tr>
</thead>
</table>
| Chain Pharmacy         | • 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    | • 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 may be able to adjudicate claims via electronic communication with the Clozapine REMS Program using established telecommunications standards (i.e., “the switch”).  
<pre><code>                     | • Outpatient pharmacies that cannot adjudicate claims via the switch must obtain a PDA via the Clozapine program. |
</code></pre>
<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Definition</th>
</tr>
</thead>
</table>
| Inpatient Pharmacy | • 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 Eligibility Check 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 certified prescriber 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 *Predispose 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.
Predisense Authorization

To determine if the safe-use conditions have been met for your patient to receive clozapine, please complete the Predisense Authorization information below and submit. If you have lab information for your patient, you may enter it here. The results of the Predisense 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

Add Patient Lab (optional)
- AHC value per milliliter (opt)
- Bleed Draw Date (opt)

Predisense Authorization Request
- Date of Service
- Manufacturer
- NDC Number
- Days Supply
- Quantity

At least one identity is required
- Prescriber DEA
- Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8078.
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)

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

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Address</th>
<th>Pharmacy Type</th>
<th>Certification ID</th>
<th>Certification Status</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>akh shay ku</td>
<td>4334 n scottsdale rd, BURKEVILLE, Virginia 23902</td>
<td>Inpatient</td>
<td>FAC5413173502</td>
<td>Certified</td>
<td>Please Select -- Go</td>
</tr>
<tr>
<td>Test Pharma</td>
<td>4334 n scottsdale rd, PHOENIX, Arizona 85054</td>
<td>Inpatient</td>
<td>FAC5413316524</td>
<td>Certified</td>
<td>Please Select -- Go</td>
</tr>
<tr>
<td>Ina Inc</td>
<td>4334 n scottsdale rd, PHX ENC, Arizona 85054</td>
<td>Outpatient</td>
<td>FAC5413657605</td>
<td>Certified</td>
<td>Please Select -- Go</td>
</tr>
<tr>
<td>JC Painy</td>
<td>4334 norte scottsdale, PHX ENC, Arizona 85054</td>
<td>Outpatient</td>
<td>FAC5413653432</td>
<td>Certified</td>
<td>Please Select -- Go</td>
</tr>
<tr>
<td>Tata Pharma</td>
<td>4345 n scottsdale rd, LANSING, Michigan 48915</td>
<td>Outpatient</td>
<td>FAC5414118715</td>
<td>Incomplete</td>
<td>View/Update Pharmacy Profile Add Lab Dispense Authorization Recently Dispensed Recently Pharmacy</td>
</tr>
<tr>
<td>Sharma Pharma</td>
<td>4343 n scottsdale rd, LANSING, Michigan 48912</td>
<td>Outpatient</td>
<td>FAC5414119840</td>
<td>Incomplete</td>
<td>Please Select -- Go</td>
</tr>
<tr>
<td>Inpatient</td>
<td>Address, SCOTTSDALE, Arizona 85250</td>
<td>Inpatient</td>
<td>FAC5414782350</td>
<td>Incomplete</td>
<td>Please Select -- Go</td>
</tr>
</tbody>
</table>

For additional information about the Clozapine REMS Program, please call 844-267-8678.
4. **Enter the patient information** on the *Dispense Rationale* screen and **click Submit**. (see screenshot below)

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

Reference ID: 4376730
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).

![Dispense Rationale Result](image)

**Do not dispense clozapine to this patient.**

Please call the Clozapine REMS Program at 844-267-8678 for more information.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per μL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

**Name Summer H**

DOB

Authorization Number

- **X** Prescriber not certified. Prescriber can certify at [www.clozapinerems.com](http://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.

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

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

Reference ID: 4376730
### REMS PROGRAM ELEMENT EVALUATED BY THE ELIGIBILITY CHECK

<table>
<thead>
<tr>
<th>POSSIBLE OUTCOMES</th>
<th>ELIGIBILITY TO RECEIVE CLOZAPINE</th>
<th>ACTION BY PHARMACY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient enrollment in the Clozapine REMS Program</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient is enrolled.</td>
<td>Eligibility Check Successful.</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td>Patient is not enrolled.</td>
<td>Eligibility Check Unsuccessful.</td>
<td>Do not dispense. Contact a certified prescriber (or his designee) to enroll new patient.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>POSSIBLE OUTCOMES</th>
<th>ELIGIBILITY TO RECEIVE CLOZAPINE</th>
<th>ACTION BY PHARMACY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient absolute neutrophil count (ANC) is on file</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANC on file.</td>
<td>Eligibility Check Successful.</td>
<td>Check if ANC is acceptable. Dispense.</td>
</tr>
<tr>
<td>No ANC on file.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A warning message will be displayed but patient will remain eligible to receive clozapine.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Last ANC value on file is acceptable</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANC is acceptable.</td>
<td>Eligibility Check Successful.</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td>ANC on file for patient indicates moderate or severe neutropenia; and a &quot;Treatment Rationale&quot; is on file.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligibility Check Successful.</td>
<td>No action necessary. Dispense.</td>
<td></td>
</tr>
<tr>
<td>ANC on file for patient indicates moderate or severe neutropenia; and a Treatment Rationale is not on file.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A warning message will be displayed but patient will remain eligible to receive clozapine.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ANC is current according to the patient’s monitoring frequency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANC is current.</td>
<td>Eligibility Check Successful.</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td>ANC is not current.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A warning message will be displayed but patient will remain eligible to receive clozapine.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Monitoring 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 Program must be drawn* within 31 days prior to the Eligibility Check date.

   2. Assumes lab draw date is day 0

2. Apply 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.

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Please refer to page 1 for step-by-step instructions for performing an *Eligibility Check* and submitting patient ANC values.
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

> 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.

> 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 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 “Predispense 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 PREDISPENSE AUTHORIZATION

<table>
<thead>
<tr>
<th>POSSIBLE OUTCOMES</th>
<th>ELIGIBILITY TO RECEIVE CLOZAPINE</th>
<th>ACTION BY PHARMACY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient enrollment in the Clozapine REMS Program</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>Patient is enrolled</td>
<td>PDA Successful</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td>Patient is not enrolled</td>
<td>PDA Unsuccessful</td>
<td>Contact a certified prescriber (or his designee) to enroll new patient. <strong>Do not dispense.</strong></td>
</tr>
<tr>
<td>Prescriber Certification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescriber is certified</td>
<td>PDA Successful</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td>Prescriber is not certified</td>
<td>PDA Unsuccessful</td>
<td>Contact prescriber to inform them they must be certified. Pharmacy can provide a “Dispense Rationale” and reattempt PDA.**(^2)</td>
</tr>
<tr>
<td>Pharmacy Certification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy is certified</td>
<td>PDA Successful</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td>Pharmacy is not certified</td>
<td>PDA Unsuccessful</td>
<td>Contact Pharmacy Manager to inform them the pharmacy must be certified to order, purchase, and dispense clozapine. <strong>Do not dispense.</strong></td>
</tr>
<tr>
<td>Patient ANC is on file</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANC on file</td>
<td>PDA Unsuccessful; A warning message will be displayed, reattempt PDA(^2) after ANC is obtained</td>
<td>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.</td>
</tr>
<tr>
<td>No ANC on file</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Last ANC value on file is acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANC is acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANC indicates moderate or severe neutropenia; and a “Treatment Rationale” is on file</td>
<td>PDA Unsuccessful; A warning message will be displayed</td>
<td></td>
</tr>
<tr>
<td>ANC on file for patient indicates moderate or severe neutropenia; and a <strong>Treatment Rationale</strong> is not on file</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANC is not current</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| ANC is current according to the patient’s monitoring frequency:\(^1\) | Do not dispense, unless one of these two possible follow-up actions are successful:  
  • 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 **Treatment Rationale** or current acceptable ANC, reattempt the PDA.\(^2\) |                                                                                   |
| ANC is not current                |                                                                                                  |                                                                                  |

\(^1\)Monitoring 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

\(^2\)Wait approximately 2 minutes to reprocess the claim transaction through the pharmacy switch system.
**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:
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

Reference: If you experience any issues with the above processes, please call the Clozapine REMS Program Contact Center at 844-267-8678.
Website Screen Captures
02/2019 REMS Modification

Clozapine REMS Program

November 2018
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1. Static Pages

1.1 Home Page

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 (NNRNF).

For additional information about the Clozapine REMS Program, please call 844-267-8678.
1.2 Site Guide – Prescriber Tab

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.

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.

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 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.

---

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

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.

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

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.

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 Predisense 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

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)


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.

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

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.

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

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 into 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)


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.

Your browser closed during certification.
Please use the Begin Now button to start your certification today.

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

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 Predisperse 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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
1.11 Patient Information – Home Page

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.

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

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
• Prescriber
  o Clozapine REMS Prescriber Enrollment Form
  o Clozapine REMS Prescriber Designee Enrollment Form
  o Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers (Education Program and Knowledge Assessment)
  o A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia
  o Clozapine REMS How to Start Clozapine & Monitor Patients Fact Sheet
  o Clozapine REMS Patient Enrollment Form
  o Clozapine REMS ANC Lab Reporting Form
  o ANC Calculator
  o ANC Monitoring Table
  o Prescriber Designee Education Program
  o Prescriber Designee Acknowledgment Form
  o Dear Prescriber Letter

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

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

Prescribing Information

Products covered under the Clozapine REMS Program

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Company</th>
<th>Link</th>
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</thead>
<tbody>
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<td>Clozaril</td>
<td>Clozapine</td>
<td>HLS Therapeutics (USA), Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Fasizoda</td>
<td>Clozapine USP</td>
<td>Jazz Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
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<td>Clozapine, USP</td>
<td>Jazz Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
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<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Company</th>
<th>Link</th>
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</thead>
<tbody>
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<td>Accord Healthcare Inc.</td>
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<td>Aurubindo Pharma USA Inc.</td>
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<tr>
<td>Clozapine</td>
<td>Clozapine, USP ODT</td>
<td>Jazz Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
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</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Dially Disintegrating Tablets</td>
<td>Mylan Pharmaceuticals Inc.</td>
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<tr>
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<td>Teva Pharmaceuticals USA Inc.</td>
<td>Full Prescribing Information</td>
</tr>
</tbody>
</table>

For additional information about the Clozapine REMS Program, please call 844-267-8678.
1.14 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.

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

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.

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

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

Frequently Asked Questions (FAQs)

- 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 assigned 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.

Note:
Resources included under the other tabs are listed below:
- Prescriber
  - How can a prescriber become certified in the single shared Clozapine REMS Program?
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 (NNRNF)?
  - 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?
How is an Eligibility Check different from a Predispose 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?
1.18 FAQ – Pharmacy Authorized Representative

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

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

<table>
<thead>
<tr>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accord Healthcare Inc.</td>
<td>919-941-7878</td>
</tr>
<tr>
<td>Aurobindo Pharma USA Inc.</td>
<td>732-639-9400</td>
</tr>
<tr>
<td>HLS Therapeutics (USA) Inc.</td>
<td>844-457-8721</td>
</tr>
<tr>
<td>Jazz Pharmaceuticals Inc.</td>
<td>800-520-5568</td>
</tr>
<tr>
<td>Mayne Pharma Inc.</td>
<td>844-625-8500</td>
</tr>
<tr>
<td>Mylan Pharmaceuticals Inc.</td>
<td>800-796-9626</td>
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<tr>
<td>Sun Pharmaceuticals Industries Inc.</td>
<td>800-818-4555</td>
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<tr>
<td>Tasman Pharmaceuticals</td>
<td>257-317-4104</td>
</tr>
<tr>
<td>Teva Pharmaceuticals USA Inc.</td>
<td>800-292-4283</td>
</tr>
</tbody>
</table>

For additional information about the Clozapine REMS Program, please call 844-267-8678.
2. User Identification and Record Search

2.1 User Identification

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

Phone/Fax User

If you began or completed certification through a tax 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 is required:

DEA (opt) or NPI

First Name Last Name Certification ID (opt)

Phone (opt) Fax (opt) Email (opt)

Search

For additional information about the Clozapine REMS Program, please call 844-267-8678.
2.3 Phone/Fax User Prescriber Search with Results

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:

- AB1234567 - NPI
- Summer - Hogan
- Phone (opt) - Fax (opt) - 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.

For additional information about the Clozapine REMS Program, please call 844-267-5678.
2.4 Phone/Fax User Prescriber Designee Search

Phone/Fax User

If you began or completed certification through a tax 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 is required:

- DEA (opt) or NPI

First Name  Last Name  Certification ID (opt)

Phone (opt)  Fax (opt)  Email (opt)

Search

For additional information about the Clozapine REMS Program, please call 844-267-8678.
2.5 Phone/Fax User Prescriber Designee Search with Results

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
AB1234599

Designee Information
Summer Hogan Certification ID (opt)
Phone (opt) Fax (opt) 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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
2.6 Phone/Fax User Pharmacy Search

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):
- Zip Code
- DEA
- NPI
- NCPDP

Authorized Representative Information:
- First Name
- Last Name
- Certification ID (opt)
- Phone (opt)
- Fax (opt)
- Email (opt)

Search

For additional information about the Clozapine REMS Program, please call 844-267-8678.
2.7 Phone/Fax User Pharmacy Search with Results

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):

10001 and AB1234567890 NPI NCPDP

Authorized Representative Information

First Name Last Name Certification ID (opt)

Phone (opt) Fax (opt) 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 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

New User Submit

For additional information about the Clozapine REMS Program, please call 844-267-8078.
2.8 Phone/Fax User

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

REMS Chain ID

Authorized Representative Information

First Name  Last Name  Certification ID (opt)

Phone (opt)  Fax (opt)  Email (opt)

Search

For additional information about the Clozapine REMS Program, please call 844-267-8678.
2.9 Phone/Fax User with Results

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

C00121

Authorized Representative Information

Summer Hogan Certification ID (opt)

Phone (opt) Fax (opt) 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, please try your search again or press the New User button to begin your enrolment process in the Clozapine REMS Program.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Pharmacy Name</th>
<th>Pharmacy Address</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summer</td>
<td>Hogan</td>
<td>Joey's Apothecary</td>
<td>1234 W Nowhere Lane Tempe, AZ 85283</td>
<td>555-555-5555</td>
</tr>
</tbody>
</table>

Showing 1 of 1 entries

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

3.1 Create Account

For additional information about the Clozapine REMS Program, please call 844-267-8678.
3.2 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
Username: summerhogan

For additional information about the Clozapine REMS Program, please call 844-267-8678.
3.3 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 844-207-8078.
4. Prescriber Certification

4.1 Prescriber Intake

For additional information about the Clozapine REMS Program, please call 844-207-8678.
4.2 Prescriber 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.
4.3 Prescriber Education Confirmation

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

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)  Summer  
Last Name  Hogan  
Credentials  M.D.  
Email Address  summer123@email.com  
Clinic / Practice Name  Joey’s Clinic  
Address  1 Main Street  
Address 2 (opt)  Suite 123  
City  New York  
State / Zip Code  NY  11001  
Phone / Ext (opt)  555-555-5555  
Fax  555-555-4444  
Contact Preference  Email  

Prescriber Identifiers

DEA  AG5255698  
NPI  1013015577  
☐ I do not have a DEA.

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

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 REMS Program at 1-844-404-9276.

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 their 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 enrollment 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 that 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
*Reference from the lab draw date is not allowed
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, it 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 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 844-267-9678.
4.6 Prescriber Confirmation

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

Certification ID: HCP123456789

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.

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

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.

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
5.2 Prescriber Designee Education Program Page 1

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 etiologic 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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
5.3 Prescriber Designee Education Program Page 2

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 Settings**: 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.

1 Patients 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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
5.4 Prescriber Designee Knowledge Assessment

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.
5.5 Prescriber Designee Knowledge Assessment Confirmation – Success

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
5.6 Prescriber Designee Knowledge Assessment Confirmation – Not Successful

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
5.7 Prescriber Designee Intake Review

[Image of the CLOZAPINE REMS Intake Review interface with a Designee Information section and a message for contacting the Clozapine REMS Program]
5.8 Prescriber Designee Attestation

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 844-404-8676.

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. **Outpatient 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.

Patients 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, in-patient 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

For additional information about the Clozapine REMS Program, please call 844-267-8676.
5.9 Prescriber Designee Confirmation

![Image of the CLOZAPINE REMS certification confirmation screen]

**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: HCP5027506077

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.
6. Pharmacy Certification

6.1 Pharmacy Certification – Home Page

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 into 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)


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.

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.

**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**.

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

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
6.4 Role Selection Confirmation – Inpatient Pharmacy

Note: This pop-up message is common to both New Users and Phone/Fax users.
6.5 Role Selection Confirmation – Outpatient Pharmacy

Note: This pop-up message is common to both New Users and Phone/Fax users.

**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.

**Cancel**  **Confirm**

For additional information about the Clozapine REMS Program, please call 844-267-8678.
6.6 Role Selection Confirmation – Chain Headquarters Pharmacy

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 systems

- **Authorized Representative Chain Headquarters Pharmacy**

  Based on the response selected, please confirm you are certifying as a Chain Headquarters Pharmacy of an 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 facilities, 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.

  [Cancel] [Confirm]

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

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

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

You have successfully completed the required authorized representative training.

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.

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

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
- Address
- Address 2 (opt)
- City
- State
- Zip
- Phone
- Fax (opt)

**Pharmacy Identifiers**
- NCPDP (opt)
- DEA (opt)
- NPI (opt)

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

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:
- 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 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.
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.
Clozapine REMS Pharmacy Classification

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

**QUESTION 18**

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.
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.
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.

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.
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.
6.11 Pharmacy 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.
6.12 Pharmacy Education Confirmation

Education Program Confirmation

You have now completed the Education Program

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.

Next

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

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.
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.

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.

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 pharmacies 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 30 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 manufacturer 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, receive 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 safety-use conditions.
9. Report dosage information for each clozapine prescription dispensed 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.

Signature: [must match First and Last name seen above]  Signature Date

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

Note: This page will be available for:
1. Inpatient Pharmacies
2. Outpatient Pharmacies who **cannot** adjudicate claims online

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.
6.16 Pharmacy Test Transactions

Note: This page will be available for Outpatient Pharmacies who can adjudicate claims online.

![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.
7. Chain Pharmacy Certification
7.1 Chain Pharmacy Store Intake

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 Name
- Address
- Address 2 (opt)
- City
- State
- Zip Code
- Phone
- Ext (opt)
- Fax
- Training Status

Pharmacy Identifiers
- NCPDP
- DEA
- NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.
7.2 Chain Pharmacy Store Confirmation

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.
8. Pharmacy Staff Enrollment

8.1 Enrollment Home Page

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 Predispense 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.

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

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):

- Zip Code
- DEA
- NPI
- NCPOE

Search

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

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 fields for Pharmacy Name, Pharmacy Address, Pharmacy Phone]

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
8.4 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.

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

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.clozapine-rem's.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 “Predis pense Authorization” (PDA)\(^1\) 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.

\(^1\)Inpatient pharmacies do not need to obtain a PDA.

\(^1\)Outpatient pharmacies with a pharmacy management system that supports electronic communication with the Clozapine REMS Program using established telecommunication 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

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

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.
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

For additional information about the Clozapine REMS Program, please call 844-267-8878.
9.2 Knowledge Assessment Question 1

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

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

Knowledge Assessment

QUESTION 3
Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000 µL
- B. An absolute neutrophil count (ANC) less than 1000 µL
- C. An absolute neutrophil count (ANC) less than 500 µL
- 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

Knowledge Assessment

**QUESTION 4**

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/µL for a patient with documented benign ethnic neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/µL 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 844-267-9678.
9.6 Knowledge Assessment Question 5

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

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


**9.7 Knowledge Assessment Question 6**

**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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.8 Knowledge Assessment Question 7

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.9 Knowledge Assessment Question 8

**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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.10 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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.11 Knowledge Assessment Question 10

**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

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 ≥ 1500/μL 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.
9.13 Knowledge Assessment Question 12

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 ≥ 1000/µL; three times weekly until ANC ≥ 1500/µL; 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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.14 Knowledge Assessment Question 13

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 ≥ 1000 μL, then three times weekly until ANC ≥ 1500 μL.
- 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

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:

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.16 Knowledge Assessment Confirmation – Not Successful

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

B. False

**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:

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

10.1 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**
- **Does the patient have Benign Neutropenia (BEN)?**

*Groups can be used to categorize your patients.*

For additional information about the Clozapine REMS Program, please call 844-287-8678.
10.2 Patient Lab Intake

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
10.3 Patient Lab Intake with Treatment Rationale

Note:
The Add Lab page allows the user to enter Patient Lab Information.
1 – Options available for Treatment Status include:
   a. Benign Ethnic Neutropenia (BEN) Patient
   b. Benefit Outweighs Risk

2 – Treatment Rationale Duration
   a. Until next ANC Lab
   b. Until (MM/DD/YYYY)
10.4 ANC Calculator

ANC Calculator

WBC count (x10^9/mm³)  Segs (%)  Bands (%)  ANC value (per µL)

WBC count (x10^9/mm³)  Neutrophils (%)  ANC value (per µL)

Clear  Calculate

NOTE:
For WBC count, data should be entered in decimal format (e.g., 4.300 should be entered as 4.3).
For Segs, Bands, or Neutrophils, data should be entered without percent sign (e.g., 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.


For additional information about the Clozapine REMS Program, please call 844-267-6678.
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

For additional information about the Clozapine REMS Program, please call 844-267-8878.
11.2 Prescriber Designee Profile

My Profile

My Information

First Name: Summer  
Last Name: Hogan  
Phone / Ext: 555-555-5555  
Fax: 555-555-4444  
Contact Preference: Email

My Certification

Certification ID: HCP123456789

Education Program

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

**My Profile**

**My Information**
- **First Name**: Summer
- **Last Name**: Hogan
- **Position/Title**: R.Ph
- **Phone / Ext**: 555-555-5555
  - Ext (opt):
- **Fax**: 555-555-4444
- **Contact Preference**: Email

**Education Program**
- Clozapine REMS Knowledge Assessment for Healthcare Providers
- Knowledge Assessment Answer Guide

For additional information about the Clozapine REMS Program, please call 844-267-8678.
11.4 Chain Headquarters Pharmacy Authorized Representative Profile

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

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

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

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
12.2 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.

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

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.
12.4 Change Password

To change your password, please complete the fields below.

Old Password
New Password
Confirm Password

Change Username
Change Email Address

For additional information about the Clozapine REMS Program, please call 844-267-6678.
12.5 Change Password Notification

To change your password, please complete the fields below:

- Old Password
- New Password
- Confirm Password

Change Username
Change Email Address

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

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

To change your email address, please complete the fields below.

- Email Address
- Confirm Email Address
- Change Username
- Change Password

For additional information about the Clozapine REMS Program, please call 844-267-8678.
12.8 Change Email Address Confirmation

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:

- Email Address
- Confirm Email Address

For additional information about the Clozapine REMS Program, please call 844-207-8678.
13. Patient Groups

13.1 Manage Groups

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

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

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

Change Group Name

To change the group, simply edit the group name in the field below and press Submit.

Group Name:  Group A

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

To remove the group below simply press Remove; otherwise, press Cancel to return to Manage Groups.

Group Name: Group A

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

![Image of the CLOZAPINE REMS system interface with a warning message]

**Warning**

 Patients are currently assigned to the group you are removing. Would you like to reassign all the patients to a new group?

- [ ] No
- [x] Yes

For additional information about the Clozapine REMS Program, please call 844-207-8676.
13.6 Reassign Patients

Reassign Patients

Please select the new group below and press Submit.

Group Name:  -- Please Select --

Search

Cancel  Submit

For additional information about the Clozapine REMS Program, please call 844-207-6676.
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.

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

Note: Notifications will be displayed for all stakeholders. The Alerts and Notifications tabs are common across all stakeholders.

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

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.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>DOB</th>
<th>Enrollment</th>
<th>Group</th>
<th>Relationship</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mike</td>
<td>Brown</td>
<td>05/01/2020</td>
<td>Enrolled</td>
<td>Active</td>
<td></td>
<td>- Please Select --</td>
</tr>
<tr>
<td>John</td>
<td>Smith</td>
<td>05/01/2020</td>
<td>Enrolled</td>
<td>Active</td>
<td></td>
<td>- Please Select --</td>
</tr>
</tbody>
</table>

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.2.2 Prescriber Dashboard Patient Tab Expanded

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
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)
14.2.3 Definitions of Terms Pop-up

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.2.4 Add Lab, Change Treatment Status, and Change Monitoring Frequency for Prescribers

![Add Lab, Change Treatment Status, and Change Monitoring Frequency for Prescribers](image)

**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
14.2.5 View Patient History Lab History Tab

Patient History

Name: Varsha Bhatia
DOB: 05/01/2000
Gender: Female

<table>
<thead>
<tr>
<th>Entry Date</th>
<th>Blood Draw Date</th>
<th>ANC</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/06/2017</td>
<td>05/06/2017</td>
<td>1509</td>
</tr>
<tr>
<td>05/06/2017</td>
<td>05/06/2017</td>
<td>500</td>
</tr>
</tbody>
</table>

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.2.6 View Patient History Treatment Status Tab

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.2.7 View Patient History Monitoring Frequency Tab

Patient History

Name: Varsha Bhatia
DOB: 06/01/2000
Gender: Female

Entry Date | Monitoring Frequency
---|---
05/08/2017 | Weekly

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.2.8 View Patient History Dispense Rationale Tab

Patient History

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

**Patient Profile**

**Patient Information**

- **First Name**: Chester
- **Last Name**: Smith
- **DOB**: 03/05/1983
- **Zip Code**: 85567
- **Gender**: Male
- **Race**: Caucasian
- **Group**: Group B
- **BEN Patient**: No
- **NNRMF Patient**: No

**Patient Enrollment Information**

**Enrollment ID**: PAT132456789

For additional information about the Clozapine REMS Program, please call 844-267-6678.
14.2.10 Prescriber Dashboard Designees Tab

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.2.11 Add Designee with Results

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**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terry</td>
<td>White</td>
</tr>
<tr>
<td>Certification ID (opt)</td>
<td></td>
</tr>
<tr>
<td>Phone (opt)</td>
<td></td>
</tr>
<tr>
<td>Fax (opt)</td>
<td></td>
</tr>
<tr>
<td>Email (opt)</td>
<td></td>
</tr>
</tbody>
</table>

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.

**Showing 1 of 1 entries**

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terry</td>
<td>White</td>
<td>555-555-5555</td>
</tr>
</tbody>
</table>

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

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.

Submit

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

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

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

14.3.1 Prescriber Designee Dashboard Patient TabCollapsed

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.3.2 Prescriber Designee Dashboard Patient Tab Expanded

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)
14.3.3 Definitions of Terms Pop-up

- **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 from neutrophils. Because of this condition, patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine.

- **NNRNF**: Patients were listed in the National Non-Rechallenge Master File (NNRNF) if a patient had a WBC less than 2,300/µL or an ANC less than 1,000/µL. All patients who were listed in the NNRNF 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.
14.3.4 Add Lab and Change Treatment Status for Prescriber Designees

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
14.3.5 View Patient History: Lab History Tab

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.3.6 View Patient History: Treatment Status Tab

**Patient History**

<table>
<thead>
<tr>
<th>Lab History</th>
<th>Treatment Status History</th>
<th>Monitoring Frequency History</th>
<th>Dispense Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Varsha Bhatta</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOB: 05/01/2000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender: Female</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Entry Date</th>
<th>Treatment Status</th>
<th>Rationale</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/08/2017</td>
<td>Active</td>
<td></td>
<td></td>
</tr>
<tr>
<td>05/05/2017</td>
<td>Active</td>
<td>Benefit Outweighs Risk</td>
<td></td>
</tr>
</tbody>
</table>

Showing 1 to 2 of 2 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.3.7 View Patient History: Monitoring Frequency Tab

Patient History

Name: Varsha Bhatia
DOB: 06/01/2000
Gender: Female

Entry Date | Monitoring Frequency
05/08/2017 | Weekly

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.3.8 View Patient History: *Dispense Rationale* Tab

For additional information about the Clozapine REMS Program, please call 844-267-8673.
14.3.9 View Patient Profile

Patient Profile

Patient Information

First Name: Chester
Last Name: Smith
DOB: 03/05/1983
Zip Code: 85067
Gender: Male
Race: Caucasian
Group: Group B
BEN Patient: No
NNRME Patient: No

Patient Enrollment Information

Enrollment ID: PAT132456789

For additional information about the Clozapine REMS Program, please call 844-267-8078.
14.3.10 Prescriber Designee Dashboard Prescribers Tab

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 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
3 – 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

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):**

- First Name
- Last Name
- DEA
- or
- NPI
- Phone (opt)

**Search**

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

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.

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

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.

For additional information about the Clozapine REMS Program, please call 844-267-3678.
### 14.4 Pharmacy Dashboard – Inpatient Pharmacies

#### 14.4.1 Inpatient Pharmacy Dashboard Pharmacies Tab

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

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Address</th>
<th>Pharmacy Type</th>
<th>Certification ID</th>
<th>Certification Status</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ale Roy Lu</td>
<td>4343 n scottsdale rd, BURKEVILLE, Virginia 23922</td>
<td>Inpatient</td>
<td>FAC5413173852</td>
<td>Certified</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>Test Pharma</td>
<td>4343 n scottsdale rd, PHOENIX, Arizona 85054</td>
<td>Inpatient</td>
<td>FAC54103345247</td>
<td>Certified</td>
<td>— Please Select — Remove Pharmacy — View/Update Pharmacy Profile — Add Lab — Eligability Check — Recertify Pharmacy</td>
</tr>
<tr>
<td>Ikea Inc</td>
<td>4343 n scottsdale rd, PHOENIX, Arizona 85054</td>
<td>Outpatient</td>
<td>FAC5410337605</td>
<td>Certified</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>JC Penny</td>
<td>4343 north scottdale, PHOENIX, Arizona 85054</td>
<td>Outpatient</td>
<td>FAC5410324942</td>
<td>Certified</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>Tata Pharma</td>
<td>4343 n scottsdale rd, LANSING, Michigan 49915</td>
<td>Outpatient</td>
<td>FAC5414198715</td>
<td>Incomplete</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>Sharma Pharma</td>
<td>4343 n scottsdale rd, LANSING, Michigan 49912</td>
<td>Outpatient</td>
<td>FAC5414119840</td>
<td>Incomplete</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>Inosent</td>
<td>Address, SCOTTDALE, Arizona 85250</td>
<td>Inpatient</td>
<td>FAC54141982350</td>
<td>Incomplete</td>
<td>— Please Select —</td>
</tr>
</tbody>
</table>

For additional information about the Clozapine REMS Program, please call 844-267-8678.
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”
14.4.2 Add Lab
Note: This Add Lab page is displayed for both Inpatient, Outpatient pharmacies on- and off-switch.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.4.3 Add Lab – Successful

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 micro litre
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

Patients lab results were successfully saved.

Ok

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.4.4 Add Lab – Unsuccessful

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

Unsuccessful due to invalid entry. Please recheck information and resubmit.

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

Note: This Eligibility Check page displayed is for Inpatient Pharmacies.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.4.6 **Eligibility Check Result – Successful**

**Eligibility Check Result**

- **The below patient is eligible to receive clozapine.**

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

**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.
Eligibility Check Result

✅ The below patient is eligible to receive clozapine.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.4.7 Eligibility Check Result – Successful with warning message

Eligibility Check Result

The below patient is eligible to receive clozapine.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

Current Monitoring Frequency: Weekly

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.4.8 Eligibility Check Result – Unsuccessful

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
14.5 Pharmacy Dashboard – Outpatient Pharmacies

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.
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”
14.5.1 Dispense Rationale

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

Add Patient Lab (optional)

ANC value per microliter (opt)
Blood Draw Date (opt)

Dispensation Information

Date of Service (opt)
Manufacturer
NDC Off 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.
14.5.2 Dispense Rationale Result Screen – Success

Dispense Rationale Result

- The below patient is eligible to receive clozapine.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

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.
### 14.5.3 Dispense Rationale Result Screen – Success (After DR is issued)

#### Dispense Rationale Result

- **The below patient is eligible to receive clozapine.**

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

**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.
14.5.4 Dispense Rationale Result Screen – Unsuccessful

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

Current Monitoring Frequency: Weekly

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per μL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

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.

Request additional assistance with this patient’s eligibility, please contact the patient’s prescriber.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.6 Pharmacy Dashboard – Outpatient Pharmacies on switch

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:
1. 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
3. Add Lab – will take the user to the Add Lab page
   
   2. Predispense Authorization – will take the user to the Predispense Authorization page
4. Dispense Rationale – will take the user to Dispense Rationale page
5. Recertify Pharmacy – will take the user to the Pharmacy Recertification page
6. For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”
14.6.1 Predispense Authorization

![Predispense Authorization Form]

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

**Add Patient Lab (optional)**
- ANC value per microlitre (opt)
- Blood Draw Date (opt)

**Predispense Authorization Request**
- Date of Service
- Manufacturer
- NDC
- 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.
14.6.2 *Predispose Authorization Result – Successful*

![Image of Predispose Authorization Result]

- **The below patient is eligible to receive clozapine.**

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

**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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.6.3 *Predispose Authorization Result – Unsuccessful*

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.
14.6.4 **Predispose Authorization** Result – Success (After DR is issued)

- **Name**: Summer H
- **DOB**
- **Authorization Number**

**Current Monitoring Frequency**: Weekly

- **Blood Draw date**: 04/20/2017
- **ANC Level (per µL)**: 1500

*The below patient is eligible to receive clozapine.*

⚠️ Prascriber not certified. Prascriber 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.

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

Pharmacy Information

- **Pharmacy Name**: Joey's Apothecary
- **Pharmacy Type**: Outpatient
- **Address**: 1 Main Street
- **Address 2**: Suite 123
- **City**: New York
- **State / Zip Code**: NY 11001
- **Phone / Ext**: 555-555-5555 Ext (opt)
- **Fax**: 555-555-4444
- **NCPDP**: 1234567
- **DEA**: AB123456789
- **NPI**: 123456789

Pharmacy Certification Information

- **Certification ID**: HCP123456789

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

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.

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

Please complete the following questionnaire to ensure the correct pharmacy type assignment.

**QUESTION 18**

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.
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.
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.

Next

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

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

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.6.7 Pharmacy Dashboard Pharmacy Staff Tab

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.
14.6.8 Remove Pharmacy Staff

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.

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

14.7.1 Chain Pharmacy Dashboard Pharmacies Tab

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

Pharmacy Profile

Pharmacy Information

- Pharmacy Name: Joey’s Apothecary
- Pharmacy Type: Outpatient
- Address: 1 Main Street
- Address 2: Suite 123
- City: New York
- State / Zip Code: NY, 11001
- Phone / Ext: 555-555-5555, Ext (opt)
- Fax: 555-555-4444
- NCPDP: 1234567
- DEA: AB123456789
- NPI: 123456789

Pharmacy Certification Information

Certification ID: HCP123456789

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

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.7.4 Chain Pharmacy Dashboard Pharmacy Staff Tab

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

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

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.

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

14.8.1 Pharmacy Staff Dashboard Pharmacies Tab

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.
14.8.2 Associate to Pharmacy

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):

10001 and DEA NPI 3465789

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.

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Pharmacy Address</th>
<th>Pharmacy Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVS</td>
<td>423 Main Street, Tamoa FL 33614</td>
<td>565-555-5555</td>
</tr>
</tbody>
</table>

Showing 1 of 1 entries

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

To determine if the safe-use conditions have been met for your patient 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

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.
14.8.4 *Eligibility Check* Result – Unsuccessful

Note: This result is displayed for the *Eligibility Check* when the result is unsuccessful.

---

**Eligibility Check Result**

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

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

Current Monitoring Frequency: Weekly

**Patient's Lab History**

*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.

---

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

![Image of Predispense Authorization form](image-url)

**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

**Add Patient Lab (optional)**
- ANC value per microlitre (opt)
- Blood Draw Date (opt)

**Predispense Authorization Request**
- Date of Service
- Manufacturer
- NDC
- Days Supply
- Quantity

At least one identifier is required:
- Prescribed DEA
- Prescribed NPI

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.8.6 *Predis pense Authorization Result – Unsuccessful*

Note: This result is displayed for the *Predis pense Authorization* when the result is unsuccessful.
15. Dispense Rationale – Static Pages

15.1 Home Page

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.
16. Dispense Rationale – Pharmacy Authorized Representative (Non-Switch)

16.1 Pharmacy – Authorized Representative Dashboard

For additional information about the Clozapine REMS Program, please call 844-267-8678.
16.2 Pharmacy – Authorized Representative *Predispense Authorization*

![Predispense Authorization Form](image)

**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**

**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.
16.3 Pharmacy – Authorized Representative *Predispose Authorization* Result - Successful

The below patient is eligible to receive clozapine.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

Current Monitoring Frequency: Weekly

**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.
16.4 Pharmacy – Authorized Representative *Predispose Authorization Result* - Unsuccessful

**Predispose Authorization Result**

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

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per μL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

**Current Monitoring Frequency:** Weekly

- **Name:** Summer H
- **DOB:**
- **Authorization Number:**

- **X** Prescriber not certified. Prescriber can certify at www.clozapinorems.com or call 844-267-8678.
- **A** Current ANC is not on file.

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.
16.5 Pharmacy – Authorized Representative *Predispose Authorization Result – Successful*

The Dispense Rationale has been provided.
Please resubmit the request to receive the authorization to dispense clozapine to the patient.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
16.6 Pharmacy – Authorized Representative *Predispose Authorization Result- Successful (After the Dispense Rationale is issued)*

For additional information about the Clozapine REMS Program, please call 844-267-8678.
16.7 Pharmacy – Authorized Representative **Predispose Authorization** Result – Unsuccessful

⚠️ 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.
### 17. Dispense Rationale – Pharmacy Staff (Non-Switch)

**Pharmacy Staff Dashboard**

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Address</th>
<th>Certification Status</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baro Pharma</td>
<td>4343 scotsdale rd, SAN JOSE, California 95128</td>
<td>Certified</td>
<td>-- Please Select -- Go</td>
</tr>
<tr>
<td>Orlando Pharma</td>
<td>4343 scotsdale rd, BENTON HARBOR, Michigan 49022</td>
<td>Decertified</td>
<td>Add Lab</td>
</tr>
<tr>
<td>Tita reliance</td>
<td>4343 scotsdale rd, PHOENIX, Arizona 85016</td>
<td>Certified</td>
<td>-- Please Select -- Go</td>
</tr>
<tr>
<td>Tomas Pharma</td>
<td>4343 scotsdale rd, OMAHA, Nebraska 68117</td>
<td>Certified</td>
<td>-- Please Select -- Go</td>
</tr>
<tr>
<td>Trader Joes</td>
<td>4343 scotsdale rd, BALTIMORE, Maryland 21215</td>
<td>Certified</td>
<td>-- Please Select -- Go</td>
</tr>
</tbody>
</table>

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
17.1 Pharmacy Staff Predispense Authorization

For additional information about the Clozapine REMS Program, please call 844-267-8678.
17.2 Pharmacy Staff *Predispose Authorization Result - Successful*

![Image of Pharmacy Staff Predispose Authorization Result](image)

- **Lab**
  - **Blood Draw date**: 04/20/2017
  - **ANC Level (per μL)**: 1500

- **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.

**Current Monitoring Frequency**: Weekly

For additional information about the Clozapine REMS Program, please call 844-267-8678.
17.3 Pharmacy Staff *Predisperse Authorization Result* - Unsuccessful

**Predisperse 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

**Name**: Summer H  
**DOB**:  
**Authorization Number**

- **X** Prescriber not certified. Prescriber can certify at www.clozapine.rems.com or call 844-267-8678.
- **A** 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.
17.4 Pharmacy Staff Predispose Authorization Result – Successful

Predispose 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)

- **The below patient is eligible to receive clozapine.**

  - **Lab**
    - **Blood Draw date**: 04/20/2017
    - **ANC Level (per μL)**: 1500

- **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 *Predis pense Authorization Result – Unsuccessful*

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.
18. Dispense Rationale – Pharmacy Authorized Representative (Switch)

18.1 Pharmacy – Authorized Representative Dashboard

For additional information about the Clozapine REMS Program, please call 844-267-8878.
18.2 Pharmacy – Authorized Representative Dispense Rationale

Note: This Dispense Rationale page is displayed for outpatient pharmacies on- & off-switch.
18.3 Pharmacy – Authorized Representative *Dispense Rationale* Result Screen- Success

**Dispense Rationale Result**

✔️ The below patient is eligible to receive clozapine.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per μL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

**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)

Dispense Rationale Result

✔️ The below patient is eligible to receive clozapine.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
18.5 Pharmacy – Authorized Representative Dispense Rationale Result Screen - Unsuccessful

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

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
18.6 Pharmacy – Authorized Representative Eligibility Check Result - Successful

Eligibility Check Result

- The below patient is eligible to receive clozapine.

Lab

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

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

Do not dispense clozapine to this patient.

Please call the Clozapine REMS Program at 844-267-8678 for more information.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per μL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

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.
19. Dispense Rationale – Pharmacy Staff (Inpatient Pharmacy)
19.1 Pharmacy Staff Dashboard

For additional information about the Clozapine REMS Program, please call 844-267-8678.
19.2 Pharmacy Staff Eligibility Check

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 no 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

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.
19.3 Pharmacy Staff Eligibility Check Result - Successful

- Blood Draw date: 04/20/2017
- ANC Level (per µL): 1500

Current Monitoring Frequency: Weekly

Lab Status: Lab was Saved

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

For additional information about the Clozapine REMS Program, please call 844-267-3678.
19.4 Pharmacy Staff Eligibility Check Result

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](http://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.
20. Dispense Rationale – Pharmacy Staff (Switch)

20.1 Pharmacy Staff Dashboard

For additional information about the Clozapine REMS Program, please call 844-267-8678.
20.2 Pharmacy Staff Dispense Rationale

Dispense Rationale

To request a Dispense Rationale for your patient, please complete the information below and Submit. If you have no 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

Add Patient Lab (optional)

- ANC value per micro litre (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.
20.3 Pharmacy Staff **Dispense Rationale Result - Success**

The below patient is eligible to receive clozapine.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw Date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per nL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

Current Monitoring Frequency: Weekly

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

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)

The below patient is eligible to receive clozapine.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/23/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

Current Monitoring Frequency: Weekly

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.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
20.5 Pharmacy Staff Dispense Rationale Result - Unsuccessful

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

<table>
<thead>
<tr>
<th>Lab</th>
<th>Current</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw date</td>
<td>04/20/2017</td>
<td>None</td>
</tr>
<tr>
<td>ANC Level (per µL)</td>
<td>1500</td>
<td>None</td>
</tr>
</tbody>
</table>

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.

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

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’.
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
21.2 Prescriber and Prescriber Designee Dispense Rationale History

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

<table>
<thead>
<tr>
<th>Name:</th>
<th>Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
<tr>
<td>Phone:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>DEA:</td>
<td>Fax:</td>
</tr>
</tbody>
</table>

Authorized Representative Information (All Fields Required)

<table>
<thead>
<tr>
<th>First Name:</th>
<th>Last Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
<td>Fax:</td>
</tr>
<tr>
<td>Email:</td>
<td></td>
</tr>
</tbody>
</table>

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

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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:

This letter is intended to inform outpatient pharmacies who must obtain a “Predispose 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 setting** 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.

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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.

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
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 Predisperse 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 Predisperse Authorization Fact Sheet
How to Start Clozapine and Monitor Patients Fact Sheet

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

02/2019
Dear Pharmacy Manager:

This letter is intended to inform outpatient pharmacies who must obtain a “Predispose 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.**

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](http://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.

2. **Prescribing clozapine for patients in an outpatient setting** 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.

3. **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](http://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.

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2 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.

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

02/2019
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

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

02/2019
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 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
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](http://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](http://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](http://www.clozapinerems.com).

2. **Prescribing clozpine 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](http://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](http://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.

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

02/2019
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

- Patient ANCs 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.

The products covered under the Clozapine REMS Program are: Clozari® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension • Fazaclo® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products

02/2019
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 • Fazaclo® (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