

**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**SINGLE SHARED SYSTEM FOR CLOZAPINE**

**I. GOALS**

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

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

**II. REMS ELEMENTS**

**A. Elements To Assure Safe Use**

- 1. Healthcare providers who prescribe clozapine are specially certified.
  - a. To become specially certified to prescribe clozapine in the Clozapine REMS Program, healthcare providers must:
    - i. Review the Prescribing Information for clozapine;
    - ii. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and successfully complete the *Knowledge Assessment for Healthcare Providers*; and
    - iii. Enroll in the Clozapine REMS Program by completing the *Clozapine REMS Prescriber Enrollment Form*.

b. As a condition of certification, prescribers must:

i. Enroll each patient in the Clozapine REMS Program by:

- 1.) Informing the patient about the risks associated with clozapine including severe neutropenia and the Clozapine REMS Program requirements by using *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers*, and providing it to the patient or caregiver unless clinical judgment indicates that the patient's adherence to the treatment regimen will be negatively impacted by providing *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers*
- 2.) Completing the *Clozapine REMS Patient Enrollment Form* for each patient. Submit the completed form to the Clozapine REMS Program and store a copy in the patient's records.

ii. Perform the following requirements on an ongoing basis for each patient and report to the Clozapine REMS Program via the online system, by fax, or by calling the Clozapine REMS Program contact center:

- 1.) Report ANC according to the monitoring schedule described in the Prescribing Information.
- 2.) Report authorization to continue treatment for patients with an ANC that falls below the acceptable range described in the Prescribing Information, when the prescriber determines the benefits exceed the risks of developing severe neutropenia.

c. Clozapine Sponsors must:

- i. Ensure that healthcare providers who prescribe clozapine are specially certified in accordance with the requirements described above.
- ii. Ensure that healthcare providers can complete the certification process, patient enrollment and management online or by fax to the Clozapine REMS Program.
- iii. Ensure that healthcare providers who prescribe clozapine are notified when they have been certified in the Clozapine REMS Program.
- iv. Maintain a validated, secure database of healthcare providers who are certified to prescribe clozapine in the Clozapine REMS Program. Clozapine Sponsors must ensure that the prescriber's REMS requirements are met and may de-certify noncompliant prescribers if

the requirements do not continue to be met.

- v. Maintain a validated, secure database of patients enrolled in the Clozapine REMS Program
- vi. Ensure that certified prescribers are provided access to the database of certified pharmacies and enrolled patients.
- vii. Provide *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* to healthcare providers who:
  - 1.) attempt to prescribe clozapine and are not yet certified, or
  - 2.) inquire about how to become certified.
- viii. Ensure that within 30 calendar days of REMS approval, the REMS materials listed below are available on the Clozapine REMS Program website ([www.clozapinerems.com](http://www.clozapinerems.com)), or by calling the Clozapine REMS Program contact center at 844-267-8678.

The following materials are part of the REMS and are appended:

- *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- *Knowledge Assessment for Healthcare Providers*
- *Clozapine REMS Prescriber Enrollment Form*
- *Clozapine REMS Prescriber Designee Enrollment Form*
- *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers*
- *Clozapine REMS Patient Enrollment Form*
- Clozapine REMS Program website

2. Pharmacies that dispense clozapine are specially certified.

- a. To become specially certified to dispense clozapine in the Clozapine REMS Program, pharmacies must:
  - i. Designate an authorized representative to complete certification on behalf of the pharmacy using the appropriate form:
    - 1.) *Clozapine REMS Pharmacy Enrollment Form*
    - 2.) *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form*
  - ii. Ensure the authorized representative will oversee implementation and compliance with the Clozapine REMS Program requirements by doing the following:
    - 1.) Review *Clozapine and the Risk of Neutropenia: A Guide for*

*Healthcare Providers* and successfully complete the *Knowledge Assessment for Healthcare Providers*.

- 2.) Ensure all relevant staff involved in the dispensing of clozapine are trained on the Clozapine REMS Program requirements as described in *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and maintain records of staff training.
  - a.) For pharmacies that have a pharmacy management system that supports electronic telecommunication verification, each pharmacist must be trained utilizing established training protocols for their certified pharmacy.
  - b.) For pharmacies that have a pharmacy management system that does NOT support electronic telecommunication verification, each pharmacist must be trained by reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and successfully completing the *Knowledge Assessment for Healthcare Providers*.
- iii. Put processes and procedures in place to ensure the following verifications and reporting requirements are completed:
  - 1.) Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine,
  - 2.) Verify the ANC is current (within 7 calendar days of the blood draw),
  - 3.) Verify the ANC is within the acceptable range described in the Prescribing Information or the prescriber has authorized the continuation of clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits exceed the risks of developing severe neutropenia prior to dispensing clozapine, and
  - 4.) Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program
- iv. Maintain appropriate documentation that all processes and procedures are in place and are being followed for the Clozapine REMS Program and provide it upon request to the Clozapine Sponsors, FDA, or a third party.
- v. Comply with audits by the Clozapine Sponsors, FDA, or a third party to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program.

b. As a condition of certification:

i. Outpatient pharmacies:

- 1.) that support electronic telecommunication verification with the Clozapine REMS Program system must:
  - a.) Ensure the pharmacy enables its pharmacy management system to support communication with the Clozapine REMS Program system using established telecommunication standards and runs the standardized validation test transaction(s) to validate the system enhancements.
  - b.) Dispense clozapine to patients only after obtaining a predispose authorization by processing all clozapine prescriptions, including cash claims, through their pharmacy management system to electronically:
    - (1) verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program.
    - (2) verify the ANC is current and within the acceptable range described in the Prescribing Information, or that the prescriber has authorized the continuation of clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits exceed the risks of developing severe neutropenia.
    - (3) report dosing information for each clozapine prescription/fill to the Clozapine REMS program.
- 2.) that do NOT support electronic telecommunication verification with the Clozapine REMS Program system must dispense clozapine to patients only after obtaining a predispose authorization by accessing the Clozapine REMS Program website or calling the Clozapine REMS Program contact center to:
  - a.) verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program.
  - b.) verify the ANC is current and within the acceptable range described in the Prescribing Information, or that the prescriber has authorized the continuation of clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the

benefits exceed the risks of developing severe neutropenia.

- c.) report dosing information for each clozapine prescription/fill to the Clozapine REMS Program.
- ii. Inpatient pharmacies must:
    - 1.) Dispense clozapine to patients only after accessing the Clozapine REMS Program website or calling the Clozapine REMS Program contact center to verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program.
    - 2.) Dispense clozapine to patients only after accessing the Clozapine REMS Program website, calling the Clozapine REMS Program contact center or checking the patient's medical record to verify the ANC is current and within the acceptable range described in the Prescribing Information, or the prescriber has authorized the continuation of clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits exceed the risks of developing severe neutropenia.
- c. Clozapine Sponsors must:
    - i. Ensure that pharmacies that dispense clozapine are specially certified, in accordance with the requirements described above.
    - ii. Ensure that authorized representatives can complete the certification process and pharmacists can complete training online or by fax to the Clozapine REMS Program.
    - iii. Ensure that pharmacies are notified when they have been certified in the Clozapine REMS Program.
    - iv. Verify every 2 years that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for the certified pharmacy. If different, require the pharmacy to re-certify with a new authorized representative.

The following materials are part of the REMS and are appended:

- *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- *Knowledge Assessment for Healthcare Providers*
- *Clozapine REMS Pharmacy Enrollment Form*
- *Clozapine REMS Chain Headquarters Pharmacy Enrollment Form*
- Clozapine REMS Program Website

3. Clozapine will be dispensed with evidence or other documentation of safe-use conditions.
  - a. To enroll a patient in the Clozapine REMS Program, each prescriber must complete a *Clozapine REMS Patient Enrollment Form* indicating that the patient or their caregiver has:
    - i. Been provided *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers* unless clinical judgment indicates that the patient's adherence to the treatment regimen will be negatively impacted by providing *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers*
    - ii. Been informed by the prescriber of the risks of clozapine and the Clozapine REMS Program requirements, using *What You Need To Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers*.
  - b. Clozapine Sponsors must:
    - i. Ensure that the certified prescriber is able to submit the completed *Clozapine REMS Patient Enrollment Form* online or by fax to the Clozapine REMS Program.
    - ii. Ensure that the certified pharmacy can verify that the prescriber is certified and each patient treated with clozapine is enrolled in the Clozapine REMS Program prior to dispensing (see Section II.A.2).

The following materials are part of the REMS and are appended:

- *Clozapine REMS Patient Enrollment Form*

4. Each patient using Clozapine is subject to certain monitoring.

Clozapine Sponsors must ensure that the certified pharmacy can verify the ANC is current and within the acceptable range described in the Prescribing Information, or that the prescriber has authorized the continuation of treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits exceed the risks of developing severe neutropenia prior to dispensing clozapine.
5. Each patient using clozapine is enrolled in a registry.
  - a. Clozapine Sponsors must ensure that certified prescribers enroll all patients in the Clozapine REMS Program using the *Clozapine REMS Patient Enrollment Form*.
  - b. Clozapine Sponsors must maintain a Clozapine REMS Program registry. The

primary objective of the Clozapine REMS Program registry is to ensure patient safety and safe use of clozapine through periodic monitoring for severe neutropenia.

- c. Clozapine Sponsors must ensure that patient enrollment can be completed via Clozapine REMS Program website or by fax.

## **B. Implementation System**

1. Clozapine Sponsors must ensure that clozapine is only distributed to certified pharmacies by:
  - a. Ensuring the wholesalers/distributors who distribute clozapine comply with the program requirements for wholesalers/distributors. In order for a wholesaler/distributor to distribute clozapine, the wholesalers/distributors must:
    - i. Put processes and procedures in place to verify, prior to distributing clozapine, that the pharmacies are certified.
    - ii. Train all relevant staff on the Clozapine REMS Program requirements.
    - iii. Agree to be audited by the Clozapine Sponsors, FDA, or a third party to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program
    - iv. Maintain appropriate documentation and make it available for audits.
    - v. Provide distribution data to the individual Clozapine Sponsors
  - b. Ensuring that wholesalers/distributors maintain distribution records of all shipments of clozapine and provide the data to the individual Clozapine Sponsors.
  - c. Clozapine Sponsors must monitor distribution data and audit the wholesalers/distributors within one year after the wholesaler/distributor is enrolled to ensure that all processes and procedures are in place and functioning to support the requirements of the Clozapine REMS Program. Clozapine Sponsors must institute corrective action if noncompliance is identified.
2. Clozapine Sponsors must maintain a validated, secure database of pharmacies that are certified to dispense clozapine in the Clozapine REMS Program.
3. Clozapine Sponsors must maintain adequate records of clozapine distribution, dispensing, certified prescribers, pharmacies, distributors/wholesalers, and patients to meet the REMS requirements.

4. Clozapine Sponsors must ensure that pharmacies' REMS requirements are met and may de-certify noncompliant pharmacies if the requirements do not continue to be met.
5. Clozapine Sponsors must maintain a validated, secure database of patients who are enrolled in the Clozapine REMS Program.
6. Clozapine Sponsors must maintain a Clozapine REMS Program contact center to support prescribers and pharmacies interfacing with the Clozapine REMS Program.
7. Clozapine Sponsors must ensure that all materials listed in or appended to the Clozapine REMS document are available through the Clozapine REMS Program website [www.clozapinerems.com](http://www.clozapinerems.com) or by calling the Clozapine REMS Program contact center.
8. The Clozapine REMS Program website ([www.clozapinerems.com](http://www.clozapinerems.com)) must continue for the duration of the REMS. The Clozapine REMS Program website must include the option to print versions of the Clozapine REMS Program materials. Individual, product-specific clozapine websites for healthcare professionals must include a prominent REMS-specific link to the Clozapine REMS Program website.
9. Clozapine Sponsors must continuously monitor the certified pharmacies to ensure the requirements of the Clozapine REMS Program are being met. Clozapine Sponsors must institute corrective action if noncompliance is identified.
10. Clozapine Sponsors must audit certified pharmacies that have ordered clozapine to ensure that all processes and procedures are in place and functioning to support the requirements of the Clozapine REMS Program on the following schedule:
  - a. Eight percent within one year from the date of initial approval of the REMS
  - b. Eight percent every two years thereafter

Clozapine Sponsors must institute corrective action if noncompliance is identified.

11. Clozapine Sponsors must take reasonable steps to improve implementation of and compliance with the requirements of the Clozapine REMS Program based on monitoring and evaluation of the Clozapine REMS Program.

### **III. Timetable for Submission of Assessments**

Clozapine NDA Sponsors must submit REMS Assessments to the FDA at 6 months and 12 months from the date of initial approval of the REMS [September 14, 2015], and then annually thereafter.

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Clozapine

Sponsors will submit each assessment so that it will be received by the FDA on or before the due date.

**Instructions**

For immediate certification, please go to [www.clozapinerems.com](http://www.clozapinerems.com).

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. You will receive a confirmation via the contact preference you list below.

**Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to become certified and prescriber clozapine, you must:**

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully complete the *Knowledge Assessment for Healthcare Providers*
3. Complete and submit this one-time *Prescriber Enrollment Form* along with the completed *Knowledge Assessment for Healthcare Providers*

If you have any questions, require additional information, or need further copies of Clozapine REMS Program documents, please visit the program website at [www.clozapinerems.com](http://www.clozapinerems.com), or call the Clozapine REMS Program at 844-267-8678.

**Prescriber Responsibilities**

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 *Knowledge Assessment for Healthcare Providers*
3. I understand the risk of severe neutropenia associated with clozapine
4. Prior to initiating treatment, I agree to provide *What You Need To Know About Clozapine: A Guide for Patients and Caregivers* to each patient and/or his/her caregiver. I will review it with him/her to inform them about the risks associated with clozapine, including severe neutropenia and the Clozapine REMS Program requirements – unless I determine that the patient's adherence to the treatment regimen will be negatively impacted by providing *What You Need To Know About Clozapine: A Guide for Patients and Caregivers*
5. I will enroll all patients I treat with a clozapine product in the Clozapine REMS Program
6. I understand the 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 Benign Ethnic Neutropenia (BEN)
8. I will order ANC testing for each patient according to the clozapine Prescribing Information
9. I will report the ANC for each patient to the Clozapine REMS Program and I understand the ANC must be provided before clozapine can be dispensed
10. I understand that, as described in *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, I must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed
11. I agree that personnel from the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
12. 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
13. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

**Prescriber Information (All Fields Required Unless Otherwise Indicated)**

First Name:	MI (opt):	Last Name:	
NPI:	DEA:		
Email:	Credentials (MD, DO, NP, PA):		
Clinic / Practice Name:			
Address:			
City:	State:	Zip Code:	
Phone:	Ext (opt):	Fax:	
Contact Preference (please select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax			
Prescriber's Signature:			Date (MM/DD/YYYY):

**Instructions**

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To submit this form via fax, please complete all required fields below and fax to 844-404-8876. You will receive a confirmation via the contact preference you list below.

**Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to access the Clozapine Program as a prescriber's designee, you must complete this form.**

If you have any questions, require additional information, or need further copies of Clozapine REMS Program documents, please visit the program website at [www.clozapinerems.com](http://www.clozapinerems.com), or call the Clozapine REMS Program at 844-267-8678.

**Prescriber Designee Responsibilities**

By signing this form, you acknowledge that you 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
3. **For Outpatients:** An ANC must be reported to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed
4. **For Inpatients:** An ANC must be reported to the Clozapine REMS Program for each patient within 7 days from the date of the blood draw
5. 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
6. 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
7. Personnel from the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
8. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

**Designee Information (All Fields Required)**

First Name:		Last Name:	
Email:			
Phone:	Ext (opt):	Fax:	
Contact Preference (please select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax			
Prescriber Designee Signature:			Date (MM/DD/YYYY):

**Prescriber Information (All Fields Required)**

First Name:		Last Name:	
REMS Certification ID (opt):	DEA:	NPI:	
Prescriber Signature:			Date (MM/DD/YYYY):

**Instructions**

For immediate certification, please go to [www.clozapinerems.com](http://www.clozapinerems.com).

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. You will receive a confirmation via the contact preference you select below.

**Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to become certified and dispense clozapine, you must:**

1. Select an authorized representative
2. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
3. Successfully complete the *Knowledge Assessment for Healthcare Providers*
4. Complete and submit this one-time Clozapine REMS Chain Headquarters Pharmacy Enrollment Form along with the completed *Knowledge Assessment for Healthcare Providers*
5. Implement the necessary staff training and processes at both a headquarter level and at each dispensing location to comply with the Clozapine REMS Program requirements.

If you have any questions, require additional information, or need further copies of Clozapine REMS Program documents, please visit the program website at [www.clozapinerems.com](http://www.clozapinerems.com), or call the Clozapine REMS Program at 844-267-8678.

**Authorized Representative Responsibilities**

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*, 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 ANC monitoring
3. There is a different ANC monitoring algorithm for patients with Benign Ethnic Neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to contact them via phone, mail, or email 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:**

5. 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:
  - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
  - Through electronic communication with the Clozapine REMS Program using established telecommunications standards, my pharmacy will dispense clozapine to each patient only after obtaining authorization by electronically verifying documentation of the following:
    - Prescriber is certified in the Clozapine REMS Program
    - Pharmacy is certified in the Clozapine REMS Program
    - Patient is enrolled in the Clozapine REMS Program
    - The ANC is current and acceptable or the prescriber has authorized continuing treatment if the ANC is abnormal
  - This information will be verified by processing all clozapine prescriptions, including cash claims, through the pharmacy management system
  - 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
6. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party or the FDA to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact pharmacists in my pharmacies to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
10. For each trained dispensing location provide the following information (Pharmacy Name, NCPDP or NPI or DEA, Address, Phone, Fax, Email, Store Number, and Responsible Pharmacist name)
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

**Chain Headquarters Pharmacy Information (All Fields Required)**

Name:		
Chain ID:		
Address:		
City:	State:	Zip Code:
Phone:	Fax:	

**Authorized Representative Information (All Fields Required)**

First Name:	Last Name:		
Credentials:	<input type="checkbox"/> R.Ph	<input type="checkbox"/> PharmD	<input type="checkbox"/> BCPS <input type="checkbox"/> Other
Phone:	Fax:	Email:	
Contact Preference (please select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax			
Authorized Representative Signature:			Date (MM/DD/YYYY):

**Next Steps**

1. Once this form is processed, you will receive instructions on submitting test transaction(s) to the Clozapine REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Clozapine REMS Program
2. After successful completion of the test transactions, you will receive a pharmacy certification confirmation. Upon receipt, your corporate pharmacy is certified and your dispensing locations are now eligible to complete their training
3. Once each dispensing location is trained, it is your responsibility to report documentation of training to the Clozapine REMS Program online through [www.clozapinerems.com](http://www.clozapinerems.com), or by contacting the Clozapine REMS Program Contact Center to obtain instructions on providing a list of certified pharmacy locations. Once the Clozapine REMS Program confirms the required dispensing location information, this dispensing location will be certified and permitted to purchase, receive, and dispense clozapine

## Instructions

For immediate certification, please go to [www.clozapinerems.com](http://www.clozapinerems.com).

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. You will receive a confirmation via the contact preference you list below.

Use this form to enroll a SINGLE pharmacy location. To enroll MULTIPLE pharmacy locations, you must go to [www.clozapinerems.com](http://www.clozapinerems.com).

Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to dispense clozapine, the pharmacy must designate an authorized representative.

### The authorized representative for the pharmacy must:

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully complete the *Knowledge Assessment for Healthcare Providers*
3. Complete and submit this one-time *Clozapine REMS Pharmacy Enrollment Form* along with the completed *Knowledge Assessment for Healthcare Providers*
4. Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

If you have any questions, require additional information, or need further copies of Clozapine REMS Program documents, please visit the program website at [www.clozapinerems.com](http://www.clozapinerems.com), or call the Clozapine REMS Program at 844-267-8678.

## Authorized Representative Responsibilities

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 ANC monitoring
3. There is a different ANC monitoring algorithm for patients with 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:

5. 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:
  - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
  - Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
  - Verify the ANC is current and acceptable or verify the prescriber's authorization for continuing clozapine treatment if the ANC is abnormal
  - 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
6. My pharmacy will establish procedures and protocols that are subject to audit, to not sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make available to the clozapine manufacturers and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact my pharmacists to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
10. Provide dispensing location information to the Clozapine REMS Program
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

**FOR INPATIENT PHARMACIES ONLY**

12. Inpatient pharmacies are not required to obtain a Predispose Authorization (PDA) prior to dispensing clozapine.

Before dispensing clozapine to an inpatient for the first time, the inpatient pharmacies must:

- Verify the prescriber is certified in the Clozapine REMS Program
- Verify the patient is enrolled in the Clozapine REMS Program

Before dispensing clozapine to an inpatient for the first time, the inpatient pharmacies must:

1. Sign in into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com), or
2. Call the Clozapine REMS Program contact center at 844-267-8678

Inpatient pharmacies must verify the ANC or prescriber's authorization for a patient to continue clozapine treatment in one of three ways:

1. By signing into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
2. By calling the Clozapine REMS Program contact center at 844-267-8678
3. By reviewing the patient's medical record in their hospital's medical record system

Prescribers or their designee(s) must submit ANC to the Clozapine REMS Program within 7 days of blood draw.

**FOR OUTPATIENT PHARMACIES ONLY**

12. Outpatient pharmacies must obtain a Predispose Authorization (PDA) before dispensing clozapine products to a patient to ensure compliance with the required safe use conditions.

**Can your outpatient pharmacy management system adjudicate claims online?**

Yes

By selecting "Yes", you are confirming that your pharmacy management system CAN support electronic communication with the Clozapine REMS Program using established telecommunications standards. Clozapine will be dispensed only after obtaining electronic authorization for all clozapine prescriptions, including cash claims, through your pharmacy management system. After submitting this form, you will receive instructions through the contact preference indicated in the authorized representative information section on how to submit test transactions to the Clozapine REMS Program. This is to ensure that your pharmacy management system has been successfully configured to allow for communication with the Clozapine REMS Program.

No

By selecting "No", you are confirming that your pharmacy management system CANNOT support electronic communication with the Clozapine REMS Program and you will access the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com) or call the Clozapine REMS Program contact center to confirm safe use conditions (as outlined in attestation #5) before dispensing each clozapine prescription. A complete Predispose Authorization request requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.

**Pharmacy Information (All Fields Required)**

Pharmacy Name:

Pharmacy Type (select one):  Inpatient Pharmacy  Outpatient Pharmacy

Address:

City: State: Zip Code:

**Inpatient Identifiers (At least one required)**

NCPDP: NPI: DEA:

**Outpatient Identifiers (NCPDP and NPI Required)**

NCPDP: NPI: DEA:

**Authorized Representative Information (All Fields Required)**

First Name: Last Name:

Credentials:  R.Ph  PharmD  BCPS  Other

Phone: Fax: Email:

Contact Preference (please select one):  Email  Fax

Authorized Representative Signature: Date (MM/DD/YYYY):

**Instructions for Prescribers**

For immediate enrollment, please go to [www.clozapinerems.com](http://www.clozapinerems.com).

For enrollment via fax, please complete all required fields below and fax to 844-404-8876. For enrollment via the contact center, please call 844-267-8678. Enrollment confirmation will be sent via the contact preference specified on the prescriber's *Clozapine REMS Prescriber Enrollment Form*.

**Complete this form for a patient if:**

- This patient has never been treated with clozapine previously, OR
- If you have never treated this patient with clozapine (regardless of the patient's history of clozapine treatment)

**Clozapine is only available through the shared Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to treat a patient with clozapine, the patient MUST be enrolled in the shared Clozapine REMS Program. To enroll a patient you must:**

1. Provide the patient or caregiver with *What You Need To Know About Clozapine: A Guide for Patients and Caregivers*
2. Inform the patient or caregiver about the risk of severe neutropenia with clozapine and the Clozapine REMS Program requirements unless you determine that the patient's adherence to the treatment regimen will be negatively impacted by providing the *What You Need To Know About Clozapine: A Guide for Patients and Caregivers* and informing them about this risk.
3. Complete and submit this *Clozapine REMS Patient Enrollment Form*

If you have any questions, require additional information, or need further copies of Clozapine REMS Program documents, please visit the program website at [www.clozapinerems.com](http://www.clozapinerems.com), or call the Clozapine REMS Program at 844-267-8678.

**PATIENT INFORMATION** (All fields required for Enrollment)

First Name:

Last Name:

Gender:  Male  FemaleRace:  Caucasian  African American  Asian  Hispanic  Other:

Date of Birth (MM/DD/YYYY):

Zip Code:

Is this patient actively on clozapine therapy?  Yes  No  Unknown**LAB INFORMATION** (ANC must be provided before clozapine is dispensed, but is not required for patient enrollment)

Blood Draw Date (MM/DD/YYYY):

ANC (per  $\mu$ L):**PRESCRIBER INFORMATION** (All Fields Required)

Name:

NPI or DEA:

Phone:

Email:

Fax:

Submitter:  Prescriber  Prescriber Designee**BENIGN ETHNIC NEUTROPENIA (BEN) PATIENT ATTESTATION\*** (Signature required only for attestation of BEN diagnosis)

By signing below, I attest that the above patient has Benign Ethnic Neutropenia (BEN).

Prescriber Signature:

Date (MM/DD/YYYY):

\*Enrollment for patients with BEN must be completed by faxing this signed document to 844-404-8876 or by accessing the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com).

**Instructions for Prescribers**

For immediate online Absolute Neutrophil Count (ANC) reporting please go to [www.clozapinerems.com](http://www.clozapinerems.com).

Use this form to submit ANC monitoring information or update patient information.

**For INPATIENTS:** The prescriber and in-patient pharmacist must review the ANC before clozapine can be dispensed. Submit ANC to the Clozapine REMS Program within 7 days of the blood draw date.

**For OUTPATIENTS:** The out-patient pharmacist must obtain a pre-dispense authorization (PDA) from the Clozapine REMS Program before clozapine can be dispensed.

- To obtain a PDA, a current and acceptable ANC must be reported to the Clozapine REMS Program or the prescriber must provide a treatment rationale (see Section 3) to authorize treatment if a patient's ANC indicates moderate to severe neutropenia (General Population) or severe neutropenia (Patients with BEN).

**Section 1: ANC Lab Reporting**

**Prescriber Information (All Fields Required)**

Name:		NPI or DEA:	
Phone:	Email:		Fax:
Submitter:	<input type="checkbox"/> Prescriber	<input type="checkbox"/> Prescriber Designee	<input type="checkbox"/> Pharmacy

**Patient Information (All Fields Required)**

Name		
Date of Birth (MM/DD/YYYY):	Zip Code:	Gender:

**ANC Monitoring (All Fields Required)**

Blood Draw Date (MM/DD/YYYY):	ANC (per $\mu$ L):
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**Section 2: Patient Updates (if applicable)**

**Change Treatment Status**

Complete this section if you want to change this patient's treatment status. If this section is left blank, no changes will be made.

I want to change this patient's treatment status to: **(check one)**

- Active (restarting or continuing clozapine requires a treatment rationale for patients with moderate or severe neutropenia. Please refer to the "Treatment Rationale" section)
- Interrupted
- Discontinued

**Change Monitoring Frequency**

Complete this section if you want to change this patient's monitoring frequency. If this section is left blank, no changes will be made.

Based on the clozapine prescribing information, my patient is eligible for a change in ANC monitoring frequency. I want to change the ANC monitoring frequency to: **(check one)**

- Weekly
- Every 2 weeks
- Every 4 weeks

**Section 3: Prescriber Authorization**

**Treatment Rationale\***

Complete this section if the patient has moderate neutropenia (ANC 500-999/ $\mu$ L for the General Population) or severe neutropenia (ANC < 500/ $\mu$ L for General Population and Patients with BEN) and you want to continue treatment.

The treatment rationale is **(check one and sign below):**

- Benefits of continuing clozapine treatment outweigh risk of neutropenia
  - Until next ANC Lab
  - Until (MM/DD/YYYY) \_\_\_\_\_  
*No more than 6 months from today*
- Patient has Benign Ethnic Neutropenia (BEN) (No Expiration)

**Hospice Care\***

For hospice patients (i.e., terminally ill patients with an estimated life expectancy of six months or less), the prescriber may reduce the ANC monitoring frequency to once every 6 months, after a discussion with the patient and his/her caregiver.

If you want to change the monitoring frequency to once every 6 months for a hospice patient, **check the box and sign below:**

- This is a hospice patient.

**Authorizing Prescriber Information (All Fields Required)**

Name:		NPI or DEA:	
Authorizing Prescriber Signature:		Date (MM/DD/YYYY):	

\*Authorizing Prescriber Signature is required for a change in treatment rationale, and/or for a hospice care patient.

# CLOZAPINE REMS

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

## **Clozapine and the Risk of Neutropenia:**

A Guide for Healthcare Providers

### **This Guide discusses:**

- What is the Clozapine REMS Program?
- Clozapine and the risk of severe neutropenia
- Treatment recommendations and patient ANC monitoring
- Prescriber requirements for the Clozapine REMS Program
- Pharmacy requirements for the Clozapine REMS Program

## Table of Contents

Section	Title	Page
1.	The Clozapine REMS Program	2
2.	ANC, Neutropenia, and Patient ANC Monitoring	3
	<ul style="list-style-type: none"> <li>• What is ANC?</li> <li>• What is the risk of severe neutropenia associated with clozapine?</li> <li>• What is Benign Ethnic Neutropenia (BEN)?</li> <li>• What are the treatment recommendations and monitoring requirements for patients taking clozapine?</li> <li>• Can a patient continue clozapine treatment with an ANC less than 1000/<math>\mu</math>L?</li> <li>• If a patient develops a fever, how is clozapine treatment managed?</li> <li>• How is clozapine discontinued for neutropenia?</li> <li>• How is a patient monitored if clozapine treatment is discontinued for neutropenia?</li> <li>• Can a patient be rechallenged with clozapine?</li> </ul>	<p>3</p> <p>3</p> <p>4</p> <p>4</p> <p>7</p> <p>7</p> <p>8</p> <p>8</p> <p>9</p>
3.	Clozapine REMS Program Requirements for Prescribers	10
	<ul style="list-style-type: none"> <li>• What is the role of prescribers in the Clozapine REMS Program?</li> <li>• What do I tell my patients about clozapine?</li> <li>• How do I enroll a patient?</li> <li>• What if my patient has been treated with clozapine before?</li> <li>• How do I find out if my patient was listed in the National Non-Rechallenge Master File?</li> <li>• How do I report ANC results for my patients?</li> <li>• How do I authorize continuation of clozapine when my patient's ANC is less than 1000/<math>\mu</math>L (General Population) or less than 500/<math>\mu</math>L (Patients with BEN)?</li> <li>• What if my clozapine patient is under hospice care?</li> </ul>	<p>10</p> <p>10</p> <p>11</p> <p>11</p> <p>12</p> <p>12</p> <p>13</p> <p>13</p>
4.	Clozapine REMS Program Requirements for Pharmacies	14
	<ul style="list-style-type: none"> <li>• What types of pharmacies must be certified?</li> <li>• What is an authorized representative?</li> <li>• What is a Predispose Authorization (PDA)?</li> <li>• What is the role of pharmacies in the Clozapine REMS Program?</li> <li>• How do I verify the patient is authorized to receive clozapine? <ul style="list-style-type: none"> <li>- Outpatient Pharmacies <u>WITH</u> Electronic Telecommunication Verification</li> <li>- Outpatient Pharmacies <u>WITHOUT</u> Electronic Telecommunication Verification</li> <li>- Inpatient Pharmacies</li> </ul> </li> </ul>	<p>14</p> <p>15</p> <p>15</p> <p>16</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p>
5.	Reporting Adverse Events Associated with Clozapine	20
6.	Clozapine REMS Program Information and Resources	20

## 1 The Clozapine REMS Program

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia.

The Clozapine REMS Program provides a **centralized** point of access:

1. For **prescribers** and **pharmacies** to certify before prescribing or dispensing clozapine
2. To enroll and manage **patients** on clozapine treatment

Clozapine is available by prescription as:

- Clozaril® (clozapine) tablets, for oral use
- Fazaclo® (clozapine, USP) orally disintegrating tablets
- Versacloz® (clozapine, USP) oral suspension
- Approved generic equivalents of these products

**To minimize the risk of severe neutropenia associated with the use of clozapine, the Clozapine REMS Program includes the following key program requirements:**

### Prescribers

- Must certify in the Clozapine REMS Program to prescribe clozapine
- Must enroll all patients in the Clozapine REMS Program
- Must report patient ANC to the Clozapine REMS Program for every prescription of clozapine

### Pharmacies

- Must certify in the Clozapine REMS Program to dispense clozapine. This includes both inpatient and outpatient pharmacies
- Must verify the prescriber is certified and the patient is enrolled, prior to dispensing clozapine
- Must verify ANC is current and acceptable for each patient, or the prescriber authorized the continuation of clozapine treatment by providing the treatment rationale, prior to dispensing clozapine

### Patients

- Must be enrolled in the Clozapine REMS Program by the prescriber to receive clozapine
- Must comply with the ANC testing requirements

## 2 ANC, Neutropenia, and Patient ANC Monitoring

### What is ANC?

ANC is the laboratory parameter for monitoring patients for clozapine-induced neutropenia. Prescribers must report the ANC before starting and during clozapine treatment.

ANC is usually available as a component of the complete blood count (CBC), including differential:

- ANC is more relevant to drug-induced neutropenia than white blood cell (WBC) count
- ANC may also be calculated using the following formula:

$$\text{ANC} = \text{Total WBC count} \times \text{Total percentage of neutrophils}^*$$

\* neutrophil includes "segs" and "bands"

Other granulocytes (basophils and eosinophils) contribute minimally to neutropenia and their measurement is not necessary.

### What is the risk of severe neutropenia associated with clozapine?

Clozapine can cause severe neutropenia, which can lead to serious infections and death. Severe neutropenia occurs in a small percentage of patients taking clozapine.

- Severe neutropenia is defined as ANC less than 500/ $\mu\text{L}$
- Severe neutropenia replaces the previous terms "severe leukopenia", "severe granulocytopenia", and "agranulocytosis"
- The risk appears greatest during the first 18 weeks of clozapine treatment
- The mechanism is not dose-dependent
- It is unclear if concurrent use of other drugs known to cause neutropenia increases the risk or severity of clozapine-induced neutropenia
- If clozapine is used concurrently with a medication(s) known to cause neutropenia:
  - consider monitoring patients more closely than the treatment guidelines recommend, and
  - consult with the treating oncologist in patients receiving concomitant chemotherapy

For a complete discussion of other risks, including other Boxed Warnings, please see the full Prescribing Information available at [www.clozapinerems.com](http://www.clozapinerems.com).

## What is Benign Ethnic Neutropenia (BEN)?

BEN is a condition observed in certain ethnic groups whose average ANC's are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients who have been diagnosed with BEN have a separate ANC monitoring algorithm when treated with clozapine.



When enrolling a patient in the Clozapine REMS Program, identify if the patient has been diagnosed with BEN, so the patient is monitored according to the correct ANC monitoring algorithm.

A few important things to know about patients diagnosed with BEN:

- It is most commonly observed in individuals of African descent (approximate prevalence of 25-50%), some Middle Eastern ethnic groups, and in other non-Caucasian ethnic groups with darker skin
- BEN is more common in men
- Patients with BEN have normal hematopoietic stem-cell number and myeloid maturation, are healthy, and do not suffer from repeated or severe infections
- Patients with BEN **are not** at increased risk for developing clozapine-induced neutropenia

Additional evaluation may be needed to determine if baseline neutropenia is due to BEN.

Consider a hematology consultation before starting or during clozapine treatment as necessary.

## What are the treatment recommendations and monitoring requirements for patients taking clozapine?

The recommended ANC monitoring schedules for patients in the General Population as well as patients who have been diagnosed with BEN are shown in **Table 1**. The table also provides recommendations for monitoring patients who experience a decrease in ANC during the course of treatment.

Patients may transition to less frequent ANC monitoring based on the number of weeks of continuous clozapine therapy and the patient's ANCs. Weekly ANC monitoring is required for all patients during the first six months of treatment. If the ANC remains in the normal range (ANC greater than or equal to 1500/ $\mu$ L for the General Population, ANC greater than or equal to 1000/ $\mu$ L for Patients with BEN) for the first six months of therapy, monitoring frequency can be reduced to every 2 weeks.

If the patient's ANC continues to remain in the normal range for the second six months of treatment, ANC monitoring may be reduced to once every 4 weeks.

The Clozapine REMS Program will alert prescribers when a patient qualifies for a change in ANC monitoring frequency.



**Before starting treatment** with clozapine, the baseline ANC must be:

- at least 1500/ $\mu$ L for the General Population
- at least 1000/ $\mu$ L for patients diagnosed with BEN

**During treatment**, monitor ANC regularly as described in **Table 1** below.

**Table 1: Recommended Monitoring Frequency and Clinical Decisions by ANC Level**

ANC Level	Treatment Recommendation	ANC Monitoring
<p><b>Normal Range for a New Patient</b> <b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>ANC ≥ 1500/μL</li> </ul>	<ul style="list-style-type: none"> <li>Initiate treatment</li> <li>If treatment interrupted:                             <ul style="list-style-type: none"> <li>&lt; 30 days, continue monitoring as before</li> <li>≥ 30 days, monitor as if new patient</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Weekly from initiation to six months</li> <li>Every 2 weeks from 6 to 12 months</li> <li>Monthly after 12 months</li> </ul>
<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>ANC ≥ 1000/μL</li> <li>Obtain at least two baseline ANC levels before initiating treatment</li> </ul>	<ul style="list-style-type: none"> <li>Discontinuation for reasons other than neutropenia</li> </ul>	<ul style="list-style-type: none"> <li>See Section 2.4 of the full Prescribing Information</li> </ul>
<p><b>Mild Neutropenia</b> (1000 - 1499/μL)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Continue treatment</li> </ul>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Three times weekly until ANC ≥ 1500/μL</li> <li>Once ANC ≥ 1500/μL return to patient's last "Normal Range" ANC monitoring interval**</li> </ul>
	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Mild Neutropenia is normal range for BEN population, continue treatment</li> <li>Obtain at least two baseline ANC levels before initiating treatment</li> <li>If treatment interrupted                             <ul style="list-style-type: none"> <li>&lt; 30 days, continue monitoring as before</li> <li>≥ 30 days, monitor as if new patient</li> </ul> </li> <li>Discontinuation for reasons other than neutropenia</li> </ul>	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Weekly from initiation to six months</li> <li>Every 2 weeks from 6 to 12 months</li> <li>Monthly after 12 months</li> </ul>
<p><b>Moderate Neutropenia</b> (500 - 999/μL)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Resume treatment once ANC normalizes to ≥ 1000/μL</li> </ul>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Daily until ANC ≥ 1000/μL, then</li> <li>Three times weekly until ANC ≥ 1500/μL</li> <li>Once ANC ≥ 1500/μL check ANC weekly for 4 weeks, then return to patient's last "Normal Range" ANC monitoring interval**</li> </ul>
	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Continue treatment</li> </ul>	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Three times weekly until ANC ≥ 1000/μL or ≥ patient's known baseline.</li> <li>Once ANC ≥ 1000/μL or patient's known baseline, check ANC weekly for 4 weeks, then return to patient's last "Normal BEN Range" ANC monitoring interval.**</li> </ul>
<p><b>Severe Neutropenia</b> (&lt; 500/μL)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Do not rechallenge unless prescriber determines benefits outweigh risks</li> </ul>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>Daily until ANC ≥ 1000/μL</li> <li>Three times weekly until ANC ≥ 1500/μL</li> <li>If patient rechallenged, resume treatment as a new patient under "Normal Range" monitoring once ANC ≥ 1500/μL</li> </ul>
	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Do not rechallenge unless prescriber determines benefits outweigh risks</li> </ul>	<p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>Daily until ANC ≥ 500/μL</li> <li>Three times weekly until ANC ≥ patient's established baseline</li> <li>If patient rechallenged, resume treatment as a new patient under "Normal Range" monitoring once ANC ≥ 1000/μL or at patient's baseline</li> </ul>

\* Confirm all initial reports of ANC less than 1500/μL (ANC < 1000/μL for BEN patients) with a repeat ANC measurement within 24 hours

\*\* If clinically appropriate

## **Can a patient continue clozapine treatment with an ANC less than 1000/ $\mu$ L?**

### **For Patients in the General Population**

Yes. Prescribers may choose to continue clozapine treatment in patients with ANCs less than 1000/ $\mu$ L. However, prescribers should follow the treatment recommendations as noted in **Table 1** and carefully determine if the benefits of continuing clozapine treatment outweigh the risks.

The recommendations to interrupt treatment are provided to ensure patient safety. If monitoring ANC and symptoms of infection is not done appropriately, patients with ANCs less than 1000/ $\mu$ L are at risk of developing complications of severe neutropenia (including death).

Refer to Section 3 of this document for more details on how to authorize a patient to continue treatment.

### **For Patients with BEN**

Yes. The Prescribing Information for clozapine recommends interrupting clozapine treatment for patients with BEN only when the ANC is *less than 500/ $\mu$ L*. No interruption in treatment is recommended for ANC 500-999/ $\mu$ L, although a hematology consultation is recommended.

## **If a patient develops a fever, how is clozapine treatment managed?**

Generally, clozapine treatment should be interrupted as a precautionary measure in any patient who develops a fever of 38.5°C (101.3°F) or greater, and an ANC should be obtained. Fever is often the first sign of a neutropenic infection.

If fever occurs in any patient with an ANC less than 1000/ $\mu$ L, initiate appropriate neutropenia workup and treatment for infection. Refer to **Table 1** for ANC monitoring recommendations.

If any patient presents with evidence of fever and/or neutropenia, consider a hematology consultation.

## How is clozapine discontinued for neutropenia?

The method of treatment discontinuation will vary depending on the patient’s last ANC. Abrupt treatment discontinuation is necessary for moderate to severe neutropenia that you suspect is caused by clozapine.



**REMEMBER** to report the decision to discontinue clozapine for a patient to the Clozapine REMS Program. You can do this one of three ways:



By signing into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)



By calling the Clozapine REMS Program contact center at 844-267-8678



By completing the “Patient Update – Change Treatment Status” section of the *ANC Lab Reporting Form* and faxing it to the Clozapine REMS Program at 844-404-8876

## How is a patient monitored if clozapine treatment is discontinued for neutropenia?

After **discontinuing** clozapine, monitor ANC according to the recommendations in **Table 1** as shown below.

<p><b>Moderate Neutropenia</b> (500 to 999/<math>\mu</math>L)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>• Daily until ANC <math>\geq</math> 1000/<math>\mu</math>L, then</li> <li>• Three times weekly until ANC <math>\geq</math> 1500/<math>\mu</math>L</li> </ul>
<p><b>Severe Neutropenia</b> (less than 500/<math>\mu</math>L)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>• Daily until ANC <math>\geq</math> 1000/<math>\mu</math>L, then</li> <li>• Three times weekly until ANC <math>\geq</math> 1500/<math>\mu</math>L</li> </ul> <p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>• Daily until ANC <math>\geq</math> 500/<math>\mu</math>L</li> <li>• Three times weekly until ANC <math>\geq</math> patients established baseline</li> </ul>

\* Confirm all initial reports of ANC less than 1500/ $\mu$ L (ANC < 1000/ $\mu$ L for BEN patients) with a repeat ANC measurement within 24 hours

- Monitor ANC in any patient reporting a fever (temperature of 38.5°C or 101.3°F or greater) during the 2 weeks after discontinuation
- Monitor all patients carefully for the recurrence of psychotic symptoms and symptoms related to cholinergic rebound such as profuse sweating, headache, nausea, vomiting, and diarrhea
- For abrupt clozapine discontinuation for a reason unrelated to neutropenia, continuation of the existing ANC monitoring is recommended for General Population patients until their ANC is greater than or equal to 1500/ $\mu$ L and for Patients with BEN until their ANC is greater than or equal to 1000/ $\mu$ L or above their baseline

Refer to Section 2.4 of the clozapine Prescribing Information for further information

### Can a patient be rechallenged with clozapine?

Yes. For some patients who experience, or have experienced, moderate clozapine-related neutropenia (ANC less than 1000/ $\mu$ L) or severe clozapine-related neutropenia (ANC less than 500/ $\mu$ L), the risk of serious psychiatric illness from discontinuing clozapine may be greater than the risk of rechallenge. This may be relevant for patients with severe schizophrenic illness who have no treatment option other than clozapine.

In making the decision to rechallenge a patient, consider:

- a hematology consult
- the ANC ranges defined in the full Prescribing Information
- the patient's medical and psychiatric history
- a discussion with the patient and his or her caregiver about the benefits and risks of clozapine rechallenge
- the severity and characteristics of the neutropenic episode

Refer to Section 2.5 Re-initiation of Treatment in the clozapine Prescribing Information for more information on how to restart clozapine in patients who have discontinued clozapine.

### 3 Clozapine REMS Program Requirements for Prescribers

#### What is the role of prescribers in the Clozapine REMS Program?

**Step 1: Review the full Prescribing Information** for clozapine

**Step 2: Certify in the Clozapine REMS Program by:**

-   Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
-   Passing the *Knowledge Assessment for Healthcare Providers*
-   Completing the *Clozapine REMS Prescriber Enrollment Form*

**Step 3: Enroll every new patient** in the Clozapine REMS Program

**Step 4: Counsel each patient** (or their caregiver) about the risk of severe neutropenia

**Step 5: Check the ANC** for each patient according to the monitoring requirements

**Step 6: Report each ANC** for each patient to the Clozapine REMS Program

**Step 7: Provide authorization to continue treatment**, if necessary, through the Clozapine REMS Program when the patient's ANC results meet criteria for interruption of therapy and you decide to continue clozapine treatment.

Refer to the section titled "What is a treatment rationale?" on page 13 for more details on how to authorize a patient to continue treatment.



Prescribers may designate other healthcare providers or office staff to enroll patients and enter ANC results on the prescriber's behalf.



Find more information about designees at [www.clozapinerems.com](http://www.clozapinerems.com).

#### What do I tell my patients about clozapine?

Use the patient counseling tool titled *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers*. Review this information with patients or their caregivers as often as needed to ensure they understand the risk of neutropenia associated with clozapine and the importance of ANC monitoring. Refer to Section 17 of the clozapine Prescribing Information for additional important counseling messages for your clozapine patients.

You may choose not to provide *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers* to the patient or caregiver, if you determine that the patient's adherence to clozapine treatment will be negatively impacted by providing it.

## How do I enroll a patient?

You can enroll a patient one of two ways:

-  By signing into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com) and enrolling the patient online
-  By downloading a *Clozapine REMS Patient Enrollment Form* from the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com), and faxing the completed form to 844-404-8876.

### Complete a *Clozapine REMS Patient Enrollment Form* if:

- The patient has never been treated with clozapine before, or
- If you have never treated this patient with clozapine, regardless of the patient's history of clozapine treatment

## What if my patient has been treated with clozapine before?

If you have treated the patient with clozapine after **October 1, 2012** and that patient was registered in any of the individual clozapine patient registries, the patient's information is listed in the Clozapine REMS Program where you can access the patient's profile.

Patient information before **October 1, 2012** was not transferred into the Clozapine REMS Program, unless the patient was listed in the National Non-Rechallenge Master File (NNRMF) (see the following Section for a definition of the NNRMF).

If another prescriber has previously treated the patient with clozapine, you must enroll the patient by completing and submitting the *Clozapine REMS Patient Enrollment Form* to the Clozapine REMS Program (online or by fax) to access the patient's ANC history.

If you cannot find the patient, contact the REMS program at 844-267-8678 for assistance or re-enroll the patient.

If you would like to inquire about a patient's previous clozapine history before enrolling the patient, please call the Clozapine REMS Program at 844-267-8678 for assistance.

## How do I find out if my patient was listed in the National Non-Rechallenge Master File (NNRMF)?

**Patients were listed in the NNRMF if a patient had a WBC less than 2,000/ $\mu$ L or an ANC less than 1,000/ $\mu$ L.**



All patients who were listed in the NNRMF and all their lab data were transferred into the Clozapine REMS Program. These patients are identified with a red flag in the Clozapine REMS Program at [www.clozapinerems.com](http://www.clozapinerems.com).

To access patient information through the Clozapine REMS Program, you must enroll the patient. If you would like to inquire about a patient's previous clozapine history before enrolling the patient, please call the Clozapine REMS Program at 844-267-8678 for assistance.

## How do I report ANC results for my patients?

### For Outpatients:

Prescribers or their designees are responsible for reporting ANC for each prescription to the Clozapine REMS Program before clozapine can be dispensed.

### For Inpatients: If your patient is hospitalized...

Before dispensing clozapine to patients, pharmacists must be able to verify the ANC is current and acceptable for each patient, or the prescriber has authorized the continuation of clozapine treatment by providing a "treatment rationale."

While you are not required to submit ANCs to the Clozapine REMS Program before clozapine can be dispensed to an inpatient, you (or the certified pharmacy responsible for the patient in the hospital) must submit ANCs to the Clozapine REMS Program within 7 days of the blood draw.



While the patient is hospitalized, remember to monitor ANC according to the patient's ANC monitoring frequency.

### For both Inpatients and Outpatients:

Prescribers or their designees must report the ANC one of three ways:

- By signing in to the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
- By calling the Clozapine REMS Program contact center at 844-267-8678
- By faxing the ANC results to the Clozapine REMS Program at 844-404-8876

## How do I authorize continuation of clozapine when my patient's ANC is less than 1000/ $\mu$ L (General Population) or less than 500/ $\mu$ L (Patients with BEN)?

### What is a treatment rationale?

When a patient's ANC is less than 1000/ $\mu$ L (General Population) or less than 500/ $\mu$ L (Patients with BEN), a prescriber may authorize clozapine treatment to continue. This authorization, called a treatment rationale, requires the prescriber to confirm that the benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia.

### How do I report a treatment rationale?

- The Clozapine REMS Program will alert the prescriber if an ANC is provided that is below the recommended thresholds for a patient. Clozapine will not be dispensed to the patient unless the prescriber provides a treatment rationale to authorize continued treatment
- The Clozapine REMS Program will change the treatment status of a patient with a low ANC to "interrupted" or "discontinued", according to the recommendations in the Prescribing Information, found in **Table 1** above
- If the prescriber wishes to continue clozapine treatment, the prescriber must change the patient's treatment status to "active", and confirm that the benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia (i.e., the 'treatment rationale')

Prescribers must confirm treatment continuation one of two ways:

-  By signing into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
-  By faxing a signed *ANC Lab Reporting Form* to 844-404-8876 with a completed "Treatment Rationale" section

- After the prescriber provides the treatment rationale, the Clozapine REMS Program will issue a Predispose Authorization (PDA) which allows the outpatient pharmacy to dispense clozapine
- 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

### What if my clozapine patient is under hospice care?

For hospice patients (i.e., terminally ill patients with an estimated life expectancy of six months or less), the prescriber may reduce the ANC monitoring frequency to once every six months, after a discussion with the patient and his/her caregiver. Individual treatment decisions should weigh the importance of monitoring ANC in the context of the need to control psychiatric symptoms and the patient's terminal illness.

## 4 Clozapine REMS Program Requirements for Pharmacies

### What types of pharmacies must be certified?

All inpatient and outpatient pharmacies must certify in the Clozapine REMS Program to purchase and dispense clozapine. The requirements for outpatient pharmacies are different from the requirements for inpatient pharmacies. The different requirements are explained in Section “What are the requirements for different pharmacy types?”

The designated authorized representative for the pharmacy will complete the *Pharmacy Enrollment Form*. This form is to certify a single inpatient *or* a single outpatient pharmacy location.

- **For outpatient pharmacies**, the authorized representative must confirm if your pharmacy management system can or cannot support electronic communication with the Clozapine REMS Program to verify the Clozapine REMS Program safe use requirements.
- **For inpatient pharmacies**, a pharmacy management system that supports electronic communication with the Clozapine REMS Program is not needed.

The authorized representative for the pharmacy or pharmacies can certify the pharmacy online or by fax. Certifying multiple pharmacy locations must be done online.

## What is an authorized representative?

In general, an authorized representative for a pharmacy:

- coordinates the activities required in the Clozapine REMS Program
- establishes and implements processes and procedures to ensure compliance with the safe use conditions required in the Clozapine REMS Program

Specific duties of an authorized representative are noted in the section, "What is the role of pharmacies in the Clozapine REMS Program?"

For a pharmacy with a single location, the authorized representative may be a:

- Pharmacy Manager
- Staff Pharmacist

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:

- Director of Pharmacy Services
- Corporate Executive overseeing Pharmacy Service

## What is a Predispense Authorization (PDA)?

Before dispensing clozapine to an **outpatient**, the pharmacy must obtain a Predispense Authorization, or PDA, from the Clozapine REMS Program. A PDA is an electronic code that indicates the Clozapine REMS Program has verified:

- Patient is enrolled in the Clozapine REMS Program
- Prescriber is certified in the Clozapine REMS Program
- Pharmacy is certified in the Clozapine REMS Program
- ANC is current (reported within 7 days of the blood draw)
- ANC is within an acceptable range, or the prescriber provided a treatment rationale



Once a PDA is obtained, the outpatient pharmacy can dispense clozapine to the patient.

### Obtain a PDA in one of three ways:

-  By enabling your pharmacy management system to support electronic communication with the Clozapine REMS Program
-  By signing into Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
-  By calling the Clozapine REMS Program contact center at 844-267-8678

Inpatient pharmacies are not required to obtain a PDA before dispensing clozapine.

### What is the role of pharmacies in the Clozapine REMS Program?

Designate an authorized representative for your pharmacy. The authorized representative for every pharmacy must:

**Step 1: Review the full Prescribing Information** for clozapine

**Step 2: Certify in the Clozapine REMS Program by:**

-   Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
-   Passing the *Knowledge Assessment for Healthcare Providers*
-   Completing the *Clozapine REMS Pharmacy Enrollment Form*

**Step 3: Ensure training for all relevant staff** involved in the dispensing of clozapine on the Clozapine REMS Program requirements

**Step 4: Put processes and procedures in place to verify:**

- The prescriber is certified in the Clozapine REMS Program prior to dispensing clozapine
- The patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine
- The ANC is current (reported within 7 days of the blood draw) and acceptable according to the patient's monitoring schedule, or the prescriber has provided a treatment rationale to authorize the continuation of clozapine treatment

**Step 5: Renew certification** in the Clozapine REMS Program every 2 years from initial enrollment

### How do I verify the patient is authorized to receive clozapine?

How you verify the patient is authorized to receive clozapine depends on your pharmacy type and your pharmacy's telecommunication capabilities.

## Outpatient Pharmacies WITH Electronic Telecommunication Verification

### Certification

As part of certification in the Clozapine REMS Program, an authorized representative for the pharmacy must:

- Ensure the pharmacy enables its pharmacy management system to support electronic communication with the Clozapine REMS Program
- Run the standardized verification test transactions to verify the system connectivity

### Dispensing

Before you dispense clozapine to each patient, you must:

- Process all clozapine prescriptions through the pharmacy management system to obtain a PDA
- Obtain a PDA. The PDA indicates that:
  - the prescriber is certified,
  - the patient is enrolled, and
  - the ANC for the patient is current and acceptable according to the patient's monitoring schedule, or the prescriber has authorized the continuation of clozapine treatment

Once a PDA is obtained, you can dispense clozapine to the patient

- You do not need to document the PDA on the prescription or in your pharmacy management system



#### Dispensing Information for **All Pharmacies**

- The amount of clozapine that can be dispensed depends on when the patient's next blood draw is, according to the monitoring requirements
- Pharmacies should dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber
- If you do not receive a PDA, you will receive a message explaining why you are not authorized to dispense clozapine to the patient

## Outpatient Pharmacies WITHOUT Electronic Telecommunication Verification

### Certification

As part of certification in the Clozapine REMS Program, the authorized representative for your pharmacy must implement processes to comply with program requirements, which include how your pharmacy will ensure a PDA is obtained for each clozapine prescription dispensed.

### Dispensing

Obtain a PDA in one of two ways:

-  By signing into Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
-  By calling the Clozapine REMS Program contact center at 844-267-8678

To obtain a PDA, you must provide the following information to the Clozapine REMS Program:

- Patient Name
- Patient Date of Birth
- Prescriber
- Dispense Date
- NDC
- Days' Supply
- Quantity

The Clozapine REMS Program will verify the following for you and issue a PDA:

- The prescriber is certified in the Clozapine REMS Program
- The patient is enrolled in the Clozapine REMS Program
- The ANC is current and acceptable according to the patient's monitoring schedule, or the prescriber has authorized the continuation of clozapine treatment

Once a PDA is obtained, you can dispense clozapine to the patient. You do not need to document the PDA on the prescription or in your pharmacy management system. If you do not receive a PDA, the Clozapine REMS Program will explain why you are not authorized to dispense clozapine to the patient.

## Inpatient Pharmacies

### Certification

As part of certification in the Clozapine REMS Program, the authorized representative for your pharmacy must implement processes to comply with program requirements.

### Dispensing

Obtaining a PDA is not required in an inpatient setting.

**Before you dispense clozapine for the first time** to each inpatient, the inpatient pharmacist must:

**Step 1: Access the Clozapine REMS Program** by:

-  Signing into the website at [www.clozapinerems.com](http://www.clozapinerems.com), or
-  Calling the Clozapine REMS Program contact center at 844-267-8678

**Step 2: Provide the following information:**

- Pharmacy Location Information
- Patient Name
- Patient Date of Birth
- Prescriber
- Dispense Date
- NDC
- Days' Supply
- Quantity

**Step 3: Verify patient eligibility** to receive clozapine by:

- Verifying the prescriber is certified in the Clozapine REMS Program
- Verifying the patient is enrolled in the Clozapine REMS Program

**Step 4: Verify that the ANC is current and acceptable** according to the patient's ANC monitoring schedule, or the prescriber has authorized the continuation of clozapine treatment by:

-  Signing into the website at [www.clozapinerems.com](http://www.clozapinerems.com),
-  Calling the Clozapine REMS Program contact center at 844-267-8678, or
-  Reviewing the patient's medical record in their hospital's medical record system

**Throughout the patient's hospitalization:** In accordance with the patient's ANC monitoring schedule, continue to verify that the ANC is current and acceptable (or the prescriber has authorized the continuation of clozapine treatment) using one of the ways listed above.

## **5 Reporting Adverse Events Associated with Clozapine**

Report suspected adverse events directly to the Clozapine REMS Program at 844-267-8678. You also may report adverse event information to the FDA MedWatch Reporting System by telephone at (800) FDA-1088 or by mail using Form 3500A, available at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## **6 Clozapine REMS Program Information and Resources**

Additional Clozapine REMS Program information and resources are available online at [www.clozapinerems.com](http://www.clozapinerems.com) or by contacting the Clozapine REMS Program contact center at 844-267-8678.

Please select the best answer for each of the following questions. All questions must be answered correctly to become certified:

**Question 1**

All clozapine products are only available under the shared Clozapine REMS Program.

- A. True
- B. False

**Question 2**

Clozapine is associated with severe neutropenia.

- A. True
- B. False

**Question 3**

Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ $\mu$ L
- B. An absolute neutrophil count (ANC) less than 1000/ $\mu$ L
- C. An absolute neutrophil count (ANC) less than 500/ $\mu$ L
- D. None of the above

**Question 4**

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ $\mu$ L for a patient with documented Benign Ethnic Neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ $\mu$ L for a patient who is part of the General Population (i.e., the patient does not have BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

**Question 5**

Before clozapine is dispensed to a patient, a prescriber must:

- A. Determine if the patient has Benign Ethnic Neutropenia (BEN)
- B. Enroll the patient in the 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 provide it to the Clozapine REMS Program
- F. All of the above

If you plan on faxing this Knowledge Assessment to the Program please provide your NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Name: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

**Question 6**

For outpatients, prescribers must report the ANC to the shared Clozapine REMS Program before the patient can be dispensed clozapine.

- A. True
- B. False

**Question 7**

Before clozapine can be dispensed, a pharmacist must:

- A. Verify the prescriber is certified in the shared Clozapine REMS Program
- B. Verify the patient is enrolled in the shared Clozapine REMS Program
- C. For outpatients - verify the ANC is acceptable or verify the prescriber authorized continuing treatment if the ANC is abnormal by obtaining a pre-dispense authorization from the Clozapine REMS Program
- D. For inpatients - verify the ANC is acceptable or verify the prescriber authorized continuing treatment if the ANC is abnormal by accessing the Clozapine REMS Program or by accessing the ANC through the hospital's medical record system
- E. All of the above

**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

**Question 9**

Regarding patients with benign ethnic neutropenia (BEN), which of the following statements are true?

- A. Patients with BEN have a different clozapine treatment algorithm and monitoring requirements
- B. Patient 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

If you plan on faxing this Knowledge Assessment to the Program please provide your NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Name: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

## 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

## Question 11

If a patient's ANC indicates mild neutropenia, which of the following statements is true?

- A. ANC monitoring should be conducted three times weekly until  $ANC \geq 1500/\mu L$  if the patient is part of the General Population (i.e., if the patient does not have Benign Ethnic Neutropenia (BEN))
- B. Mild neutropenia is within the normal range for a patient with BEN
- C. If the patient has 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

## 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 Benign Ethnic Neutropenia (BEN)
- B. If the patient is part of the General Population (i.e., if the patient does not have BEN), interrupt therapy and conduct ANC monitoring: daily until  $ANC \geq 1000/\mu L$ ; three times weekly until  $ANC \geq 1500/\mu L$ ; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the General Population or has BEN
- D. None of the above

## 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 Benign Ethnic Neutropenia (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 BEN), interrupt treatment and conduct ANC monitoring: daily until  $ANC \geq 1000/\mu L$ ; three times weekly until  $ANC \geq 1500/\mu L$
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
- D. All of the above

If you plan on faxing this Knowledge Assessment to the Program please provide your NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Name: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

# CLOZAPINE REMS

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

## A Guide for Patients and Caregivers:

What You Need to Know about Clozapine  
and Neutropenia

## What is clozapine?

Clozapine is a prescription medicine to treat people with schizophrenia who have not responded to other medicines. Clozapine may also reduce the risk of suicidal behavior.

## What is the most serious risk information about clozapine treatment?

**Clozapine can cause severe neutropenia.** Neutropenia is a blood disorder that occurs when a certain type of white blood cells called neutrophils are not made or not enough of them are made. This makes it harder for your body to fight infections.

Before you can start clozapine and during treatment, you must have regular blood tests to measure the number of neutrophils you have in your blood. This test is called absolute neutrophil count (ANC). If the number of neutrophils, or ANC, is too low, you may have to stop clozapine. Your doctor will decide if or when it is safe to restart clozapine.

This is not the only serious risk associated with clozapine treatment. Talk to your doctor about the other serious risks.

## What are the symptoms of neutropenia?

You might not have any symptoms at all. Getting your blood tested to measure the number of neutrophils is the only way to check for neutropenia. This helps your doctor know if you are more likely to get an infection.



### **If you have any of these symptoms, talk to your doctor right away**

- Infection, including skin, throat, urinary tract, vaginal, pneumonia, or any other infection
- Fever or chills
- Sores or ulcers inside your mouth, gums, or on your skin
- Wounds that take a long time to heal
- Feel like you have the flu
- Pain or burning while urinating
- Unusual vaginal discharge or itching
- Abdominal pain
- Sores or pain in or around your rectal area
- Feel extremely weak or tired

## What can I do to help reduce the risk of developing neutropenia?

### **Three important things you can do:**

1. Have your blood tested as instructed by your doctor
2. Tell your doctor about all the medicines you are taking (prescription and over-the-counter), and if you start a new medicine
3. Tell your doctor right away if you get a fever or feel sick

## What is the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program?

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.

## What are the Clozapine REMS Program requirements for me?

### **To receive clozapine:**

1. **Review this Guide** with your doctor, pharmacist, or nurse
2. Ask questions! **Make sure you understand** what you need to do to take part in the Clozapine REMS Program
3. **Get your blood tested** as directed by your doctor  
You must get your blood tested before you can receive clozapine from your pharmacy
4. **Pick up your clozapine prescription** from a pharmacy that is part of the Clozapine REMS Program. Your doctor will help you find a pharmacy that participates in the Clozapine REMS Program
5. **Tell your doctor right away** if you suffer any flu-like illness or fever while taking clozapine

## What are the blood testing requirements for clozapine?

### Get your Blood Tested

- Your doctor will give you an order to have blood tests done
- You will need to get your blood tested on the following schedule or as directed by your doctor:
  - Weekly blood tests for the first 6 months you are taking clozapine
  - Every 2 weeks for the next 6 months if your ANC stays normal
  - Every 4 weeks after the first year if your ANC stays normal

### Monitoring Results

- If your ANC is too low, your doctor will schedule blood tests more frequently

### Stay on Clozapine

- The Clozapine REMS Program will keep track of your blood test results so your doctor and pharmacist know if it is safe to fill your clozapine prescription

### No Blood, No Drug

- *Remember: You must get your blood tested before you can receive clozapine from your pharmacy!*

## Where can I get more information about clozapine?

If you would like more information, talk to your doctor or visit [www.clozapinerems.com](http://www.clozapinerems.com).

Report any side effects directly to the Clozapine REMS Program at [844-267-8678](tel:844-267-8678).

You can also report negative side effects to the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call [800-FDA-1088](tel:800-FDA-1088).

**CLOZAPINE REMS**

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# **Clozapine REMS Program Website Screen Captures**

**September 2015**

# CLOZAPINE REMS

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## Table of Contents

1.	Static Pages.....	9
1.1	Home Page.....	9
1.2	Site Guide – Prescriber Tab.....	10
1.3	Site Guide – Pharmacy Tab.....	11
1.4	Site Guide – Patient Tab.....	12
1.5	Site Guide – Designee Tab .....	13
1.6	Site Guide – Pharmacy Staff Tab .....	14
1.7	Prescriber Certification .....	15
1.8	Prescriber Designee Certification .....	16
1.9	Pharmacy Certification .....	17
1.10	Pharmacy Staff Enrollment .....	18
1.11	Patient Information.....	19
1.12	Program Materials.....	20
1.13	Prescribing Information.....	22
1.14	Certification Lookup .....	23
1.15	Certification Lookup Results.....	24
1.16	Site Map .....	25
1.17	FAQs.....	26
1.18	Contact Us .....	27
2.	User Identification and Record Search.....	28
2.1	User Identification .....	28
2.2	Previous Registry User Prescriber.....	30
2.3	Previous Registry User Prescriber Search with Results.....	31
2.4	Previous Registry User Prescriber Designee Search .....	32
2.5	Previous Registry User Prescriber Designee Search with Results .....	33
2.6	Previous Registry User Pharmacy Search .....	34
2.7	Previous Registry User Pharmacy Search with Results. ....	35
2.8	Previous Registry User Pharmacy Staff Search .....	36
2.9	Previous Registry User Pharmacy Staff Search with Results .....	37
2.10	Previous Registry User Chain Pharmacy Headquarters.....	38
2.11	Previous Registry User Chain Pharmacy Headquarters with Results.....	39

# CLOZAPINE REMS

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

2.12	Phone/Fax User Prescriber Search.....	40
2.13	Phone/Fax User Prescriber Search with Results .....	41
2.14	Phone/Fax User Prescriber Designee Search .....	42
2.15	Phone/Fax User Prescriber Designee Search with Results.....	43
2.16	Phone/Fax User Pharmacy Search .....	44
2.17	Phone/Fax User Pharmacy Search with Results.....	45
2.18	Phone/Fax User Chain Pharmacy Headquarters .....	46
2.19	Phone/Fax User Chain Pharmacy Headquarters with Results .....	47
3.	Web Account .....	48
3.1	Create an Account.....	48
3.2	Account Verification.....	49
3.3	Account Confirmation.....	50

# CLOZAPINE REMS

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

4.	Prescriber Certification .....	51
4.1	Prescriber Intake.....	51
4.2	Prescriber Education Program .....	52
4.3	Prescriber Education Confirmation.....	53
4.4	Prescriber Intake Review .....	54
4.5	Prescriber Attestation .....	55
4.6	Prescriber Confirmation .....	56
5.	Prescriber Designee Certification. ....	57
5.1	Prescriber Designee Intake .....	57
5.2	Prescriber Designee Education Program Page 1 .....	58
5.3	Prescriber Designee Education Program Page 2.....	59
5.4	Prescriber Designee Education Confirmation .....	60
5.5	Prescriber Designee KA .....	61
5.6	Prescriber Designee KA Confirmation – Success.....	62
5.7	Prescriber Designee KA Confirmation – Not Successful.....	63
5.8	Prescriber Designee Intake Review .....	64
5.9	Prescriber Designee Attestation .....	65
5.10	Prescriber Designee Confirmation.....	66
6.	Pharmacy Certification .....	67
6.1	Role Selection.....	67
6.2	Role Selection Confirmation – Inpatient Pharmacy .....	68
6.3	Role Selection Confirmation – Outpatient Pharmacy .....	69
6.4	Role Selection Confirmation – Chain Pharmacy Headquarters .....	70
6.5	Authorized Representative Intake .....	71
6.6	Authorized Representative Confirmation .....	72
6.7	Pharmacy Intake.....	73
6.8	Pharmacy Education Program .....	74
6.9	Pharmacy Education Confirmation.....	75
6.10	Pharmacy Attestation – Inpatient Pharmacy .....	76
6.11	Pharmacy Attestation – Outpatient Pharmacy .....	77
6.12	Pharmacy Attestation – Outpatient Pharmacy with Adjudication.....	78

# CLOZAPINE REMS

The Single Shared System for Clozapine  
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6.13	Pharmacy Confirmation .....	79
6.14	Pharmacy Test Transactions .....	80
7.	Chain Pharmacy Certification .....	81
7.1	Chain Headquarters Identification .....	81
7.2	Chain Headquarters Identification Results.....	82
7.3	Chain Authorized Representative Intake .....	83
7.4	Chain Pharmacy Education Program .....	84
7.5	Chain Pharmacy Education Confirmation .....	85
7.6	Chain Authorized Representative Confirmation.....	84
7.7	Chain Pharmacy Headquarters Intake.....	85
7.8	Chain Pharmacy Headquarters Attestation.....	86
7.9	Pharmacy Test Transactions .....	87
7.10	Chain Pharmacy Store Intake .....	88
7.11	Chain Pharmacy Store Confirmation .....	89
8.	Pharmacy Staff Enrollment.....	90
8.1	Pharmacy Search .....	91
8.2	Pharmacy Search Results .....	92
8.3	Pharmacy Staff Intake .....	93
8.4	Pharmacy Staff Attestation .....	94
8.5	Pharmacy Staff Confirmation.....	95
9.	Knowledge Assessment .....	96
9.1	Knowledge Assessment Landing Page .....	97
9.2	KA Question 1 .....	98
9.3	KA Question 2 .....	99
9.4	KA Question 3 .....	100
9.5	KA Question 4 .....	101
9.6	KA Question 5 .....	102
9.7	KA Question 6 .....	103
9.8	KA Question 7 .....	104
9.9	KA Question 8 .....	105
9.10	KA Question 9 .....	106
9.11	KA Question 10.....	107
9.12	KA Question 11.....	108

# CLOZAPINE REMS

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

9.13	KA Question 12 .....	109
9.14	KA Question 13 .....	110
9.15	KA Confirmation - Success .....	111
9.16	KA Confirmation – Not Successful .....	112
10.	Patient Enrollment.....	113
10.1	Patient Intake.....	113
10.2	Patient Lab Intake .....	114
10.3	Patient Lab Intake with Treatment Rationale .....	115
10.4	ANC Calculator .....	116
11.	Stakeholder Profiles .....	117
11.1	Prescriber Profile.....	118
11.2	Prescriber Designee Profile.....	119
11.3	Authorized Representative Profile.....	120
11.4	Chain Authorized Representative Profile .....	121
11.5	Chain Headquarters Profile.....	122
11.6	Pharmacy Staff Profile .....	123
12.	My Account.....	124
12.1	Change Username.....	124
12.2	Change Username Confirmation .....	125
12.3	Change Password .....	126
12.4	Change Password Confirmation .....	127
12.5	Change Email Address.....	128
12.6	Change Email Address Confirmation .....	129
13.	Patient Groups.....	130
13.1	Manage Groups. ....	130
13.2	Add Group.....	131
13.3	Change Group Name .....	132
13.4	Remove Group.....	133
13.5	Remove Group Warning .....	134
13.6	Reassign Patients.....	135

# CLOZAPINE REMS

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

14.	Dashboard.....	136
14.1	Dashboard Alerts and Notifications.....	136
14.1.1	Dashboard Alerts.....	136
14.1.2	Dashboard Notifications.....	137
14.2	Prescriber Dashboard.....	138
14.2.1	Prescriber Dashboard Patient Tab Collapsed.....	138
14.2.2	Prescriber Dashboard Patient Tab Expanded.....	139
14.2.3	Definitions of Terms Pop-up.....	141
14.2.4	Add Lab, Change Treatment Status, Change Monitoring Frequency, and Change Treatment Rationale for Prescribers.....	142
14.2.5	View Patient History Lab History Tab.....	143
14.2.6	View Patient History Treatment Status Tab.....	144
14.2.7	View Patient History Monitoring Frequency Tab.....	145
14.2.8	View Patient Profile.....	146
14.2.9	Eligibility Check.....	147
14.2.10	Prescriber Dashboard Designees Tab.....	149
14.2.11	Add Designee with Results.....	150
14.2.12	Remove Designee.....	151
14.2.13	Approve Designee.....	152
14.3	Prescriber Designee Dashboard.....	153
14.3.1	Prescriber Designee Dashboard Patient Tab Collapsed.....	153
14.3.2	Prescriber Designee Dashboard Patient Tab Expanded.....	154
14.3.1	Definitions of Terms Pop-up.....	156
14.3.2	Add Lab and Change Treatment Status for Prescriber Designees.....	157
14.3.3	View Patient History Lab History Tab.....	158
14.3.4	View Patient History Treatment Status Tab.....	159
14.3.5	View Patient History Monitoring Frequency Tab.....	160
14.3.6	View Patient Profile.....	161
14.3.7	Eligibility Check.....	162
14.3.8	Prescriber Designee Dashboard Prescribers Tab.....	163
14.3.9	Associate to Prescriber.....	164
14.3.10	Remove Designee Relationship.....	165

# CLOZAPINE REMS

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

14.3.11	Cancel Designee Request .....	166
14.4	Pharmacy Dashboard .....	167
14.4.1	Pharmacy Dashboard Pharmacies Tab.....	167
14.4.2	Add Lab and Eligibility Check.....	169
14.4.3	Eligibility Check Result – Unsuccessful .....	170
14.4.4	Add Lab and Predispense Authorization.....	171
14.4.5	Predispense Authorization Result – Successful .....	172
14.4.6	View Pharmacy Profile .....	173
14.4.7	Remove Pharmacy.....	174
14.4.8	Pharmacy Dashboard Pharmacy Staff Tab .....	175
14.4.9	Remove Pharmacy Staff.....	176
14.5	Chain Pharmacy Dashboard .....	177
14.5.1	Chain Pharmacy Dashboard Pharmacies Tab .....	177
14.5.2	View Pharmacy Profile .....	179
14.5.3	Remove Pharmacy .....	180
14.5.4	Chain Pharmacy Dashboard Pharmacy Staff Tab .....	181
14.5.5	Remove Pharmacy Staff.....	182
14.6	Pharmacy Staff Dashboard.....	183
14.6.1	Pharmacy Staff Dashboard Pharmacies Tab.....	183
14.6.2	Associate to Pharmacy.....	184
14.6.3	Add Lab and Eligibility Check .....	185
14.6.4	Eligibility Check Result – Unsuccessful .....	186
14.6.5	Add Lab and Predispense Authorization.....	187
14.6.6	Predispense Authorization Result – Successful .....	188

# CLOZAPINE REMS

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## 1. Static Pages

### 1.1 Home Page

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What's New »

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

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

#### Prescriber

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

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

[Start Prescriber Certification](#)

#### Pharmacy

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

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

[Start Pharmacy Certification](#)

### What is the Clozapine REMS Program?

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L). 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 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.**

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## 1.2 Site Guide – Prescriber Tab



### Site Guide

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

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

**Prescriber** Pharmacy Patient Designee Pharmacy Staff

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

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

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

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

[Learn More](#)

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# CLOZAPINE REMS

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## 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 **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

Prescriber **Pharmacy** Patient Designee Pharmacy Staff

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 into 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 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.

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# CLOZAPINE REMS

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## 1.4 Site Guide – Patient Tab



### Site Guide

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

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

Prescriber   Pharmacy   **Patient**   Designee   Pharmacy Staff

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

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

[Learn More](#)

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## 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 **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

PrescriberPharmacyPatientDesigneePharmacy Staff

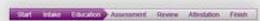
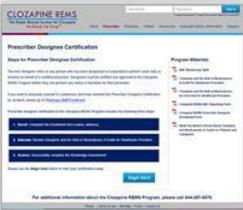
Prescriber Designees can learn more about the certification process by using the **Learn More** button below, which will navigate the prescriber designee to the certification landing page or by visiting the **Prescriber** link at the top of the page.

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

Once signed into 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.

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# CLOZAPINE REMS

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## 1.6 Site Guide – Pharmacy Staff Tab



### Site Guide

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

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

Prescriber Pharmacy Patient Designee **Pharmacy Staff**

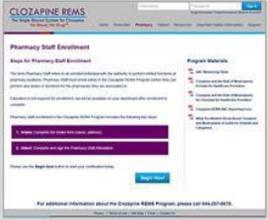
Pharmacy Staff can learn more about the enrollment process by using the **Learn More** button below which will navigate the pharmacy staff to the enrollment landing page or by visiting the **Pharmacy** link at the top of the page.

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

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

[Learn More](#)



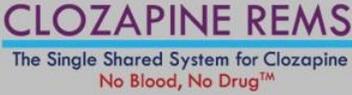
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## 1.7 Prescriber Certification



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### Prescriber Certification

#### Steps for Prescriber Certification

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

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

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

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

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

**3. Assess:** Successfully complete the Knowledge Assessment

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

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

[Begin Now!](#)

#### Program Materials

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

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

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## 1.8 Prescriber Designee Certification

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

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

[Begin Now!](#)

#### Program Materials

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

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

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## 1.9 Pharmacy Certification

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### 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 PDA from the REMS website, to enter 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 three steps:

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

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

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

[Begin Now!](#)

#### Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [Clozapine REMS Chain Pharmacy Enrollment Form](#)
-  [Clozapine REMS Pharmacy Enrollment Form](#)
-  [What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers](#)

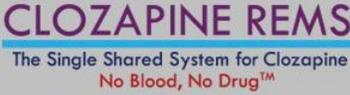
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## 1.10 Pharmacy Staff Enrollment



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### 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 pre-dispense authorization (PDA) before dispensing each clozapine prescription. Pharmacy Staff who are enrolled can obtain a PDA by calling the Clozapine REMS 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 website.

**For Inpatient Pharmacies:** Pharmacy Staff must enroll to perform eligibility checks through the Clozapine REMS website or the Clozapine REMS 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 enrollment today.

**Begin Now!**

#### Program Materials

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

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## 1.11 Patient Information

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### 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 *What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers* program material and talk with their prescriber if they have questions or concerns about using clozapine.

### Program Materials



**What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers**

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

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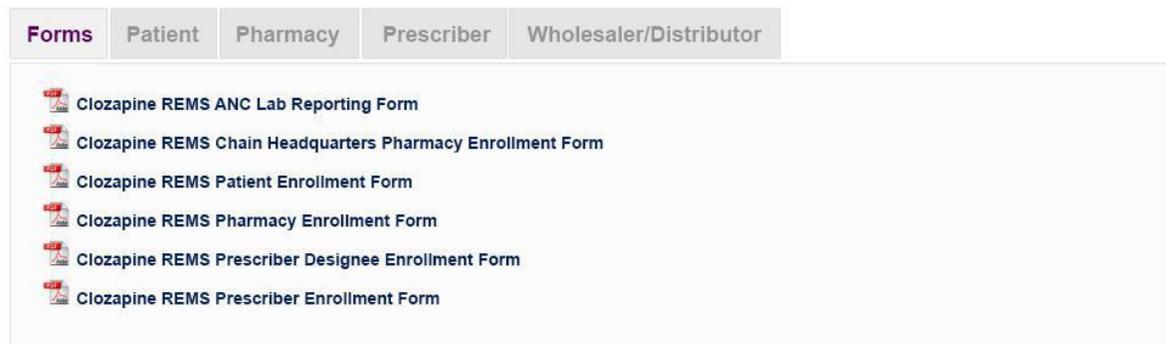
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## 1.12 Program Materials



### Program Materials



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

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Resources included under the other tabs are listed below:

- Patient
  - What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers
  - Clozapine REMS Patient Enrollment Form
  - Clozapine REMS ANC Lab Reporting Form
- Pharmacy
  - What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers
  - Dear Healthcare Provider Letter
  - Clozapine REMS Pharmacy Enrollment Form
  - Clozapine REMS Chain Headquarters Pharmacy Enrollment Form
  - Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers
  - Clozapine REMS Patient Enrollment Form
  - Clozapine REMS ANC Lab Reporting Form
  - Important Safety Information

# CLOZAPINE REMS

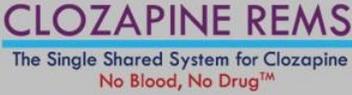
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- ANC Calculator
  - ANC Monitoring Table
- Prescriber
  - What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers
  - Dear Healthcare Provider Letter
  - Clozapine REMS Prescriber Enrollment Form
  - Clozapine REMS Prescriber Designee Enrollment Form
  - Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers
  - Clozapine REMS Patient Enrollment Form
  - Clozapine REMS ANC Lab Reporting Form
  - Important Safety Information
  - ANC Calculator
  - ANC Monitoring Table
- Wholesaler/Distributor
  - Contact the Clozapine REMS Program by sending an email to [info@clozapinedistributor.com](mailto:info@clozapinedistributor.com)

# CLOZAPINE REMS

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## 1.13 Prescribing Information



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### Prescribing Information

Products covered under the Clozapine REMS Program

Brand Name Products			
Trade Name	Generic Name	Company	Link

Generic Products			
Drug Name	Generic Name	Company	Link

The CPMG attests that the table above will only include products listed in the link titled "List of approved application numbers and sponsors" on the FDA Approved REMS Website.

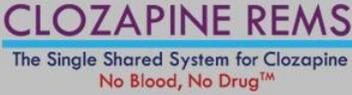
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## 1.14 Certification Lookup



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### Certification Lookup

To search for a certified pharmacy, please complete at least one field below and press **Search**. Search results include contact information for pharmacies that are certified in the Clozapine REMS Program.

Pharmacy Information (at least one identifier is required):

or  or  or  or

or  and

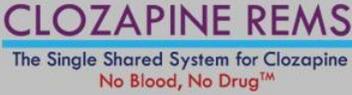
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## 1.15 Certification Lookup Results



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### Certification Lookup

To search for a certified pharmacy, please complete at least one field below and press **Search**. Search results include contact information for pharmacies that are certified in the Clozapine REMS Program.

Pharmacy Information (at least one identifier is required):

or  or  or  or

or  and

Pharmacy Name	Certification ID	Pharmacy Address	Pharmacy Phone
Hogan Rx	FAC123456789	1234 W Scottsdale Rd. Scottsdale, AZ 85411	555-555-5555

Showing 1 of 1 entries

 1 

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# CLOZAPINE REMS

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## 1.16 Site Map

**CLOZAPINE REMS**  
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### Site Map

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

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## 1.17FAQs

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### Frequently Asked Questions (FAQs)

- General**
- Patient
- Pharmacy
- Prescriber
- Technical Support
- Wholesaler/Distributor

- ▶ **What is the Clozapine REMS Program?**
- ▶ **What are the goals of the Clozapine REMS Program?**
- ▶ **What do I do if I am a user of one of the previous individual registries?**
- ▼ **How do I certify in the program?**

Stakeholders can be certified online through the Clozapine REMS Program website or by submitting the appropriate Prescriber, Pharmacy, or Designee Enrollment form via fax to the program contact center at 844-404-8876. To complete certification on the program website, from the Home page you will use the "Get Started" button. You will be taken to the applicable stakeholder certification page, which will explain what is expected and required of you from the Clozapine REMS Program. From that certification page, you can use the "Begin Now" button to start your certification in the program.
- ▶ **Who is a designee?**
- ▶ **How do I enroll my patient?**
- ▶ **What is the National Non-Rechallenge Master File (NNRMF)?**
- ▶ **How do I report patient lab ANC values?**
- ▶ **How do I report an adverse event, product complaint, or need medical information about clozapine?**
- ▶ **How can I find additional forms and program materials?**
- ▶ **How do I view and update my program profile?**
- ▶ **Will the program send me notices if my patient experiences a low ANC count or substantial drop?**
- ▶ **How do I contact the program?**

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

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## 1.18 Contact Us

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### Contact Us

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

**Phone Number**  
844-267-8678

**Fax Number**  
844-404-8876

**Mailing Address**  
Clozapine REMS Program  
PO BOX 29058  
PHOENIX AZ 85038-9058

#### Program Manufacturers

Company	Phone Number

The CPMG attests that the table above will only include products listed in the link titled "List of approved application numbers and sponsors" on the FDA Approved REMS Website."

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## 2. User Identification and Record Search

### 2.1 User Identification

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### User Identification

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

What type of user are you?

Please choose your program role:

[Next](#)

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

1 - The options for type of user are New User, Previous Registry User, and Phone/Fax User. The tooltip next to the field will include a definition of each for the user, which are also below.

- New User – Users who are new to clozapine and are not part of a previous clozapine registry.
- Previous Registry User – Users who are part of a previous clozapine registry
  - These users will search for their records and start the enrollment or certification process.
- Phone/Fax User – Users who submitted an enrollment form through the contact center via fax and have received an enrollment or certification ID.

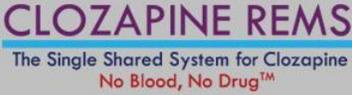
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- When the system locates the user's record and creates a web account, the user's web account and their enrollment or certification record are linked.

2 – The options for role are Prescriber, Authorized Representative for Pharmacy, Prescriber Designee, and Pharmacy Staff

## 2.2 Previous Registry User Prescriber



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### Previous Registry User

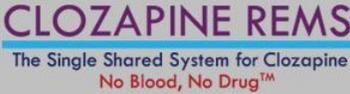
If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	and	<input type="text" value="DEA"/>	or	<input type="text" value="NPI"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>			

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## 2.3 Previous Registry User Prescriber Search with Results



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### Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

<input type="text" value="Summer"/>	<input type="text" value="Hogan"/>	and	<input type="text" value="AB12345789"/>	or	<input type="text" value="NPI"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>			

[Search](#)

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

First Name	Last Name	Phone	DEA	NPI
Summer	Hogan	555-555-5555	AB1234567	

Showing 1 of 1 entries

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

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## 2.4 Previous Registry User Prescriber Designee Search



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### Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

**Prescriber Information**

**Designee Information**

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## 2.5 Previous Registry User Prescriber Designee Search with Results



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### Previous Registry User

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

**Prescriber Information**

**Designee Information**

[Search](#)

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

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

Showing 1 of 1 entries 1 » 10

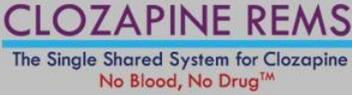
[New User](#) [Submit](#)

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

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## 2.6 Previous Registry User Pharmacy Search



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### Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="Zip Code"/>	and	<input type="text" value="DEA"/>	or	<input type="text" value="NPI"/>	or	<input type="text" value="NCPDP"/>
---------------------------------------	-----	----------------------------------	----	----------------------------------	----	------------------------------------

Authorized Representative Information

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

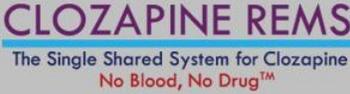
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## 2.7 Previous Registry User Pharmacy Search with Results



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### Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. 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):

and  or  or

Authorized Representative Information

[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](#)

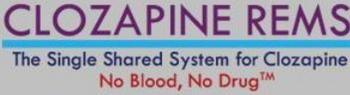
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## 2.8 Previous Registry User Pharmacy Staff Search



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### Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. 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):

and  or  or

Pharmacy Staff Information

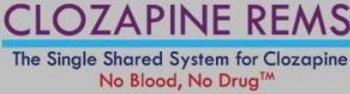
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## 2.9 Previous Registry User Pharmacy Staff Search with Results



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### Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

**Pharmacy Information**

**Designee Information**

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

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

Showing 1 of 1 entries

1 » 10 ▾

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## 2.10 Previous Registry User Chain Pharmacy Headquarters



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### Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. 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):

**Authorized Representative Information**

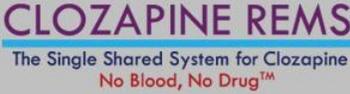
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## 2.11 Previous Registry User Chain Pharmacy Headquarters with Results



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### Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. 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):

Authorized Representative Information

[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 certification process in the Clozapine REMS Program.

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

Showing 1 of 1 entries 1 » 10

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

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## 2.12 Phone/Fax User Prescriber Search

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### Phone/Fax User

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

At least one identifier below is required:

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

[Search](#)

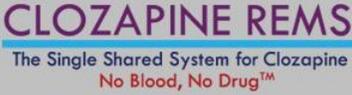
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## 2.13 Phone/Fax User Prescriber Search with Results



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### Phone/Fax User

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

At least one identifier below is required:

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

[Search](#)

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

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

Showing 1 of 1 entries

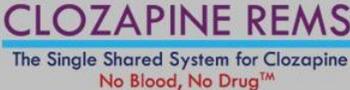
[New User](#) [Submit](#)

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

# CLOZAPINE REMS

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## 2.14 Phone/Fax User Prescriber Designee Search



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### Phone/Fax User

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

**Prescriber Information**

**Designee Information**

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

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## 2.15 Phone/Fax User Prescriber Designee Search with Results



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### Phone/Fax User

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

**Prescriber Information**

**Designee Information**

[Search](#)

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

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

Showing 1 of 1 entries

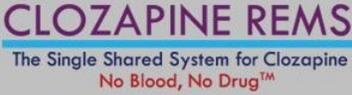
[New User](#) [Submit](#)

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

# CLOZAPINE REMS

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## 2.16 Phone/Fax User Pharmacy Search



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### Phone/Fax User

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

Pharmacy Information (at least one identifier is required):

<input type="text" value="Zip Code"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="NCPDP"/>
---------------------------------------	-----	----------------------------------	----------------------------------	------------------------------------

Authorized Representative Information

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

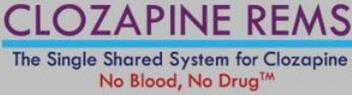
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# CLOZAPINE REMS

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## 2.17 Phone/Fax User Pharmacy Search with Results



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### Phone/Fax User

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

Pharmacy Information (at least one identifier is required):

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

Authorized Representative Information

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

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

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

Showing 1 of 1 entries

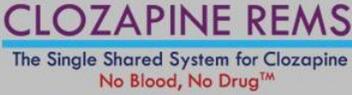
For additional information about the Clozapine REMS Program, please call 844-267-8678.

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# CLOZAPINE REMS

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## 2.18 Phone/Fax User Chain Pharmacy Headquarters



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### Phone/Fax User

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

**Pharmacy Information**

**Authorized Representative Information**

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

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## 2.19 Phone/Fax User Chain Pharmacy Headquarters with Results



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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

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### Phone/Fax User

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

Pharmacy Information

Authorized Representative Information

[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 enrollment process in the Clozapine REMS Program.

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

Showing 1 of 1 entries

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

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

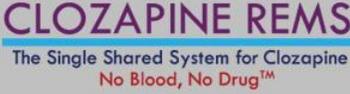
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# CLOZAPINE REMS

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## 3. Web Account

### 3.1 Create an Account



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#### Create an Account

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

#### My Information

Account Type

First Name

Last Name

Email Address

Confirm Email Address

Phone Number

#### Sign in

Username

Use Email Address as Username

Password

Confirm Password

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

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## 3.2 Account Verification

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Username  Password  [Sign in](#)

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

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Account Verification



A verification email has been sent to [remsprogram@gmail.com](mailto: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](mailto:remsprogram@gmail.com)

Phone Number [480-555-5555](tel:480-555-5555)

Username [summerhogan](#)

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

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# CLOZAPINE REMS

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## 3.3 Account Confirmation

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

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Account Confirmation



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

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# CLOZAPINE REMS

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## 4. Prescriber Certification

### 4.1 Prescriber Intake

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Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake **Education** Assessment Review Attestation Finish

#### Prescriber Intake

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

**Prescriber Information**

First Name  MI (opt)

Last Name

-- Credentials -- ▾

Email Address

Clinic / Practice Name

Address

Address 2 (opt)

City

-- State -- ▾ Zip Code

Phone  Ext (opt)

Fax

-- Contact Preference -- ▾

**Prescriber Identifiers**

DEA

NPI

I do not have a DEA.

Cancel Next

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

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# CLOZAPINE REMS

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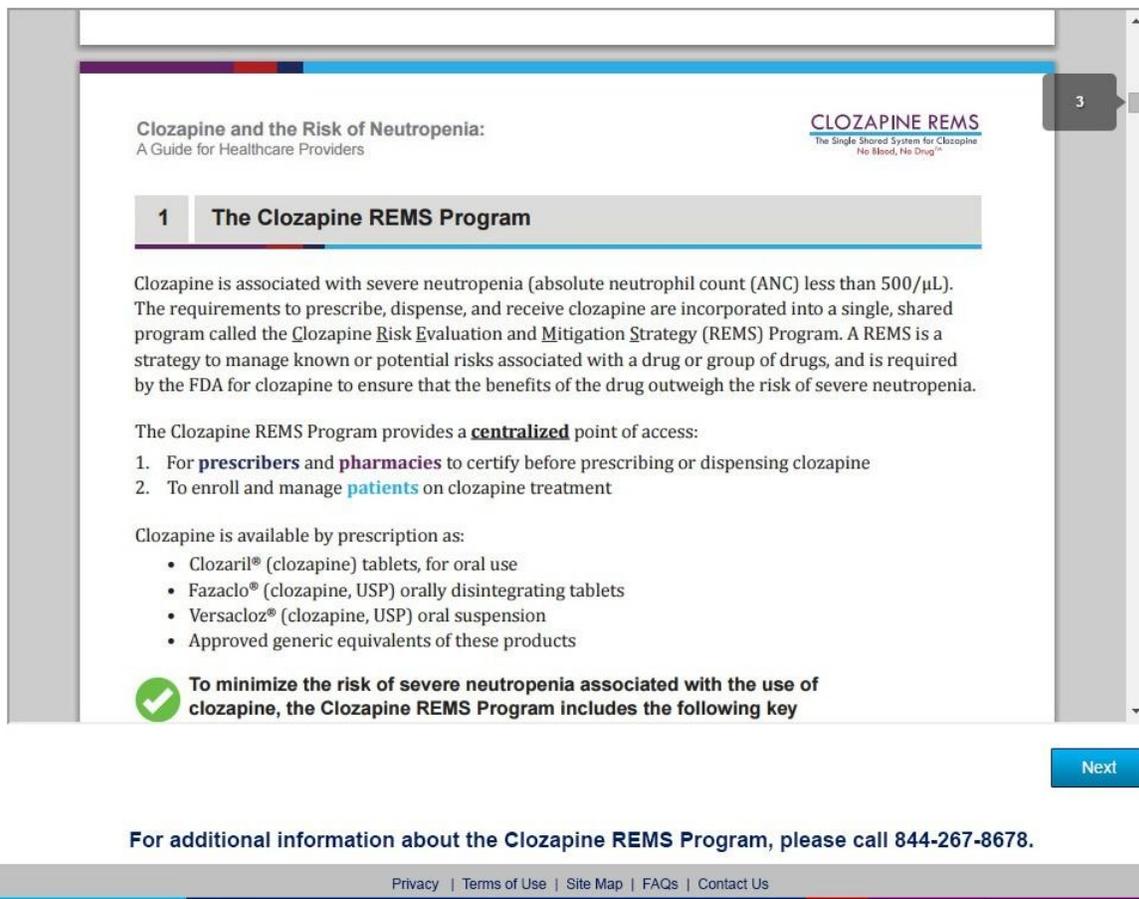
## 4.2 Prescriber Education Program



Start Intake Education Assessment Review Attestation Finish

### Education Program

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



**Clozapine and the Risk of Neutropenia:**  
A Guide for Healthcare Providers

**1 The Clozapine REMS Program**

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia.

The Clozapine REMS Program provides a **centralized** point of access:

1. For **prescribers** and **pharmacies** to certify before prescribing or dispensing clozapine
2. To enroll and manage **patients** on clozapine treatment

Clozapine is available by prescription as:

- Clozaril® (clozapine) tablets, for oral use
- Fazaclo® (clozapine, USP) orally disintegrating tablets
- Versacloz® (clozapine, USP) oral suspension
- Approved generic equivalents of these products

 **To minimize the risk of severe neutropenia associated with the use of clozapine, the Clozapine REMS Program includes the following key**

**Next**

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# CLOZAPINE REMS

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## 4.3 Prescriber Education Confirmation

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

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

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## 4.4 Prescriber Intake Review

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Start Intake Education Assessment **Review** Attestation Finish

### Prescriber Intake Review

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

**Prescriber Information**

First Name / MI (opt) Summer A

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 Ext (opt)

Fax 555-555-4444

Contact Preference Email

**Prescriber Identifiers**

DEA AG5255698

NPI 1013015577

I do not have a DEA.

Cancel Next

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## 4.5 Prescriber Attestation

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

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

### Prescriber Attestation

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

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Clozapine REMS Program at 844-404-8876. 

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

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 *Knowledge Assessment for Healthcare Providers*
3. I understand the risk of severe neutropenia associated with clozapine
4. Prior to initiating treatment, I agree to provide *What You Need To Know About Clozapine: A Guide for Patients and Caregivers* to each patient and/or his/her caregiver. I will review it with him/her to inform them about the risks associated with clozapine, including severe neutropenia and the Clozapine REMS Program requirements – unless I determine that the patient's adherence to the treatment regimen will be negatively impacted by providing *What You Need To Know About Clozapine: A Guide for Patients and Caregivers*
5. I will enroll all patients I treat with a clozapine product in the Clozapine REMS Program
6. I understand the 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 Benign Ethnic Neutropenia (BEN)
8. I will order ANC testing for each patient according to the clozapine Prescribing Information
9. I will report the ANC for each patient to the Clozapine REMS Program and I understand the ANC must be provided before clozapine can be dispensed
10. I understand that, as described in *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, I must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed
11. I agree that personnel from the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
12. 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
13. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into 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

[Back](#)

[Submit](#)

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# CLOZAPINE REMS

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## 4.6 Prescriber Confirmation

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Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake Education Assessment Review Attestation Finish

### Certification Confirmation

✓ 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:** 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.**

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## 5. Prescriber Designee Certification

### 5.1 Prescriber Designee Intake

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

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

#### Designee Intake

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

**Designee Information**

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

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

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## 5.2 Prescriber Designee Education Program Page 1

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

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

### General Information

Prescribers have the ability to identify and associate designees to their Clozapine REMS Program certification record. This allows prescribers the ability to approve responsible individual(s) to act on behalf of the certified prescriber for patients who are being treated with clozapine. Prescriber designees have the ability to provide ANC, and enroll and manage patients with the following exceptions:

- Designees cannot categorize a patient as diagnosed with BEN
- Designees cannot authorize the continuation of clozapine treatment for patients with moderate (General Population) or severe neutropenia (Patients with BEN)
- Designees cannot categorize a patient as a hospice patient.

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

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# CLOZAPINE REMS

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## 5.3 Prescriber Designee Education Program Page 2

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

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

### Prescriber Designee Responsibilities

To be a designee for a certified prescriber in the Clozapine REMS Program, you must understand that you are acting on behalf of the certified prescriber, that clozapine is available only through the Clozapine REMS Program, and that you 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
- The ANC testing and monitoring requirements as described in the clozapine Prescribing Information
- **For Outpatients:** An ANC must be reported to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed
- **For Inpatients:** An ANC must be reported to the Clozapine REMS Program for each patient within 7 days from the date of blood draw
- To continue treatment with clozapine, the certified prescriber must provide a valid treatment rationale before clozapine can be dispensed to a patient, if the patient has moderate or severe neutropenia
- 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 may contact me to gather information or 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 into the website using my credentials

1 | 2

[Back](#)

[Next](#)

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## 5.4 Prescriber Designee Education Confirmation

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Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake **Education** Assessment Review Attestation Finish

### 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.

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# CLOZAPINE REMS

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## 5.5 Prescriber Designee KA

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

### Knowledge Assessment

Please select the **best** answer for the question. This question must be answered to proceed with the process to become certified in the program.

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.

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## 5.6 Prescriber Designee KA Confirmation – Success

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

### Knowledge Assessment Results

✔ 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 Confirmation Code: **1422-FEAF-BE87** 

I have reviewed the requirements of the Clozapine REMS Program.

✔ A. Yes

[Next](#)

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## 5.7 Prescriber Designee KA Confirmation – Not Successful

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

### Knowledge Assessment Results

**You did not pass the Knowledge Assessment.**

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

I have reviewed the requirements of the Clozapine REMS Program.

✘ B. No

ATTEMPT

1 2 3 4 5 6

[Retake Assessment](#)

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## 5.8 Prescriber Designee Intake Review

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### Designee Intake Review

Please review the information below 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.

#### Designee Information

First Name	<input type="text" value="Joe"/>
Last Name	<input type="text" value="Smith"/>
Email Address	<input type="text" value="jsmith@xyz.com"/>
Phone / Ext (opt)	<input type="text" value="555-555-5555"/> <input type="text" value="123"/>
Fax (opt)	<input type="text" value="Fax (opt)"/>
Contact Preference	<input type="text" value="Email"/>

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

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

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## 5.9 Prescriber Designee Attestation

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Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake Education Assessment Review **Attestation** Finish

### Designee Attestation

To complete the designee certification for **Joe Smith** 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 the Clozapine REMS Program at 844-404-8876.

As a designee, 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
3. **For Outpatients:** An ANC must be reported to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed
4. **For Inpatients:** An ANC must be reported to the Clozapine REMS Program for each patient within 7 days from the date of the blood draw
5. 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
6. 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
7. Personnel from the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
8. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

By checking this box, I acknowledge that I will act on behalf of a certified prescriber to comply with the Clozapine REMS Program requirements. I hereby state that all of the information I have submitted is truthful and accurate.

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

Signature Date

Back

Submit

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

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# CLOZAPINE REMS

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## 5.10 Prescriber Designee Confirmation

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Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake Education Assessment Review Attestation Finish

### Certification Confirmation

✔ 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: **HCP123456789** 🖨️

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.**

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## 6. Pharmacy Certification

### 6.1 Role Selection

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Username  Password  [Sign in](#)

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

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

#### Program Role Selection

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

- Authorized Representative of Chain Pharmacy Headquarters** – An authorized representative of a chain pharmacy headquarters 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.
- 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.
- 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.

[Continue](#)

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

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## 6.2 Role Selection Confirmation – Inpatient Pharmacy

The screenshot displays the Clozapine REMS website interface. At the top, there is a navigation bar with the site logo, a sign-in form (Username, Password, Sign in), and links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. The main content area is titled 'Program Role Selection' and contains a confirmation dialog box. The dialog box has a purple border and contains the following text:

**Authorized Representative of Inpatient Pharmacy**

Based on the response selected, please confirm you are certifying as an Inpatient Pharmacy.

An inpatient pharmacy is where the patient's treatment is coordinated at a site of care where pharmacy claims are submitted as a medical benefit.

If the pharmacy you are certifying does not meet the definition of an inpatient pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

At the bottom of the dialog are two buttons: 'Cancel' and 'Confirm'. The background of the website is dimmed, showing radio button options for 'Authorized Representative' roles.

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

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## 6.3 Role Selection Confirmation – Outpatient Pharmacy

The screenshot displays the Clozapine REMS website interface. At the top, there is a navigation bar with the site logo, a login section (Username, Password, Sign in), and a menu (Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, Support). A central dialog box is open, titled "Authorized Representative of Outpatient Pharmacy". The dialog contains the following text:

**Authorized Representative of Outpatient Pharmacy**

Based on the response selected, please confirm that you are certifying as an **Outpatient Pharmacy**.

An outpatient pharmacy is a retail or institutional outpatient pharmacy not affiliated with any corporate pharmacy chain. The outpatient pharmacy has an authorized representative that is responsible for ensuring the education and training of pharmacy staff within the individualized location.

If the pharmacy you are certifying does not meet the definition of an outpatient pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

At the bottom of the dialog are two buttons: "Cancel" and "Confirm".

In the background, the "Program Role Selection" page is visible, showing three radio button options for "Authorized Representative" roles. The "Continue" button is also visible at the bottom left of the page.

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## 6.4 Role Selection Confirmation – Chain Pharmacy Headquarters

The screenshot displays the Clozapine REMS website interface. At the top, there is a navigation bar with the logo and tagline, a search bar, and a 'Sign in' button. Below the navigation bar, there are links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. The main content area is titled 'Program Role Selection' and contains a form with three radio button options. A modal dialog box is overlaid on the form, titled 'Authorized Representative of Chain Pharmacy Headquarters'. The dialog box contains the following text: 'Based on the response selected, please confirm you are certifying as a Chain Pharmacy Headquarters. A chain pharmacy headquarters is a retail, mail order, or institutional outpatient pharmacy organization where a head office directs, coordinates and oversees a minimum of 10 outpatient pharmacies. If the pharmacy you are certifying does not meet the definition for a chain pharmacy headquarters, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.' The dialog box has 'Cancel' and 'Confirm' buttons at the bottom. Below the dialog box, there is a 'Continue' button. At the bottom of the page, there is a footer with the text 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation bar with links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

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

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Program Role Selection

Please select the option below that best describes your role:

- Authorized Representative of Chain Pharmacy Headquarters**  
responsible for ensuring that all pharmacies in a pharmacy network participate with the program.
- Authorized Representative of Outpatient Pharmacy**  
certification and training for the pharmacy. Claims are submitted and managed by the pharmacy.
- Authorized Representative of Retail Pharmacy**  
certification and training for the pharmacy. Claims cannot be affiliated with the program.

Continue

**Authorized Representative of Chain Pharmacy Headquarters**

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

A chain pharmacy headquarters is a retail, mail order, or institutional outpatient pharmacy organization where a head office directs, coordinates and oversees a minimum of 10 outpatient pharmacies.

If the pharmacy you are certifying does not meet the definition for a chain pharmacy headquarters, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

Cancel Confirm

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## 6.5 Authorized Representative Intake

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

[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### Authorized Representative Intake

To begin the process as an authorized representative in the Clozapine REMS Program, please complete the form below and press **Next**. All fields listed below are required unless otherwise indicated.

**Authorized Representative Information**

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

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

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## 6.6 Authorized Representative Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left, the logo reads "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". The user name "Summer Hogan" and a "My Dashboard" button are in the top right. A navigation menu includes "Home", "Prescriber", "Pharmacy" (highlighted), "Patient", "Resources", "Important Safety Information", and "Support". Below the menu is a progress bar with four steps: "Intake", "Education", "Assessment", and "Confirmation" (the current step). The main heading is "Confirmation". A green-bordered box contains a checkmark and the text: "You have successfully completed the required authorized representative training." Below this, a paragraph states: "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 for today, simply close your browser." At the bottom, a footer contains the text: "For additional information about the Clozapine REMS Program, please call 1-844-267-8678." and a link menu: "Privacy | Terms of Use | Site Map | FAQs | Contact Us".

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## 6.7 Pharmacy Intake

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[Intake](#) [Attestation](#) [Confirmation](#)

### 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**

Pharmacy Name

Pharmacy Type  ?

Address

Address 2 (opt)

City

-- State --  Zip Code

Phone  Ext (opt)

Fax

**Pharmacy Identifiers**

NCPDP

DEA (opt)

NPI

Can your pharmacy management system adjudicate claims online?

-- Please Select --  **1**

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

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1 – Adjudicate claims online question – This question will be displayed only if the Pharmacy Type selected on this page is ‘Outpatient Pharmacy’.

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## 6.8 Pharmacy Education Program

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Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Intake Education Assessment Confirmation

### Education Program

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

Clozapine and the Risk of Neutropenia:  
A Guide for Healthcare Providers

CLOZAPINE REMS  
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3

### 1 The Clozapine REMS Program

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia.

The Clozapine REMS Program provides a **centralized** point of access:

1. For **prescribers** and **pharmacies** to certify before prescribing or dispensing clozapine
2. To enroll and manage **patients** on clozapine treatment

Clozapine is available by prescription as:

- Clozaril® (clozapine) tablets, for oral use
- Fazaclo® (clozapine, USP) orally disintegrating tablets
- Versacloz® (clozapine, USP) oral suspension
- Approved generic equivalents of these products

 **To minimize the risk of severe neutropenia associated with the use of clozapine, the Clozapine REMS Program includes the following key**

Next

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## 6.9 Pharmacy Education Confirmation

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

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

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## 6.10 Pharmacy Attestation – Inpatient Pharmacy

This page includes only the attestation text for the Inpatient Pharmacy from the Clozapine REMS Pharmacy Enrollment Form.

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Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Intake Attestation Confirmation

### Pharmacy Attestation

To complete the certification for <Pharmacy Name> 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 using the print icon to the right and fax it to the Clozapine REMS Program at 844-404-8876. 

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of ANC monitoring
3. There is a different ANC monitoring algorithm for patients with 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:

5. 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:
  - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
  - Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
  - Verify the ANC is current and acceptable or verify the prescriber's authorization for continuing clozapine treatment if the ANC is abnormal
  - 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
6. My pharmacy will establish procedures and protocols that are subject to audit, to not sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make available to the clozapine manufacturers and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact my pharmacists to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
10. Provide dispensing location information to the Clozapine REMS Program
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials
12. Inpatient pharmacies are not required to obtain a Predispose Authorization (PDA) prior to dispensing clozapine.

Before dispensing clozapine to an inpatient for the first time, the inpatient pharmacies must:

- Verify the prescriber is certified in the Clozapine REMS Program
- Verify the patient is enrolled in the Clozapine REMS Program

Before dispensing clozapine to an inpatient for the first time, the inpatient pharmacies must:

1. Sign in into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com), or
2. Call the Clozapine REMS Program contact center at 844-267-8678

Inpatient pharmacies must verify the ANC or prescriber's authorization for a patient to continue clozapine treatment in one of three ways:

1. By signing into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
2. By calling the Clozapine REMS Program contact center at 844-267-8678
3. By reviewing the patient's medical record in their hospital's medical record system

Prescribers or their designee(s) must submit ANC to the Clozapine REMS Program within 7 days of blood draw.

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

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

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

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## 6.11 Pharmacy Attestation – Outpatient Pharmacy

This page includes only the attestation text for the Outpatient Pharmacy from the Clozapine REMS Pharmacy Enrollment Form.

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Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Intake **Attestation** Confirmation

### Pharmacy Attestation

To complete the certification for <Pharmacy Name> 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 using the print icon to the right and fax it to the Clozapine REMS Program at 844-404-8876. 

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of ANC monitoring
3. There is a different ANC monitoring algorithm for patients with 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:

5. 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:
  - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
  - Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
  - Verify the ANC is current and acceptable or verify the prescriber's authorization for continuing clozapine treatment if the ANC is abnormal
  - 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
6. My pharmacy will establish procedures and protocols that are subject to audit, to not sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make available to the clozapine manufacturers and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact my pharmacists to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
10. Provide dispensing location information to the Clozapine REMS Program
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials
12. Outpatient Pharmacies must obtain a Predispose Authorization (PDA) before dispensing clozapine products to a patient to ensure compliance with the required safe use conditions. You are confirming that your pharmacy management system CANNOT support electronic communication with the Clozapine REMS Program and you will access the Clozapine REMS Program website or call the Clozapine REMS Program contact center to confirm safe use conditions (as outlined in attestation #5) before dispensing each clozapine prescription. A complete Predispose Authorization request requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.

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

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

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

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## 6.12 Pharmacy Attestation – Outpatient Pharmacy with Adjudication

This page includes only the attestation text for the Outpatient Pharmacy from the Clozapine REMS Pharmacy Enrollment Form.

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[Intake](#) [Attestation](#) [Confirmation](#)

### Pharmacy Attestation

To complete the certification for <Pharmacy Name> 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 using the print icon to the right and fax it to the Clozapine REMS Program at 844-404-8876. 

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of ANC monitoring
3. There is a different ANC monitoring algorithm for patients with 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:

5. 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:
  - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
  - Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
  - Verify the ANC is current and acceptable or verify the prescriber's authorization for continuing clozapine treatment if the ANC is abnormal
  - 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
6. My pharmacy will establish procedures and protocols that are subject to audit, to not sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make available to the clozapine manufacturers and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact my pharmacists to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
10. Provide dispensing location information to the Clozapine REMS Program
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials
12. Outpatient Pharmacies must obtain a Predispose Authorization (PDA) before dispensing clozapine products to a patient to ensure compliance with the required safe use conditions. You are confirming that your pharmacy management system CAN support electronic communication with the Clozapine REMS Program using established telecommunications standards. Clozapine will be dispensed only after obtaining electronic authorization for all clozapine prescriptions, including cash claims, through your pharmacy management system. As part of your certification process, you will receive instructions through the contact preference indicated in the authorized representative information section on how to submit test transactions to the Clozapine REMS Program. This is to ensure that your pharmacy management system has been successfully configured to allow for communication with 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 (see above)      Signature Date:

[Back](#) [Submit](#)

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

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# CLOZAPINE REMS

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## 6.13 Pharmacy Confirmation

This page will be available for:

1. Inpatient Pharmacies
2. Outpatient Pharmacies who cannot adjudicate claims online

The screenshot shows the Clozapine REMS website interface. At the top left is the logo "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". To the right of the logo is the user name "Summer Hogan" and a "My Dashboard" button. Below the logo is a navigation menu with links for "Home", "Prescriber", "Pharmacy" (highlighted), "Patient", "Resources", "Important Safety Information", and "Support". A secondary navigation bar contains three buttons: "Intake", "Attestation", and "Confirmation". The main heading is "Certification Confirmation" with a decorative graphic of colored squares. A green-bordered box contains a checkmark icon and the text: "Your pharmacy is now certified in the Clozapine REMS Program." Below this, a message states: "Below is your Clozapine REMS Program Certification ID. Please retain this information for your records." The certification ID is displayed as "Certification ID: FAC123456789" with a printer icon. A note follows: "To add additional pharmacies or manage your pharmacies, please use the My Dashboard button at the top of the page." Another note says: "Please download the Education Program, Knowledge Assessment, 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." At the bottom, a call to action reads: "For additional information about the Clozapine REMS Program, please call 844-267-8678." The footer contains links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

# CLOZAPINE REMS

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## 6.14 Pharmacy Test Transactions

This page will be available for:

1. Outpatient Pharmacies who can adjudicate claims online
2. Chain Pharmacy Headquarters

The screenshot shows the Clozapine REMS website interface. At the top, the logo and tagline are present, along with a user name 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'. Below the navigation is a secondary menu with 'Intake', 'Attestation', and 'Confirmation' options. The main heading is 'Pharmacy Test Transactions'. A green-bordered box contains a checkmark and the text: 'Thank you! Your enrollment form was successfully submitted.' Below this, a paragraph explains the next step: 'To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system. This will ensure that your pharmacy management system has been successfully configured to allow communication with the Clozapine REMS Program.' Another paragraph states: 'You will soon receive a communication via your contact preference with instructions on how to submit test transactions to the Clozapine REMS Pharmacy Program.' A third paragraph says: 'To download the instructions now, please use the **Download Instructions** link 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.' Below this is a link with a document icon labeled 'Download Instructions'. At the bottom, a footer contains the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation bar with 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

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## 7. Chain Pharmacy Certification

### 7.1 Chain Headquarters Identification

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

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

#### Chain Headquarters Identification

Please enter the REMS Chain ID assigned to your chain below and press **Search**. If you do not know your REMS Chain ID please contact the Clozapine REMS Program at 844-267-8678.

[Search](#)

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

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## 7.2 Chain Headquarters Identification Results

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

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Chain Headquarters Identification

Please enter the REMS Chain ID assigned to your chain below and press **Search**. If you do not know your REMS Chain ID please contact the Clozapine REMS Program at 844-267-8678.

[Search](#)

The chain headquarters associated with the REMS Chain ID provided is participating in the Clozapine REMS Program. Press **Next** to continue.

[Next](#)

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# CLOZAPINE REMS

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## 7.3 Chain Authorized Representative Intake

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

[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### Authorized Representative Intake

To begin the process as an authorized representative in the Clozapine REMS Program, please complete the form below and press **Next**. All fields listed below are required unless otherwise indicated.

**Authorized Representative Information**

▾

▾

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# CLOZAPINE REMS

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## 7.4 Chain Pharmacy Education Program

Summer Hogan ▾ [My Dashboard](#)

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

[Intake](#) **[Education](#)** [Assessment](#) [Confirmation](#)

### Education Program

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

**Clozapine and the Risk of Neutropenia:**  
A Guide for Healthcare Providers

**CLOZAPINE REMS**  
The Single Shared System for Clozapine  
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**1 The Clozapine REMS Program**

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia.

The Clozapine REMS Program provides a **centralized** point of access:

1. For **prescribers** and **pharmacies** to certify before prescribing or dispensing clozapine
2. To enroll and manage **patients** on clozapine treatment

Clozapine is available by prescription as:

- Clozaril® (clozapine) tablets, for oral use
- Fazaclo® (clozapine, USP) orally disintegrating tablets
- Versacloz® (clozapine, USP) oral suspension
- Approved generic equivalents of these products

 **To minimize the risk of severe neutropenia associated with the use of clozapine, the Clozapine REMS Program includes the following key**

[Next](#)

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

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## 7.5 Chain Pharmacy Education Confirmation

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, the user name 'Summer Hogan' is displayed next to a 'My Dashboard' button. Below the logo, a horizontal navigation menu includes links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

A horizontal progress bar with seven steps: 'Start', 'Intake', 'Education', 'Assessment', 'Review', 'Attestation', and 'Finish'. The 'Education' step is highlighted with a dark purple background and a white arrow pointing to the right, indicating the current step in the process.

### 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.

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

Note: Attestation will occur at the pharmacy level during the Certify Headquarters process.

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## 7.6 Chain Authorized Representative Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left, the logo 'CLOZAPINE REMS' is shown with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The user 'Summer Hogan' is logged in, with a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'. A secondary navigation bar highlights 'Intake', 'Education', 'Assessment', and 'Confirmation'. The 'Confirmation' section features a green checkmark icon and the message: 'You have successfully completed the required authorized representative training.' Below this, a text block instructs the user: 'If you are ready to enroll your headquarters now please use [Certify Headquarters](#). If you have completed your session for today, simply close your browser.' At the bottom, a footer provides contact information: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a list of links: 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

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## 7.7 Chain Pharmacy Headquarters Intake

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

[Intake](#) [Attestation](#) [Confirmation](#)

### Chain Pharmacy Headquarters Intake

To certify your headquarters, 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.

**Headquarters Information**

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

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## 7.8 Chain Pharmacy Headquarters Attestation

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

[Intake](#) **[Attestation](#)** [Confirmation](#)

### Chain Pharmacy Headquarters Attestation

To complete the certification for **Rite Aid** 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 the Clozapine REMS Program at 844-404-8876. 

As the authorized representative responsible for this chain headquarters, I, **Summer Hogan**, attest to the following Clozapine REMS program requirements:

I am the authorized representative designated by this chain headquarters to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, the Prescribing Information, and I understand:

- Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
- The risk of severe neutropenia associated with clozapine and the importance of ANC monitoring
- There is a different ANC monitoring algorithm for patients with Benign Ethnic Neutropenia (BEN)
- Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to contact them via phone, mail, or email 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 safe use conditions required in the Clozapine REMS Program, including the following, before dispensing clozapine:
  - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
  - Through electronic communication with the Clozapine REMS Program using established telecommunications standards, my pharmacy will dispense clozapine to each patient only after obtaining authorization by electronically verifying documentation of the following:
    - Prescriber is certified in the Clozapine REMS Program
    - Pharmacy is certified in the Clozapine REMS Program
    - Patient is enrolled in the Clozapine REMS Program
    - The ANC is current and acceptable or the prescriber has authorized continuing treatment if the ANC is abnormal
  - This information will be verified by processing all clozapine prescriptions, including cash claims, through the pharmacy management system
  - Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine.
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party or the FDA to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact pharmacists in my pharmacy to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. For each trained dispensing location provide the following information (Pharmacy Name, NCPDP or NPI or DEA, Address, Phone, Fax, Email, Store Number, and Responsible Pharmacist name)
7. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into 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

[Back](#)

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## 7.9 Pharmacy Test Transactions

At this point in the chain pharmacy process, the authorized representative must complete test transactions prior to being "Certified" in the program. Once they finish the test transactions they will have the ability to access their My Dashboard page and add a chain store.

The screenshot shows the Clozapine REMS website interface. At the top left is the logo "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". To the right of the logo is a user profile "Summer Hogan" and a "My Dashboard" button. Below the logo is a navigation menu with links for "Home", "Prescriber", "Pharmacy", "Patient", "Resources", "Important Safety Information", and "Support". A secondary navigation bar contains buttons for "Intake", "Attestation", and "Confirmation". The main heading is "Pharmacy Test Transactions". A green checkmark icon is followed by the text "Thank you! Your enrollment form was successfully submitted." Below this, a paragraph states: "To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system. This will ensure that your pharmacy management system has been successfully configured to allow communication with the Clozapine REMS Program." Another paragraph says: "You will soon receive a communication via your contact preference with instructions on how to submit test transactions to the Clozapine REMS Pharmacy Program." A third paragraph reads: "To download the instructions now, please use the **Download Instructions** link 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." Below this text is a link labeled "Download Instructions" with a document icon. At the bottom of the page, a footer contains the text "For additional information about the Clozapine REMS Program, please call 844-267-8678." and a navigation bar with links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

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## 7.10 Chain Pharmacy Store Intake

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Summer Hogan ▾ [My Dashboard](#)

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

### Chain Pharmacy Store 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 -- ▾

Phone  Ext (opt)

Fax

--Training Status-- ▾

**Pharmacy Identifiers**

NCPDP

Please provide at least one:

DEA

NPI

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

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## 7.11 Chain Pharmacy Store Confirmation

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Summer Hogan ▾ [My Dashboard](#)

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

### Chain Store Confirmation

✓ The chain pharmacy store has been successfully added.

To add another store, please use the **Add Store** button below.

[Add Store](#) [My Dashboard](#)

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

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# CLOZAPINE REMS

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## 8. Pharmacy Staff Enrollment

### 8.1 Pharmacy Search

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Summer Hogan ▾ [My Dashboard](#)

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

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

#### Pharmacy Search

To identify the pharmacy you represent, please complete the fields below and press **Search**. Once you are able to access your dashboard, you will be able to associate to additional pharmacies. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

and

[Search](#)

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## 8.2 Pharmacy Search Results

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Summer Hogan ▾ [My Dashboard](#)

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

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

### Pharmacy Search

To identify the pharmacy you represent, please complete the fields below and press **Search**. Once you are able to access your dashboard, you will be able to associate to additional pharmacies. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="3456789"/>
------------------------------------	-----	----------------------------------	----------------------------------	--------------------------------------

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Clozapine REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
CVS	423 Main Street, Tampa FL 33614	555-555-5555

Showing 1 of 1 entries

[Submit](#)

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

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## 8.3 Pharmacy Staff Intake

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Summer Hogan ▾ [My Dashboard](#)

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

[Start](#) **[Intake](#)** [Attestation](#) [Finish](#)

### Pharmacy Staff Intake

To enroll as a pharmacy staff in the Clozapine REMS Program, please complete the form below and press **Next**. Once enrolled, you will receive an enrollment confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

**Pharmacy Staff Information**

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

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

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## 8.4 Pharmacy Staff Attestation

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Summer Hogan ▾ [My Dashboard](#)

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

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

### Pharmacy Staff Attestation

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

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

Pharmacy Staff can access the Clozapine REMS Program online to do the following:

- Enter an ANC for a patient
- Verify a prescriber is certified in the Clozapine REMS Program
- Verify a patient is enrolled in the Clozapine REMS Program
- Obtain a Predispose Authorization (PDA) (Inpatient Pharmacies do not have to obtain a PDA)

For online access to perform the above tasks, you must enroll by creating an account.

By enrolling, you agree not to share your credentials for the Clozapine REMS Program website or allow others to sign into the website using your credentials.

As part of your enrollment, you must select the certified pharmacy location(s) where you fill and/or dispense clozapine. It is your responsibility to update this information as necessary.

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

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

Signature Date

[Back](#)

[Submit](#)

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

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## 8.5 Pharmacy Staff Confirmation

The screenshot shows the Clozapine REMS website interface. At the top left is the logo and tagline. On the top right, the user name 'Summer Hogan' and a 'My Dashboard' button are visible. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy' (highlighted), 'Patient', 'Resources', 'Important Safety Information', and 'Support'. Below the navigation is a progress bar with four steps: 'Start', 'Intake', 'Attestation', and 'Finish'. The main heading is 'Enrollment Confirmation', followed by a decorative graphic of colored squares. A green-bordered box contains a checkmark and the text: 'You have now enrolled in the Clozapine REMS Program.' Below this, a message states: 'Below is your Clozapine REMS Program Enrollment ID. Please retain this information for your records.' The enrollment ID is displayed as 'Enrollment ID: HCP123456789'. A final instruction reads: 'To return to your dashboard for other activities, please use the My Dashboard button at the top of the page. If you have completed your session for today, simply close your browser.' At the bottom, a call to action says: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' The footer contains links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

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Start Intake Attestation Finish

### Enrollment Confirmation

✓ You have now enrolled in the Clozapine REMS Program.

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

**Enrollment ID:** [HCP123456789](#)

To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page. If you have completed your session for today, simply close your browser.

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# CLOZAPINE REMS

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## 9. Knowledge Assessment

The Knowledge Assessment pages below are for prescribers, prescriber designees, and authorized representatives.

### 9.1 Knowledge Assessment Landing Page

The screenshot shows the Clozapine REMS website interface. At the top left is the logo: "CLOZAPINE REMS" in purple, with "The Single Shared System for Clozapine" and "No Blood, No Drug™" below it. To the right of the logo is the user name "Summer Hogan" with a dropdown arrow and a "My Dashboard" button. Below the logo is a navigation menu with links: Home, Prescriber (highlighted in purple), Pharmacy, Patient, Resources, Important Safety Information, and Support. A secondary navigation bar contains buttons for "Start", "Intake", "Education", "Assessment" (highlighted in purple), "Review", "Attestation", and "Finish".

### Knowledge Assessment

You are now going to review questions that will test your knowledge of appropriate use and administration of clozapine. To be a certified prescriber in the Clozapine REMS Program you will need to answer ALL questions correctly. Please select the **best** option for each question.

You will have a maximum of six attempts to pass the assessment. After three unsuccessful attempts, the education program is required to be reviewed again before retaking the knowledge assessment. After six unsuccessful attempts, your access to retake the knowledge assessment will be suspended and you will need to contact the Clozapine REMS Program to reinstate your ability to complete the knowledge assessment.

[Start Assessment](#)

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## 9.2 KA Question 1

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Intake Education Assessment **Confirmation**

### Knowledge Assessment

#### QUESTION 1

All clozapine products are only available under the shared Clozapine REMS Program.

- A. True
- B. False

Next

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# CLOZAPINE REMS

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## 9.3 KA Question 2

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[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### Knowledge Assessment

#### QUESTION 2

Clozapine is associated with severe neutropenia.

- A. True
- B. False

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## 9.4 KA Question 3

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[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### Knowledge Assessment

#### QUESTION 3

Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ $\mu$ L
- B. An absolute neutrophil count (ANC) less than 1000/ $\mu$ L
- C. An absolute neutrophil count (ANC) less than 500/ $\mu$ L
- D. None of the above

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## 9.5 KA Question 4

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[Intake](#) [Education](#) **[Assessment](#)** [Confirmation](#)

### Knowledge Assessment

**QUESTION 4**

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ $\mu$ L for a patient with documented Benign Ethnic Neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ $\mu$ L for a patient who is part of the General Population (i.e., the patient does not have BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

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# CLOZAPINE REMS

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## 9.6 KA Question 5

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[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### Knowledge Assessment

#### QUESTION 5

**Before** clozapine is dispensed to a patient, a prescriber must:

- A. Determine if the patient has Benign Ethnic Neutropenia (BEN)
- B. Enroll the patient in the Clozapine REMS Program
- C. Educate the patient/caregiver about the risk of severe neutropenia
- D. Order blood work to obtain ANC
- E. Review the ANC result and provide it into the Clozapine REMS Program
- F. All of the above

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## 9.7 KA Question 6

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Intake Education Assessment **Confirmation**

### Knowledge Assessment

#### QUESTION 6

For outpatients, prescribers must report the ANC to the shared Clozapine REMS Program before the patient can be dispensed clozapine.

- A. True
- B. False

Next

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## 9.8 KA Question 7

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### Knowledge Assessment

#### QUESTION 7

**Before** clozapine can be dispensed, a pharmacist must:

- A. Verify the prescriber is certified in the shared Clozapine REMS Program
- B. Verify the patient is enrolled in the shared Clozapine REMS Program
- C. For outpatients - verify the ANC is acceptable or verify the prescriber authorized continuing treatment if the ANC is abnormal by obtaining a pre-dispense authorization from the Clozapine REMS Program
- D. For inpatients - verify the ANC is acceptable or verify the prescriber authorized continuing treatment if the ANC is abnormal by accessing the Clozapine REMS Program or by accessing the ANC through the hospital's medical record system
- E. All of the above

Next

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# CLOZAPINE REMS

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## 9.9 KA Question 8

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[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### 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

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# CLOZAPINE REMS

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## 9.10KA Question 9

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### Knowledge Assessment

#### QUESTION 9

Regarding patients with benign ethnic neutropenia (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

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# CLOZAPINE REMS

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## 9.11KA Question 10

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### 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

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# CLOZAPINE REMS

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## 9.12KA Question 11

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[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### Knowledge Assessment

#### QUESTION 11

If a patient's ANC indicates mild neutropenia, which of the following statements is true?

- A. ANC monitoring should be conducted three times weekly until ANC  $\geq 1500/\mu\text{L}$  if the patient is part of the General Population (i.e., if the patient does not have Benign Ethnic Neutropenia (BEN))
- B. Mild neutropenia is within the normal range for a patient with BEN
- C. If the patient has 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

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# CLOZAPINE REMS

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## 9.13KA Question 12

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[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### 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 Benign Ethnic Neutropenia (BEN)
- B. If the patient is part of the General Population (i.e., if the patient does not have BEN), interrupt therapy and conduct ANC monitoring: daily until ANC  $\geq$  1000/ $\mu$ L; three times weekly until ANC  $\geq$  1500/ $\mu$ L; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the General Population or has BEN
- D. None of the above

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## 9.14KA Question 13

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[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

### 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 Benign Ethnic Neutropenia (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 BEN), interrupt treatment and conduct ANC monitoring: daily until  $ANC \geq 1000/\mu L$ ; three times weekly until  $ANC \geq 1500/\mu L$
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
- D. All of the above

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## 9.15KA Confirmation - Success

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Intake Education Assessment **Confirmation**

### Knowledge Assessment Results

✔ 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: **1422-FEAF-BE87** 🖨

**QUESTION 1**

All clozapine products are only available under the shared Clozapine REMS Program.

✔ A. True

**QUESTION 2**

Clozapine is associated with severe neutropenia.

✔ A. True

Next

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## 9.16KA Confirmation – Not Successful

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Intake Education Assessment **Confirmation**

### Knowledge Assessment Results

**You did not pass the Knowledge Assessment.**

Below is a summary of your responses. We recommend you review the Education Program 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 shared Clozapine REMS Program.

✓ A. True

**QUESTION 2**

Clozapine is associated with severe neutropenia.

✗ A. False

ATTEMPT  
1 2 3 4 5 6

Retake Assessment

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## 10. Patient Enrollment

### 10.1 Patient Intake

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[Start](#) [Intake](#) [Lab Info](#) [Finish](#)

#### Patient Intake

To enroll your patient in the Clozapine REMS Program, please complete the form below and press **Next**. Once the patient enrollment is complete, you will receive an enrollment confirmation via your contact preference. All fields listed below are required.

**Patient Information**

-- Gender -- ▾

-- Race -- ▾

-- Patient Group -- ▾ ?

Does the patient have Benign Ethnic Neutropenia (BEN)?

-- Please Select -- ▾

[Cancel](#)

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## 10.2 Patient Lab Intake

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### Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

**Mike Jones**

#### Lab Entry

ANC value (per  $\mu$ L)

Blood Draw Date

[Verify Lab](#)

Treatment Status

Pretreatment ▾

Monitoring Frequency

Weekly ▾

Lab	Current	Highest	Lowest
Blood Draw Date	None	None	None
ANC value (per $\mu$ L) ?	None	None	None

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## 10.3 Patient Lab Intake with Treatment Rationale

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[Start](#) [Intake](#) [Lab Info](#) [Finish](#)

### Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

**Mike Jones**

#### Lab Entry

ANC value (per  $\mu$ L)

Blood Draw Date

[Modify Lab](#)

Lab	Current	Highest	Lowest
Blood Draw Date	None	None	None
ANC value (per $\mu$ L)	None	None	None

Treatment Status

Treatment Rationale

Treatment Rationale Duration

Monitoring Frequency

I attest that this patient is terminally ill/in hospice care and monitoring can be reduced per the label.

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## 10.4 ANC Calculator

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### ANC Calculator

WBC count (x10 <sup>9</sup> /mm <sup>3</sup> )	Segs (%)	Bands (%)	ANC value (per $\mu$ L)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

WBC count (x10 <sup>9</sup> /mm <sup>3</sup> )	Neutrophils (%)	ANC value (per $\mu$ L)
<input type="text"/>	<input type="text"/>	<input type="text"/>

**NOTE:**  
For WBC count, data should be entered in decimal format (a value of 4,300 should be entered as 4.3).  
For Segs, Bands, or Neutrophils, data should be entered without percent sign (20% should be entered as 20).  
If the ANC value is populated with a value, the same value is populated in the ANC value field on the form.

Source: Mosby's Diagnostic and Laboratory Test Reference, 8th ed. 2003. White blood cell count and differential, page 942.

**Lab Information**

The Treatment Status and Monitoring Frequency should be entered in the fields provided below.

**Frank Adam**

**Lab Entry**

ANC value (per  $\mu$ L)

Blood Draw Date

Treatment Status

Treatment Rationale

Treatment Rationale Duration

Monitoring Frequency

I attest that this patient is terminally ill/in hospice care and monitoring can be reduced per the label.

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## 11. Stakeholder Profiles

Stakeholder profiles are accessed via the drop down next to the signed in users name at the top of every page.

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## 11.1 Prescriber Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### My Profile

**My Information** [Edit](#)

First Name / MI

Last Name

Credentials  ▾

Clinic / Practice Name

Address

Address 2

City

State / Zip Code  ▾

Phone / Ext

Fax

Contact Preference  ▾

DEA

NPI

**My Certification**

Certification ID: [HCP123456789](#) ⇄

 Education Program

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## 11.2 Prescriber Designee Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### My Profile

#### My Information Edit

First Name

Last Name

Phone / Ext

Fax

Contact Preference

#### My Certification

Certification ID: **HCP123456789**

Education Program

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## 11.3 Authorized Representative Profile

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### My Profile

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Last Name

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Phone / Ext

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 **Education Program**

 **Knowledge Assessment**

 **Knowledge Assessment Answer Guide**

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## 11.4 Chain Authorized Representative Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### My Profile

#### My Information [Edit](#)

First Name

Last Name

Position / Title  ▾

Phone / Ext

Fax

Contact Preference  ▾

 **Education Program**

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## 11.5 Chain Headquarters Profile

The chain authorized representative will have two options via the drop down next to the signed in users name at the top of every page; one for My Profile (authorized representative profile above) and Chain Headquarters Profile (below).

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### My Profile

#### My Information Edit

First Name

Last Name

Position/Title

Phone / Ext

Fax

Contact Preference

Chain Name

Address

Address 2

City

State / Zip

Phone / Ext

Fax

Chain ID

#### My Certification

Certification ID: **FAC258523458**

Education Program

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## 11.6 Pharmacy Staff Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### My Profile

#### My Information Edit

First Name

Last Name

Phone / Ext

Fax  ▾

Contact Preference

#### My Enrollment

Enrollment ID: **HCP123456789** 

[Cancel](#) [Save](#)

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## 12. My Account

My Account pages are accessed via the drop down next to the signed in users name at the top of every page.

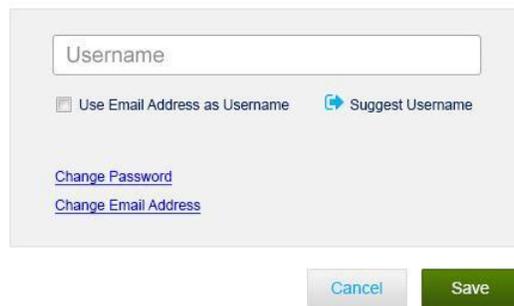
### 12.1 Change Username



The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo 'CLOZAPINE REMS' with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. On the right, the user name 'Summer Hogan' is displayed with a dropdown arrow, and a blue button labeled 'My Dashboard' is next to it. Below the logo, a horizontal menu contains links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

#### Change Username

To change your username, please provide your new username below. The information you provide for your username must be unique within the Clozapine REMS Program website.



The form is a light gray box containing a text input field labeled 'Username'. Below the field is a checkbox labeled 'Use Email Address as Username' and a blue button with a right-pointing arrow labeled 'Suggest Username'. At the bottom of the form are two links: 'Change Password' and 'Change Email Address'. Below the form are two buttons: a light gray 'Cancel' button and a green 'Save' button.

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## 12.2 Change Username Confirmation

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Change Username

✔ Your username has been successfully saved.

To change your username, please provide your new username below. The information you provide for your username must be unique within the Clozapine REMS Program website.

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.

## 12.3 Change Password

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### Change Password

To change your password, please complete the fields below.

[Change Username](#)  
[Change Email Address](#)

[Cancel](#) [Save](#)

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## 12.4 Change Password Confirmation

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### Change Password

✔ Your password has been successfully saved.

To change your password, please complete the fields below.

[Change Username](#)  
[Change Email Address](#)

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

## 12.5 Change Email Address

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Change Email Address

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

[Change Username](#)  
[Change Password](#)

[Cancel](#) [Save](#)

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

## 12.6 Change Email Address Confirmation

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Change Email Address

✓ Your email address has been successfully updated. A verification email has been sent to <email address>. Please use the link within the email to confirm this change.

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

[Change Username](#)  
[Change Password](#)

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## 13. Patient Groups

### 13.1 Manage Groups

Summer Hogan ▾ [My Dashboard](#)

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Manage Groups

The table below contains all of your patient groups. If you need to add a new patient group, please use the **Add Group** button.

[Add Group](#)

Group Name	Actions
Group A	-- Please Select -- <input type="button" value="Go"/>
Group B	-- Please Select -- <input type="button" value="Go"/>

[My Dashboard](#)

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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

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## 13.2 Add Group

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### Add Group

To add a new group, please specify the group name below and press **Submit**. You can add a patient to the group by accessing the patients profile.

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

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## 13.3 Change Group Name

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### Change Group Name

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

Group Name

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

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## 13.4 Remove Group

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### Remove Group

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

Group Name: **Group A**

[Cancel](#) [Remove](#)

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## 13.5 Remove Group Warning

The screenshot displays the Clozapine REMS website interface. At the top, the logo 'CLOZAPINE REMS' is followed by the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'. The user 'Summer Hogan' is logged in, with a 'My Dashboard' button. The main content area is titled 'Remove Group' and shows a form with 'Group Name: Group A'. A white warning dialog box is centered on the screen, featuring a red warning icon and the text: 'Warning', 'Patients are currently assigned to the group you are removing.', and 'Would you like to reassign all the patients to a new group?'. Below the text are two buttons: a red 'No' button and a green 'Yes' button. In the background, a 'Cancel' button and a green 'Remove' button are visible. At the bottom of the page, a footer contains the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation bar with links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

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## 13.6 Reassign Patients

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### Reassign Patients

Please select the new group below and press **Submit**.

Group Name:

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## 14. Dashboard

### 14.1 Dashboard Alerts and Notifications

#### 14.1.1 Dashboard Alerts

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

The screenshot shows the 'Alerts' tab selected in the dashboard. The header includes the Clozapine REMS logo and navigation links. Below the tabs, a message states: 'All program alerts are listed below. Please use the link within an alert to take the necessary action to satisfy the alert.' A search bar is present. A table displays one alert entry with columns for Alert Date, Alert Category, Alert Reference Name, and Alert Subject. The alert is dated 03/02/2015, categorized as 'Certification', and references 'Hogan, Summer' with a 'Begin Certification' link. A pagination bar at the bottom indicates 'Showing 1 of 1 entries'.

Alert Date	Alert Category	Alert Reference Name	Alert Subject
03/02/2015	Certification	Hogan, Summer	<a href="#">Begin Certification</a>

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## 14.1.2 Dashboard Notifications

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

The screenshot shows the Clozapine REMS dashboard interface. At the top, the user is identified as Summer Hogan, with a 'My Dashboard' button. The main navigation bar includes links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. Below this, there are tabs for Alerts (1), Notifications (1), Patients, and Designees. The Notifications tab is active, displaying a message: 'All program notifications are listed below. Please select a notification and use the Acknowledge button to clear the notification.' A search bar is present. A table lists one notification:

<input type="checkbox"/>	Notification Date	Notification Category	Notification Reference Name	Notification Subject
<input type="checkbox"/>	01/15/2015	General	Hogan, Summer	Certification Confirmation

Below the table, it says 'Showing 1 of 1 entries' and includes pagination controls for 1, 10, and 100 entries. An 'Acknowledge' button is located at the bottom right of the notification area.

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## 14.2 Prescriber Dashboard

### 14.2.1 Prescriber Dashboard Patient Tab Collapsed

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts <sup>1</sup> Notifications <sup>1</sup> Patients Designees Manage Groups

The table below contains the patients you have treated with clozapine. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates an NNRMF patient.

[Enroll Patient](#) [Eligibility Check](#) Search

First Name	Last Name	DOB	Treatment Status	Enrollment Status	Group	Relationship	Actions
 Anantharaman	Manickavasagam	11/15/1980	Interrupted	Enrolled	Group A	Active	-- Please Select -- <input type="button" value="Go"/>
 Chester	Smith	03/05/1983	Active	Enrolled	Group B	Active	-- Please Select -- <input type="button" value="Go"/>
 Jane	Brown	07/13/1975	Pretreatment	Incomplete	Group C	Transferred	-- Please Select -- <input type="button" value="Go"/>
 Mike	Jones	11/07/1977	Active	Incomplete	Group D	Active	-- Please Select -- <input type="button" value="Go"/>
 Terry	White	01/15/1988	Active	Enrolled	Group E	Active	-- Please Select -- <input type="button" value="Go"/>

Showing 10 of 10 entries 1 » 10 ▾

 = NNRMF (National Non-Rechallenge Master File) Patients

For definitions of terms used on this page, click [here](#).

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## 14.2.2 Prescriber Dashboard Patient Tab Expanded

Summer Hogan ▾ My Dashboard

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts 1 Notifications 1 Patients Designees Manage Groups

1 2

The table below contains the patients you have treated with clozapine. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates an NNRMF patient.

Enroll Patient Eligibility Check Search

First Name	Last Name	DOB	Treatment Status	Enrollment Status	Group	Relationship	Actions
Anantharaman	Manickavasagam	11/15/1980	Interrupted	Enrolled	Group A	Active	-- Please Select -- Go
Chester	Smith	03/05/1983	Active	Enrolled	Group B	Active	-- Please Select -- Go
Enrollment ID: PAT123456		View ANC Monitoring table			Current	Highest	Lowest
Gender: Male		Blood Draw Date			N/A	N/A	N/A
NNRMF: No		ANC value (per µL)			N/A	N/A	N/A
BEN: No							
Jane	Brown	07/13/1975	Pretreatment	Incomplete	Group C	Transferred	-- Please Select -- Go
Mike	Jones	11/07/1977	Active	Incomplete	Group D	Active	-- Please Select -- Go
Terry	White	01/15/1988	Active	Enrolled	Group E	Active	-- Please Select -- Go

Showing 10 of 10 entries 1 10 ▾

▣ = NNRMF (National Non-Rechallenge Master File) Patients

3

4

For definitions of terms used on this page, click [here](#).

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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 the users to the Patient Intake page and through the patient enrollment process

2 – Eligibility Check – will take the users to the Eligibility Check page. *This page will not be available until the 12/14 launch.*

For patients with an enrollment status of "Enrolled" the prescriber can take the following actions:

3 – Add Lab – will take the user to the Lab Information page

3 – Change Treatment Status – will take the user to the Lab Information page

3 – Change Treatment Rationale – will take the user to the Lab Information page

3 – View Patient History – will take the user to the Patient History page

3 – View Patient Profile – will take the user to the Patient Profile page

4 – For definitions of terms used on this page – will pop-up the definitions on the page (see next mockup)

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## 14.2.3 Definitions of Terms Pop-up

**Definition of Terms**

**Treatment Status**

**Pretreatment** - Patient has been enrolled in the Clozapine REMS Program, prior to beginning therapy on clozapine

**Active** - Patient is actively taking clozapine

**Interrupted** - Patient is temporarily removed from clozapine therapy

**Discontinued** - Patient is removed from clozapine therapy (includes permanent discontinuation due to severe neutropenia or other reasons, patient death, etc...)

**Enrollment Status**

**Enrolled (for 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 Ethic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANC's are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients who have been diagnosed with BEN have a separate ANC monitoring algorithm when treated with clozapine

**NNRMF** - Patients were listed in the National Non-Rechallenge Master File (NNRMF) if a patient had a WBC less than 2,000/ $\mu$ L or an ANC less than 1000/ $\mu$ L. All patients who were listed in the NNRMF, and all their lab data were transferred into the Clozapine REMS Program

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## 14.2.4 Add Lab, Change Treatment Status, Change Monitoring Frequency, and Change Treatment Rationale for Prescribers

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### Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

**Mike Jones**

#### Lab Entry

ANC value (per  $\mu$ L)

Blood Draw Date

[Modify Lab](#)

Lab	Current	Highest	Lowest
Blood Draw Date	None	None	None
ANC value (per $\mu$ L)	None	None	None

Treatment Status

Treatment Rationale

Treatment Rationale Duration

Monitoring Frequency

I attest that this patient is terminally ill/in hospice care and monitoring can be reduced per the label.

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

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## 14.2.5 View Patient History Lab History Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Patient History

Lab History Treatment Status History Monitoring Frequency History

Name **Chester Smith**  
DOB **03/5/1983**  
Gender **Male**

Entry Date	Blood Draw Date	ANC
01/27/2015	01/26/2015	1570
02/27/2015	02/26/2015	900
03/27/2015	03/26/2015	1650



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## 14.2.6 View Patient History Treatment Status Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Patient History

	Lab History	Treatment Status History	Monitoring Frequency History	
Name <b>Chester Smith</b>				
DOB <b>03/5/1983</b>				
Gender <b>Male</b>				
	Entry Date	Treatment Status	Rationale	Duration
	01/27/2015	Active		
	02/27/2015	Interrupted		
	02/27/2015	Active	Benefit Outweighs Risk	07/27/2015

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## 14.2.7 View Patient History Monitoring Frequency Tab

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### Patient History

[Lab History](#) [Treatment Status History](#) **[Monitoring Frequency History](#)**

Name <b>Chester Smith</b>	Entry Date ▾	Monitoring Frequency ▾
DOB <b>03/5/1983</b>	01/27/2015	Monthly
Gender <b>Male</b>		

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## 14.2.8 View Patient Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Patient Profile

**Patient Information** [Edit](#)

First Name

Last Name

DOB

Zip Code

Gender  ▾

Race  ▾

Group  ▾

BEN Patient No

NNRMF Patient No

**Patient Enrollment Information**

Enrollment ID: [PAT132456789](#) 🖨

[Cancel](#) [Save](#)

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## 14.2.9 Eligibility Check

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### Eligibility Check

This Eligibility Check is only intended for **inpatient pharmacy** use to determine if the safe use conditions have been met for your inpatient to receive clozapine. Please complete the Eligibility Check information below and **Submit**. If you have lab updated information you wish to also submit for your inpatient, you may enter it here. The results of the Eligibility Check will be displayed after the information is submitted. All fields below are required unless otherwise indicated.

#### Patient Information

?

▾

▾

At least **one** identifier is required

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Prescriber Eligibility Check Screen (1.2.9) and Prescriber Designee Eligibility Check Screen (1.3.7):

- The eligibility check will be the only option for selection from web dashboards for prescribers, prescriber designees, pharmacy auth reps, and pharmacy staff (for both inpatient and outpatient pharmacies) for Phase 2 (Oct 12<sup>th</sup> through Dec 14<sup>th</sup>) to allow any stakeholder to check eligibility before PDA functionality is available
- The eligibility check fields have been updated to not require manufacturer and NDC knowing these may not be fields that prescribers or their designees may have or know
- At PDA launch (Dec 14<sup>th</sup>), prescribers, prescriber designees, authorized representatives and pharmacy staff for **inpatient** pharmacies will only have the option to access patient eligibility check from their dashboard (not PDA)
  - Additional Point: For consistency, functionality has been provided to both Prescribers and Prescriber Designees.
- At PDA launch (Dec 14<sup>th</sup>), authorized representatives and pharmacy staff for **outpatient** pharmacies will only have the option to access patient PDA request from their dashboard (not eligibility)
- Instructions on the Prescriber and Prescriber Designee Eligibility Check Screens have been updated to clearly explain the purpose of the eligibility check.

## 14.2.10 Prescriber Dashboard Designees Tab

The table below contains all the designees that are currently assigned or requesting approval from you. If you need to add a new designee to your list, please use the **Add Designee** button.

First Name	Last Name	Certification ID	Approval Status	Actions
Anantharaman	Manickavasagam	HCP123456	Approved	-- Please Select -- Remove Designee
Chester	Smith	HCP123456	Approved	-- Please Select --
Jane	Brown	HCP055254	Pending	-- Please Select -- Approve Designee
Mike	Jones	HCP173277	Approved	-- Please Select --
Terry	White	HCP173285	Approved	-- Please Select --

Showing 10 of 10 entries

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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

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## 14.2.11 Add Designee with Results

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### Add Designee

To add a designee, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Designee Information

<input type="text" value="Terry"/>	<input type="text" value="White"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

[Search](#)

If the search results have returned the designee you want to associate to, please select the row and press **Submit**. If you do not see the designee you are looking for, please try your search again or contact the designee to ensure they are certified in the program.

First Name	Last Name	Phone
Terry	White	555-555-5555

Showing 1 of 1 entries

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

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## 14.2.12 Remove Designee

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Remove Designee

Removing this designee will revoke their ability to perform actions on your behalf. To continue, please check the box below and press **Submit**.

Designee Name: [Anantharaman Manickavasagam](#)

Certification ID: [HCP123456](#)

I hereby remove this designee's ability to perform actions on my behalf in the Clozapine REMS Program.

Cancel

Submit

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## 14.2.13 Approve Designee

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Designee Determination

This designee will act on my behalf in fulfilling the requirements for the Clozapine REMS Program.

Designee Name: [Jane Brown](#)

Certification ID: [HCP055254](#)

Decline

Approve

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## 14.3 Prescriber Designee Dashboard

### 14.3.1 Prescriber Designee Dashboard Patient Tab Collapsed

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Alerts <sup>1</sup> Notifications <sup>1</sup> Patients Prescribers Manage Groups

The table below contains the patients you have treated with clozapine. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates an NNRMF patient.

Enroll Patient Eligibility Check Search

First Name	Last Name	DOB	Treatment Status	Enrollment Status	Group	Relationship	Actions
Anantharaman	Manickavasagam	11/15/1980	Interrupted	Enrolled	Group A	Active	-- Please Select -- Go
Chester	Smith	03/05/1983	Active	Enrolled	Group B	Active	-- Please Select -- Go
Jane	Brown	07/13/1975	Pretreatment	Incomplete	Group C	Transferred	-- Please Select -- Go
Mike	Jones	11/07/1977	Active	Incomplete	Group D	Active	-- Please Select -- Go
Terry	White	01/15/1988	Active	Enrolled	Group E	Active	-- Please Select -- Go

Showing 10 of 10 entries 1 » 10 ▾

= NNRMF (National Non-Rechallenge Master File) Patients

For definitions of terms used on this page, click [here](#).

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## 14.3.2 Prescriber Designee Dashboard Patient Tab Expanded

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts <sup>1</sup> Notifications <sup>1</sup> Patients Prescribers Manage Groups

Enroll Patient Eligibility Check Search

The table below contains the patients you have treated with clozapine. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates an NNRMF patient.

First Name	Last Name	DOB	Treatment Status	Enrollment Status	Group	Relationship	Actions
Anantharaman	Manickavasagam	11/15/1980	Interrupted	Enrolled	Group A	Active	-- Please Select -- Go
Chester	Smith	03/05/1983	Active	Enrolled	Group B	Active	-- Please Select -- Go
Jane	Brown	07/13/1975	Pretreatment	Incomplete	Group C	Transferred	-- Please Select -- Go
Mike	Jones	11/07/1977	Active	Incomplete	Group D	Active	-- Please Select -- Go
Terry	White	01/15/1988	Active	Enrolled	Group E	Active	-- Please Select -- Go

Enrollment ID: PAT123456  
Gender: Male  
NNRMF: No  
BEN: No

View ANC Monitoring table	Current	Highest	Lowest
Blood Draw Date	N/A	N/A	N/A
ANC value (per µL)	N/A	N/A	N/A

Add Lab  
Change Treatment Status  
View Patient History  
View Patient Profile

Showing 10 of 10 entries 1 10 ▾

▀ = NNRMF (National Non-Rechallenge Master File) Patients

For definitions of terms used on this page, click [here](#).

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The dashboard for the prescriber designee will include a list of all patients the designee's prescribers are managing. The actions the prescriber designee can take are:

For patients with an enrollment status of "Incomplete" the prescriber designee can "Resume Patient Enrollment"

1 – Enroll Patient – will take the users to the Patient Intake page and through the patient enrollment process

# CLOZAPINE REMS

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2 – Eligibility Check – will take the users to the Eligibility Check page. *This page will not be available until the 12/14 launch.*

For patients with an enrollment status of “Enrolled” the prescriber can take the following actions:

3 – Add Lab – will take the user to the Lab Information page

3 – Change Treatment Status – will take the user to the Lab Information page

3 – View Patient History – will take the user to the Patient History page

3 – View Patient Profile – will take the user to the Patient Profile page

4 – For definitions of terms used on this page – will pop-up the definitions on the page (see next mockup)

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## 14.3.1 Definitions of Terms Pop-up

**Definition of Terms**

**Treatment Status**

**Pretreatment** - Patient has been enrolled in the Clozapine REMS Program, prior to beginning therapy on clozapine

**Active** - Patient is actively taking clozapine

**Interrupted** - Patient is temporarily removed from clozapine therapy

**Discontinued** - Patient is removed from clozapine therapy (includes permanent discontinuation due to severe neutropenia or other reasons, patient death, etc...)

**Enrollment Status**

**Enrolled (for 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 Ethic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANC's are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients who have been diagnosed with BEN have a separate ANC monitoring algorithm when treated with clozapine

**NNRMF** - Patients were listed in the National Non-Rechallenge Master File (NNRMF) if a patient had a WBC less than 2,000/ $\mu$ L or an ANC less than 1000/ $\mu$ L. All patients who were listed in the NNRMF, and all their lab data were transferred into the Clozapine REMS Program

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## 14.3.2 Add Lab and Change Treatment Status for Prescriber Designees

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### Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values you may do so in the fields provided below.

**Mike Jones**

#### Lab Entry

ANC value (per  $\mu$ L)

Blood Draw Date

Treatment Status

Active ▾

Treatment Rationale

-- Please Select -- ▾

Monitoring Frequency

-- Please Select -- ▾

Alert this prescriber that this patient should be under hospice care.

Lab	Current	Highest	Lowest
Blood Draw Date	None	None	None
ANC value (per $\mu$ L) ?	None	None	None

[Cancel](#)

[Submit](#)

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# CLOZAPINE REMS

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## 14.3.3 View Patient History Lab History Tab

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### Patient History

Lab History Treatment Status History Monitoring Frequency History

Name **Chester Smith**  
DOB **03/5/1983**  
Gender **Male**

Entry Date	Blood Draw Date	ANC
01/27/2015	01/26/2015	1570
02/27/2015	02/26/2015	900
03/27/2015	03/26/2015	1650



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## 14.3.4 View Patient History Treatment Status Tab

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### Patient History

	Lab History	Treatment Status History	Monitoring Frequency History	
Name <b>Chester Smith</b>				
DOB <b>03/5/1983</b>				
Gender <b>Male</b>				
	Entry Date	Treatment Status	Rationale	Duration
	01/27/2015	Active		
	02/27/2015	Interrupted		
	02/27/2015	Active	Benefit Outweighs Risk	07/27/2015

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## 14.3.5 View Patient History Monitoring Frequency Tab

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### Patient History

	Lab History	Treatment Status History	<b>Monitoring Frequency History</b>
Name <b>Chester Smith</b>	Entry Date		Monitoring Frequency
DOB <b>03/5/1983</b>	01/27/2015		Monthly
Gender <b>Male</b>			

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# CLOZAPINE REMS

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## 14.3.6 View Patient Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Patient Profile

**Patient Information** [Edit](#)

First Name

Last Name

DOB

Zip Code

Gender

Race

Group

BEN Patient  No

NNRMF Patient  No

**Patient Enrollment Information**

Enrollment ID: [PAT132456789](#) 

[Cancel](#) [Save](#)

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# CLOZAPINE REMS

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## 14.3.7 Eligibility Check

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### Eligibility Check

This Eligibility Check is only intended for **inpatient pharmacy** use to determine if the safe use conditions have been met for your inpatient to receive clozapine. Please complete the Eligibility Check information below and **Submit**. If you have lab updated information you wish to also submit for your inpatient, you may enter it here. The results of the Eligibility Check will be displayed after the information is submitted. All fields below are required unless otherwise indicated.

**Patient Information**

?

▾

▾

At least **one** identifier is required

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

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## 14.3.8 Prescriber Designee Dashboard Prescribers Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts 1 Notifications 1 Patients Prescribers

The table below contains all the prescribers you are currently a designee for. If you need to be a designee for a prescriber not in your list, please use the **Associate to Prescriber** button.

Associate to Prescriber Search

Last Name	First Name	Certification ID	Approval Status	Actions
Anantharaman	Manickavasagam	HCP123456	Approved	-- Please Select --
Chester	Smith	HCP223245	Approval Pending	Remove Designee Relationship -- Please Select --
Jane	Brown	HCP173277	Approved	Cancel Designee Request -- Please Select --
Mike	Jones	HCP373240	Approved	-- Please Select -- Go
Terry	White	HCP173285	Approved	-- Please Select -- Go

Showing 10 of 10 entries

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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 – Cancel Designee Request – will take the user to the Cancel Designee Request page

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## 14.3.9 Associate to Prescriber

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

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Associate to Prescriber

To associate to 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):

and  or

[Search](#)

If the search results have returned the prescriber you want to associate to, please select the row and press **Submit**. If you do not see the prescriber you are looking for, please try your search again or contact the prescriber to ensure they are certified in the program.

First Name	Last Name	Phone	DEA	NPI
Terry	White	555-555-5555	TW1234567	

Showing 1 of 1 entries

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

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## 14.3.10 Remove Designee Relationship

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Remove Designee Relationship

To remove your relationship with this prescriber, please check the box below and press **Submit**.

Prescriber Name: **Summer Hogan**

Relationship Status: **Approved**

I hereby remove my relationship with this prescriber and understand that I will no longer have the ability to perform actions on their behalf in the Clozapine REMS Program.

Cancel

Submit

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## 14.3.11 Cancel Designee Request

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Cancel Designee Request

To cancel the approval request to act on behalf of this prescriber, please check the box below and press **Submit**.

Prescriber Name: **Summer Hogan**

Relationship Status: **Pending**

I hereby cancel my request to act on behalf of this prescriber in the Clozapine REMS Program.

Cancel

Submit

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## 14.4 Pharmacy Dashboard

### 14.4.1 Pharmacy Dashboard Pharmacies Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts <sup>3</sup> Notifications <sup>1</sup> Pharmacies Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you need to add a new pharmacy to your list, please use the Add Pharmacy button. For patient actions, use the Actions list below.

Add Pharmacy Search

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
Joey's Apothecary	1 East Main Street, New York NY 10001	Inpatient	FAC1002345831	Certified	-- Please Select -- Go
Hogan RX	2 Park Avenue, New York NY 10201	Independent Outpatient	FAC2234583304	Certified	Add Lab and Eligibility Check View Pharmacy Profile Remove Pharmacy Go
Walgreens	311 Bell Road, Anaheim CA 92805	Inpatient	FAC0057124807	Incomplete	-- Please Select -- Go
CVS	423 Main Street, Tampa FL 33614	Inpatient	FAC0057124807	Incomplete	-- Please Select -- Go
Rite Aid	52 Milky Way Dr, Anchorage, AK 99508	Inpatient	FAC2585234583	Certified	Resume Pharmacy Certification -- Please Select -- Go

Showing 10 of 10 entries

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The dashboard for the authorized representative of inpatient and 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 – Add Lab and Eligibility Check – will take the user to the Add Lab and Eligibility Check page. *This page will only be available between 10/12 and 12/14. On 12/14, PDA will take over and Eligibility Check will be removed.*

2 – Add Lab and Predispose Authorization – will take the user to the Add Lab and Predispose Authorization page. *This page will not be available between 10/12 and 12/14. On 12/14, PDA will take over and Eligibility Check will be removed.*

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- 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 – For pharmacies with an enrollment status of “Incomplete” the authorized representative can “Resume Pharmacy Certification”

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## 14.4.2 Add Lab and Eligibility Check

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### 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 results of the Eligibility Check will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

**Patient Information**

**Add Patient Lab (optional)**

**Eligibility Check Request (optional)**

[?](#)

▾

▾

At least one identifier is required

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

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## 14.4.3 Eligibility Check Result – Unsuccessful

This result is displayed for both the Predispose Authorization and the Eligibility Check when the result is unsuccessful.

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline 'The Single Shared System for Clozapine No Blood, No Drug™' are visible. A navigation menu includes links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. A user profile for 'Summer Hogan' and a 'My Dashboard' button are in the top right. The main heading is 'Eligibility Check Result'. A prominent red warning box states: 'Do not dispense clozapine to this patient.' Below this, a patient summary shows the name 'Chester Smith' and 'DOB'. To the right, a list of reasons for the failed check is provided: 'The patient is not enrolled in the REMS program', 'The prescriber is not certified in the REMS program', 'Acceptable patient lab is not on file', and 'Lab Status Lab was not saved'. A note at the bottom of this list suggests contacting the prescriber for further assistance. A footer contains the contact number '844-267-8678' and a navigation bar with links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

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

Name **Chester Smith**  
DOB

- ✘ The patient is not enrolled in the REMS program
- ✘ The prescriber is not certified in the REMS program
- ✘ Acceptable patient lab is not on file
- ✘ **Lab Status Lab was not saved**

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

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## 14.4.4 Add Lab and Predispose Authorization

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Predispose Authorization

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

**Patient Information**

**Add Patient Lab (optional)**

**Predispose Authorization Request**

?

▾

▾

At least one identifier is required

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

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## 14.4.5 Predispense Authorization Result – Successful

This result is displayed for both the Predispense Authorization and the Eligibility Check when the result is successful.

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the text 'CLOZAPINE REMS' and 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, there is a user profile 'Summer Hogan' with a dropdown arrow and a 'My Dashboard' button. Below the logo, a horizontal navigation menu contains links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

### Predispense Authorization

✓ You are now authorized to dispense clozapine to the below patient.

Name	Chester Smith	Lab Status	Lab was saved
DOB	03/05/1983		
Predispense Authorization Code	XXXXXXX		

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# CLOZAPINE REMS

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## 14.4.6 View Pharmacy Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Pharmacy Profile

#### Pharmacy Information Edit

Pharmacy Name

Pharmacy Type

Address

Address 2

City

State / Zip Code

Phone / Ext

Fax

NCPDP

DEA

NPI

#### Pharmacy Certification Information

Certification ID: **HCP123456789**

[Cancel](#) [Save](#)

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# CLOZAPINE REMS

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## 14.4.7 Remove Pharmacy

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press **Submit**.

Pharmacy Name: **Joey's Apothecary**

Certification ID: **PRS123456789**

I hereby remove this pharmacy from the Clozapine REMS Program.

Cancel

Submit

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# CLOZAPINE REMS

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## 14.4.8 Pharmacy Dashboard Pharmacy Staff Tab

The screenshot shows the 'Pharmacy Staff' tab selected in a dashboard. The header includes the user's name 'Summer Hogan' and a 'My Dashboard' button. The main navigation bar contains links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. Below the navigation, there are tabs for Alerts, Notifications, Pharmacies, and Pharmacy Staff. A search bar is located above the table. The table lists one pharmacy staff member: Sally Smith, associated with Joey's Apothecary, located at 1 East Main Street, New York NY 10001, with enrollment ID HCP123456789 and an enrolled status. An 'Actions' dropdown menu is open for the first row, showing options: '-- Please Select --' and 'Remove Pharmacy Staff'. A callout box with the number '1' points to the 'Remove Pharmacy Staff' option. The page indicates 'Showing 1 of 1 entries'.

First Name	Last Name	Pharmacy Name	Address	Enrollment ID	Enrollment Status	Actions
Sally	Smith	Joey's Apothecary	1 East Main Street, New York NY 10001	HCP123456789	Enrolled	-- Please Select -- Remove Pharmacy Staff

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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

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## 14.4.9 Remove Pharmacy Staff

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

### Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press **Submit**.

Staff Member: [Sally Smith](#)

Pharmacy Name: [Joey's Apothecary](#)

Enrollment ID: [HCP123456789](#)

I hereby remove this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

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

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## 14.5 Chain Pharmacy Dashboard

### 14.5.1 Chain Pharmacy Dashboard Pharmacies Tab

Summer Hogan ▾ My Dashboard

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts <sup>3</sup> Notifications <sup>1</sup> Pharmacies Pharmacy Staff

To certify a store that has been trained on all program requirements, select the store(s) and use the **Certify Store** button.  
To add a store not in your list, use the **Add Chain Store** button. For all other activities, use the Actions list for the store.

**Add Chain Store** Search

<input type="checkbox"/>	Store Name	Address	Certification ID	Certification Status	Actions
<input type="checkbox"/>	Joey's Apothecary	1 East Main Street, New York NY 10001	FAC1002345831	Certified	-- Please Select -- Go
<input type="checkbox"/>	Hogan RX	2 Park Avenue, New York NY 10201	FAC2234583304	Certified	View Pharmacy Profile Remove Pharmacy
<input type="checkbox"/>	Apollo Pharmacy	311 Bell Road, Anaheim CA 92805	FAC0057124807	Incomplete	-- Please Select -- Go
<input type="checkbox"/>	Life Pharmacy	423 Main Street, Tampa FL 33614	FAC0057124807	Certified	-- Please Select -- Go
<input type="checkbox"/>	Mercury Drug	52 Milky Way Dr, Anchorage, AK 99508	FAC2585234583	Certified	-- Please Select -- Go

Showing 10 of 10 entries

**Certify Store**

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The dashboard for the authorized representative of chain pharmacy headquarters 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

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3 – 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 Certify Store button to certify the store once the staff is trained.

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## 14.5.2 View Pharmacy Profile

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### Pharmacy Profile

#### Pharmacy Information Edit

Pharmacy Name

Pharmacy Type

Address

Address 2

City

State / Zip Code

Phone / Ext

Fax

NCPDP

DEA

NPI

#### Pharmacy Certification Information

Certification ID: [HCP123456789](#) 🖨️

[Cancel](#) [Save](#)

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## 14.5.3 Remove Pharmacy

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### Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press **Submit**.

Pharmacy Name: [Joey's Apothecary](#)

Certification ID: [PRS123456789](#)

I hereby remove this pharmacy from the Clozapine REMS Program.

[Cancel](#)

[Submit](#)

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## 14.5.4 Chain Pharmacy Dashboard Pharmacy Staff Tab

The table below contains all the pharmacy staff that are currently assigned to you.

First Name	Last Name	Pharmacy Name	Address	Enrollment ID	Enrollment Status	Actions
Sally	Smith	Joey's Apothecary	1 East Main Street, New York NY 10001	HCP123456789	Enrolled	<ul style="list-style-type: none"><li>-- Please Select --</li><li>Remove Pharmacy Staff</li></ul>

Showing 10 of 10 entries

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The dashboard for the authorized representative of chain pharmacy headquarters 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

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## 14.5.5 Remove Pharmacy Staff

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

### Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press **Submit**.

Staff Member: [Sally Smith](#)

Pharmacy Name: [Joey's Apothecary](#)

Enrollment ID: [HCP123456789](#)

I hereby remove this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

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

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## 14.6 Pharmacy Staff Dashboard

### 14.6.1 Pharmacy Staff Dashboard Pharmacies Tab

The screenshot displays the Pharmacy Staff Dashboard Pharmacies Tab. At the top, there is a navigation bar with the CLOZAPINE REMS logo and the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. Below the logo, there are links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. The main content area has tabs for Alerts, Notifications, and Pharmacies. A search bar and an 'Associate to Pharmacy' button are present. A table lists several pharmacies with their addresses and certification statuses. The Actions column for each pharmacy includes a dropdown menu with options like 'Please Select' and 'Add Lab and Eligibility Check'. A callout box labeled '1' points to the 'Associate to Pharmacy' button, and another callout box labeled '2' points to the 'Add Lab and Eligibility Check' option in the Actions column for the 'Berry Store' row. At the bottom, there is a footer with links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

Pharmacy Name	Address	Certification Status	Actions
Berry Store	Address One, TAMPA, Florida 33004	Certified	-- Please Select -- Go
Cherry Store	Address Two, ORLANDO, Florida 32807	Certified	Add Lab and Eligibility Check Go
Complete Pharmacy Name	Address, WEST MONROE, Louisiana 71291	Certified	-- Please Select -- Go
Complete Training STORE	Address, MIAMI, Florida 33135	Certified	-- Please Select -- Go
New Apple Store	Address, MALIBU, California 90265	Certified	-- Please Select -- Go
Pharmacy One	Address, SHREVEPORT, Louisiana 71109	Certified	-- Please Select -- Go
Test Pharmacy	1234123434, MONROE, Louisiana 71201	Certified	-- Please Select -- Go

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 and Eligibility Check – will take the user to the Add Lab and Eligibility Check page. *This page will only be available between 10/12 and 12/14. On 12/14, PDA will take over and Eligibility Check will be removed.*

2 – Add Lab and Predisense Authorization – will take the user to the Add Lab and Predisense Authorization page. *This page will not be available between 10/12 and 12/14. On 12/14, PDA will take over and Eligibility Check will be removed.*

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## 14.6.2 Associate to Pharmacy

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### Associate to Pharmacy

To identify the pharmacy you represent, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="3456789"/>
------------------------------------	-----	----------------------------------	----------------------------------	--------------------------------------

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Clozapine REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
CVS	423 Main Street, Tampa FL 33614	555-555-5555

Showing 1 of 1 entries

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## 14.6.3 Add Lab and Eligibility Check

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### 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 results of the Eligibility Check will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

**Patient Information**

**Add Patient Lab (optional)**

**Eligibility Check Request (optional)**

[?](#)

▾

▾

At least one identifier is required

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## 14.6.4 Eligibility Check Result – Unsuccessful

This result is displayed for both the Predispose Authorization and the Eligibility Check when the result is unsuccessful.

The screenshot shows the Clozapine REMS website interface. At the top, the logo and tagline are present. A navigation bar includes links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. A user profile for Summer Hogan and a My Dashboard button are also visible. The main heading is "Eligibility Check Result". A prominent red warning box states: "Do not dispense clozapine to this patient." Below this, a table lists the reasons for the failed check:

Name: <b>Chester Smith</b>	<ul style="list-style-type: none"><li>✘ The patient is not enrolled in the REMS program</li><li>✘ The prescriber is not certified in the REMS program</li><li>✘ Acceptable patient lab is not on file</li><li>✘ <b>Lab Status</b> <b>Lab was not saved</b></li></ul> <p>For further assistance with this patient's eligibility, please contact the patient's prescriber.</p> 
DOB:	

At the bottom, a call to action reads: "For additional information about the Clozapine REMS Program, please call 844-267-8678." A footer contains links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

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## 14.6.5 Add Lab and Predispose Authorization

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### Predispose Authorization

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

**Patient Information**

**Add Patient Lab (optional)**

**Predispose Authorization Request**

?

▾

▾

At least one identifier is required

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

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## 14.6.6 Predispense Authorization Result – Successful

This result is displayed for both the Predispense Authorization and the Eligibility Check when the result is successful.

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the text 'CLOZAPINE REMS' and 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, there is a user profile 'Summer Hogan' with a dropdown arrow and a 'My Dashboard' button. Below the logo, a horizontal navigation menu contains the following links: Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support.

### Predispense Authorization

✓ You are now authorized to dispense clozapine to the below patient.

Name <b>Chester Smith</b>	Lab Status <b>Lab was saved</b>
DOB <b>03/05/1983</b>	
Predispense Authorization Code <b>XXXXXXX</b>	

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