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. Certain Healthcare Providers who prescribe clozapine are certified

   a. All Healthcare Providers who prescribe clozapine for outpatient use must be certified.

   b. All Healthcare Providers who prescribe clozapine to a patient who is not yet enrolled must be certified.

   c. To become certified to prescribe clozapine, 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 Clozapine REMS Knowledge Assessment for Healthcare Providers; and,
iii. Enroll in the Clozapine REMS Program by completing the *Clozapine REMS Prescriber Enrollment Form*.

d. 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 *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia* 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 *A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia*

2.) Completing the *Clozapine REMS Patient Enrollment Form* for each patient. Submit the completed form to the Clozapine REMS Program

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

1.) Order ANC according to the monitoring schedule described in the Prescribing Information

2.) Submit ANC according to the patient’s monitoring frequency on file with the Clozapine REMS Program as described in the Monitoring Schedule of the Prescribing Information:

   a) For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw date

   b) For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw date

   c) For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of the lab draw date

3.) Provide authorization of treatment for patients (i.e., Treatment Rationale) with an ANC that falls below the acceptable range described in the Prescribing Information, when the prescriber determines the benefits outweigh the risks of developing severe neutropenia

4.) Verify the patient monitoring frequency on file with the Clozapine REMS Program is aligned with the patient’s monitoring frequency as described in the Prescribing Information
e. Clozapine Sponsors must:

i. Ensure that Healthcare Providers who prescribe clozapine as described in II.A.1.a-b are 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 as described in II.A.1.a-b 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


1.) Attempt to prescribe clozapine as described in II.A.1.a-b 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, and by calling the Clozapine REMS Program Contact Center at 844-267-8678

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

- Clozapine REMS Knowledge Assessment for Healthcare Providers
- Clozapine REMS Prescriber Enrollment Form
- Clozapine REMS Prescriber Designee Enrollment Form
- A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia
- Clozapine REMS Patient Enrollment Form
- Clozapine REMS Program Website
2. Pharmacies that dispense clozapine are certified

Outpatient Pharmacies

a. To become certified to dispense clozapine, outpatient pharmacies must:

i. Designate an authorized representative to complete certification on behalf of the pharmacy using the appropriate form:

1.) Clozapine REMS Outpatient 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:


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 Clozapine REMS Knowledge Assessment for Healthcare Providers

iii. Put processes and procedures in place to ensure the following requirements are completed:

1.) Obtain a Predis pense Authorization each time from the Clozapine REMS Program by accessing the Clozapine REMS Program Website, Clozapine REMS Program Contact Center, or enabling the pharmacy management system to support communication with the Clozapine REMS Program system

2.) 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 or a third party acting on behalf of the Clozapine Sponsors

Reference ID: 4376730
3.) Recertify in the Clozapine REMS Program every two years

4.) Comply with audits by the Clozapine Sponsors or a third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program

b. As a condition of certification:

i. Pharmacies that support electronic communication verification with the Clozapine REMS Program system must:

1.) Ensure the pharmacy enables its pharmacy management system to support communication with the Clozapine REMS Program system using established telecommunication standards and runs validation test transaction(s) to validate the system enhancements

2.) Dispense clozapine to patients only after obtaining a Predispense Authorization each time by processing all clozapine prescriptions, including cash claims, through their pharmacy management system to electronically:

a.) Verify the prescriber is certified in the Clozapine REMS Program

b.) Verify the patient is enrolled in the Clozapine REMS Program

c.) Verify the ANC is current (within 7 days of the Predispense Authorization transaction date for weekly monitoring, 15 days for every two weeks monitoring and 31 days for monthly monitoring)

d.) Verify the ANC is within the acceptable range described in the Prescribing Information, or that a certified prescriber has authorized clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia

e.) Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program

ii. Pharmacies that do not support electronic telecommunication verification with the Clozapine REMS Program system must dispense clozapine to patients only after obtaining a Predispense Authorization each time by accessing the Clozapine REMS Program Website or calling the Clozapine REMS Program Contact Center to:

1.) Verify the prescriber is certified in the Clozapine REMS Program

2.) Verify the patient is enrolled in the Clozapine REMS Program
3.) Verify the ANC is current (within 7 days of the Predispense Authorization transaction date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring)

4.) Verify the ANC is within the acceptable range described in the Prescribing Information, or that the certified prescriber has authorized clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia

5.) Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program

**Inpatient Pharmacies**

c. To become certified to dispense clozapine, inpatient pharmacies must:

i. Designate an authorized representative to complete the certification process on behalf of the pharmacy using the *Clozapine REMS Inpatient 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 *Clozapine REMS 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. Each pharmacist must be trained by reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and successfully completing the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

iii. Put processes and procedures in place to ensure the following requirements are completed prior to the initial inpatient dispensing of clozapine:

   1.) Perform an Eligibility Check from the Clozapine REMS Program by accessing the Clozapine REMS Program Website or contacting the Clozapine REMS Program Contact Center to verify the patient is enrolled in the Clozapine REMS Program

   2.) Obtain a current ANC by accessing the Clozapine REMS Program Website, contacting the Clozapine REMS Program Contact Center, or by accessing the inpatient medical record

   3.) Verify that the ANC is within the acceptable range described in the Prescribing Information or that the prescriber has authorized clozapine treatment for patients
with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia

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 or a third party acting on behalf of the Clozapine Sponsors

v. Comply with audits by the Clozapine Sponsors or a third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program

d. As a condition of certification, inpatient pharmacies must:

i. Dispense clozapine only after:

1.) Performing an Eligibility Check by accessing the Clozapine REMS Program Website or calling the Clozapine REMS Program Contact Center to verify the patient is enrolled in the Clozapine REMS Program;

2.) Verifying that the patient’s ANC obtained from the Clozapine REMS Program Website, the Clozapine REMS Program Contact Center, or the patient’s inpatient medical record is current; and,

3.) Verifying that the ANC is within the acceptable range described in the Prescribing Information or that the prescriber has authorized clozapine treatment for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia

ii. Dispense no more than a 7-day temporary supply of clozapine to an enrolled patient upon discharge from the healthcare facility

e. Clozapine Sponsors must:

i. Ensure that pharmacies that dispense clozapine are certified, in accordance with the requirements described above

ii. Ensure that authorized representatives can complete the pharmacy certification process and 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. Ensure that pharmacies renew certification in the Clozapine REMS Program every two years

v. Verify every two years that the authorized representative’s name and contact information corresponds to that of the current designated authorized representative for
the certified pharmacy; and if different, require the pharmacy to recertify with a new authorized representative

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

- Clozapine REMS Knowledge Assessment for Healthcare Providers
- Clozapine REMS Inpatient Pharmacy Enrollment Form
- Clozapine REMS Outpatient 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 A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia unless clinical judgment indicates that the patient’s adherence to the treatment regimen will be negatively impacted by providing A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia

   ii. Been informed by the prescriber of the risks of clozapine and the Clozapine REMS Program requirements, using A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia

b. Clozapine Sponsors must:

   i. Ensure that the certified prescriber can 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 Pharmacies that dispense clozapine are certified’)

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

a. Clozapine Sponsors must ensure that before dispensing clozapine the certified pharmacy can verify the ANC is current and,

   i. Within the acceptable range described in the Prescribing Information; or,
ii. The prescriber has authorized clozapine treatment (Treatment Rationale) for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia

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 the 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 the 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. 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 or a third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program

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. Monitoring distribution data and auditing 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 Clozapine REMS Program requirements.

4. Clozapine Sponsors must ensure that pharmacies’ REMS requirements are met and may decertify 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 within 70 calendar days of approval of the 02/2019 REMS modification, the Clozapine REMS Program Website is fully operational and all materials listed in or appended to the Clozapine REMS Program document are available through the Clozapine REMS Program Website (www.clozapinerems.com) or by calling the Clozapine REMS Program Contact Center at 844-267-8678.

8. The Clozapine REMS Program Website (www.clozapinerems.com) must continue for the duration of the REMS. Additionally,

   a. The Clozapine REMS Program Website must include the following online capabilities for certified Healthcare Providers, their designees, or pharmacy staff, as applicable:

      i. completion of prescriber and pharmacy certification,

      ii. enrollment and management of patients,

      iii. provision of Predispose Authorizations; and,

      iv. provision of Eligibility Check results

   b. The Clozapine REMS Program Website must include the option to print versions of the Clozapine REMS Program materials.

   c. The individual, product-specific clozapine websites for Healthcare Providers 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. Initial pharmacy audit must be implemented within 180 days following approval of the current Clozapine REMS modification;

b. Subsequent audits will be administered every two years thereafter; and,

c. 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 annually beginning February 28, 2020. 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.
This guide is intended to educate Healthcare Providers about clozapine and the Clozapine REMS Program. During the launch of the Clozapine REMS Program, there were challenges that required an extension of the phased implementation period. This guide is reflective of the full implementation of the Clozapine REMS Program, which is expected in [TBD]. For the current state of the Clozapine REMS Program, expected full implementation dates and important updates on the transition period, please see the Clozapine REMS Frequently Asked Questions (FAQs) on the Clozapine REMS Program Website at www.clozarinerems.com.

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 absolute neutrophil count (ANC) monitoring
- Prescriber requirements for the Clozapine REMS Program
- Pharmacy requirements for the Clozapine REMS Program
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The Clozapine REMS Program</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>• Important Terms</td>
<td>4</td>
</tr>
<tr>
<td>2.</td>
<td>ANC, Neutropenia, and Patient ANC Monitoring</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>• What is ANC?</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>• What is the risk of severe neutropenia associated with clozapine?</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>• What is Benign Ethnic Neutropenia (BEN)?</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>• What are the treatment recommendations and monitoring requirements for patients taking clozapine?</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>• Can a patient continue clozapine treatment with an ANC less than 1000/µL?</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>• If a patient develops a fever, how is clozapine treatment managed?</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>• How is clozapine discontinued for neutropenia?</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>• How is a patient monitored if clozapine treatment is discontinued for neutropenia?</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>• Can a patient be rechallenged with clozapine?</td>
<td>10</td>
</tr>
<tr>
<td>3.</td>
<td>Clozapine REMS Program Requirements for Prescribers</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>• What is the role of prescribers in the Clozapine REMS Program?</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>• What do I tell my patients about clozapine?</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>• How do I enroll a patient?</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>• What if my patient has been treated with clozapine before?</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>• How do I find out if my patient was listed in the National Non-Rechallenge Master File?</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>• How do I submit ANC results for my patients?</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>• When should I submit a patient's ANC to the Clozapine REMS Program?</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>• How do I authorize continuation of clozapine when my patient's ANC is less than 1000/µL (general population) or less than 500/µL (patients with BEN)?</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>• What is a Treatment Rationale?</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>• How can I provide a Treatment Rationale?</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>• What if my clozapine patient is under hospice care?</td>
<td>15</td>
</tr>
<tr>
<td>4.</td>
<td>Clozapine REMS Program Requirements for Pharmacies</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>• What types of pharmacies must be certified?</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>• What is an Authorized Representative?</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>• What is a Predispose Authorization (PDA)?</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>• What is the role of pharmacy Authorized Representative in the Clozapine REMS Program?</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>• How do I verify the patient is authorized to receive clozapine?</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>- Outpatient Pharmacies WITH Electronic Telecommunication Verification</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>- Outpatient Pharmacies WITHOUT Electronic Telecommunication Verification</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>- Inpatient Pharmacies</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>• How does an outpatient pharmacy authorize continuation of clozapine when the patient’s prescriber is not certified in the Clozapine REMS Program?</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>• What is a Dispense Rationale?</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>• How can I provide a Dispense Rationale?</td>
<td>22</td>
</tr>
<tr>
<td>5.</td>
<td>Reporting Adverse Events Associated with Clozapine</td>
<td>24</td>
</tr>
<tr>
<td>6.</td>
<td>Clozapine REMS Program Information and Resources</td>
<td>24</td>
</tr>
</tbody>
</table>
Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/µL). 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
- Fazaclor® (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 (who prescribe clozapine for outpatient use)**
- Must certify in the Clozapine REMS Program to prescribe clozapine
- Must enroll all patients in the Clozapine REMS Program
- Must submit patients’ ANCs to the Clozapine REMS Program for every prescription of clozapine according to the patient’s monitoring frequency:
  - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
  - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
  - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date

*Assumes the lab draw date is day 0

**Pharmacies**
- Must certify in the Clozapine REMS Program to dispense clozapine
- Must verify the prescriber is certified and the patient is enrolled prior to dispensing clozapine
- Must verify the ANC is within the acceptable range described in the Prescribing Information, or that the prescriber has authorized the continuation of clozapine treatment by providing a “Treatment Rationale” for patients with an ANC that falls below the acceptable range when the prescriber determines the benefits outweigh the risks of developing severe neutropenia
- Prior to dispensing clozapine, verify ANC is current (within 7/15/31 days prior to the “Predisperse Authorization”/“Eligibility Check” transaction date)

**Patients**
- Must be enrolled in the Clozapine REMS Program by the prescriber to receive clozapine
- Must comply with the ANC testing requirements
Important Terms Used in the Clozapine REMS Program:

- **Predis pense Authorization (PDA):** An authorization given to outpatient pharmacies which reflects that the safe-use conditions for that patient have been met. The PDA is an electronic code provided by the Clozapine REMS Program verifying that the patient is enrolled, the prescriber and pharmacy are certified, and that the ANC is on file, current and within acceptable range. This PDA then permits dispensing of clozapine to the patient.

- **Treatment Rationale (TR):** A justification used by a prescriber to allow a patient having moderate neutropenia (ANC 500-999/µL for the general population) or severe neutropenia (ANC < 500/µL for general population and patients with documented BEN) to continue treatment. Only prescribers can confirm that benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia.

- **Dispense Rationale (DR):** The opportunity provided by the Clozapine REMS Program to certified outpatient pharmacies to apply clinical judgment and continue to dispense clozapine to enrolled patients when a patient’s prescriber is not certified in the Clozapine REMS Program. The Clozapine REMS Program alerts the pharmacy if the prescriber is not certified in the Clozapine REMS Program, and prevents a PDA from being issued for a clozapine dispense unless the pharmacy provides a “Dispense Rationale” authorizing dispensing. The Dispense Rationale is valid for only 72 hours (3 calendar days) and can be provided a maximum of 3 times in a rolling six-month period.

- **Eligibility Check (EC):** The process inpatient pharmacies use to determine whether a patient can receive clozapine. Obtained by using the Clozapine REMS Program Website or Clozapine REMS Program Call Center, the EC verifies the patient is enrolled, the ANC is on file, current, and within acceptable range.

- **Inpatient pharmacy:** a pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).

- **Outpatient pharmacy:** a pharmacy dispensing clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

- **Absolute neutrophil count (ANC):** laboratory parameter for monitoring patients for clozapine-induced neutropenia.

- **Benign Ethnic Neutropenia (BEN):** a condition observed in certain ethnic groups whose average ANC is lower than “standard” laboratory ranges for neutrophils compared to the general population. Patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine.
Clozapine and the Risk of Neutropenia:
A Guide for Healthcare Providers

2 Absolute Neutrophil Count (ANC), Neutropenia, and Patient ANC Monitoring

What is ANC?

Absolute neutrophil count (ANC) is the laboratory parameter for monitoring patients for clozapine-induced neutropenia. Prescribers must submit 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:

\[
\text{Absolute Neutrophil Count} = \left( \frac{\text{Total WBC Count}}{\text{Total percentage of neutrophils}^*} \right) \times \text{obtained from the differential}
\]

* neutrophils 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/μL
- 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.
What is Benign Ethnic Neutropenia (BEN)?

BEN is a condition observed in certain ethnic groups whose average ANCs are lower than “standard” laboratory ranges for neutrophils. Because of this condition, patients 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 documented BEN, so the patient is monitored according to the correct ANC monitoring algorithm.

A few important things to know about patients documented 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 frequency for patients in the general population as well as patients who have documented BEN is 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/µL for the general population, ANC greater than or equal to 1000/µL for patients with BEN) for the first six months of therapy, monitoring frequency can be reduced to every two 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 monthly.

The Clozapine REMS Program will alert prescribers via their website dashboard when a patient qualifies for a change in ANC monitoring frequency.
### Table 1: Recommended Monitoring Frequency and Clinical Decisions by ANC Level

<table>
<thead>
<tr>
<th>ANC Level</th>
<th>Treatment Recommendation</th>
<th>ANC Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Normal Range for a New Patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GENERAL POPULATION</strong></td>
<td>• Initiate treatment</td>
<td>• Weekly from initiation to six months</td>
</tr>
<tr>
<td>• ANC ≥ 1500/µL</td>
<td>• If treatment interrupted:</td>
<td>• Every two weeks from 6 to 12 months</td>
</tr>
<tr>
<td></td>
<td>- &lt; 30 days, continue monitoring as before</td>
<td>• Monthly after 12 months</td>
</tr>
<tr>
<td>• Obtain at least two baseline ANC levels</td>
<td>• Discontinuation for reasons other than neutropenia</td>
<td>• See Section 2.4 of the full Prescribing Information</td>
</tr>
<tr>
<td>before initiating treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BEN POPULATION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ANC ≥ 1500/µL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Obtain at least two baseline ANC levels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>before initiating treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **Mild Neutropenia**                          |                                                                  |                                                    |
| (1000 - 1499/µL)*                             | • Continue treatment                                           |                                                    |
| **GENERAL POPULATION**                       |                                                                  |                                                    |
| **BEN POPULATION**                            | • Mild neutropenia is normal range for BEN population,          |                                                    |
| • Obtain at least two baseline ANC levels     | continue treatment                                             |                                                    |
| before initiating treatment                   |                                                                  |                                                    |
| • If treatment interrupted:                   |                                                                  |                                                    |
| - < 30 days, continue monitoring as before    |                                                                  |                                                    |
| - ≥ 30 days, monitor as if new patient        |                                                                  |                                                    |
| • Discontinuation for reasons other than      |                                                                  |                                                    |
| neutropenia                                    |                                                                  |                                                    |

| **Moderate Neutropenia**                      |                                                                  |                                                    |
| (500 - 999/µL)*                               | • Recommend hematology consultation                             |                                                    |
| **GENERAL POPULATION**                       | • Interrupt treatment for suspected clozapine-induced neutropenia |                                                    |
| • Resume treatment once ANC normalizes to     | • Daily until ANC ≥ 1000/µL, then                                |                                                    |
| ≥ 1000/µL                                     | • Three times weekly until ANC ≥ 1500/µL                       |                                                    |
| • If patient rechallenged, resume treatment   | • Once ANC ≥ 1500/µL check ANC weekly for 4 weeks,             |                                                    |
| as a new patient under “Normal BEN Range”     | then return to patient’s last “Normal Range” ANC monitoring    |                                                    |
| *ANC monitoring interval**                    | interval**                                                      |                                                    |
| **BEN POPULATION**                            | • Recommend hematology consultation                             |                                                    |
| • Continue treatment                          | • Three times weekly until ANC ≥ 1000/µL or patient’s known     |                                                    |
| • Obtain at least two baseline ANC levels     | baseline.                                                      |                                                    |
| before initiating treatment                   | • Once ANC ≥ 1000/µL or patient’s known baseline,               |                                                    |
| • If patient rechallenged, resume treatment   | check ANC weekly for 4 weeks, then return to patient’s last     |                                                    |
| as a new patient under “Normal BEN Range”     | “Normal BEN Range” ANC monitoring interval**                   |                                                    |
| *ANC monitoring interval**                    |                                                                |                                                    |
| **Severe Neutropenia**                        | • Recommend hematology consultation                             |                                                    |
| (< 500/µL)*                                   | • Interrupt treatment for suspected clozapine-induced neutropenia |                                                    |
| **GENERAL POPULATION**                       | • Do not rechallenge unless prescriber determines benefits     |                                                    |
| • Do not rechallenge unless prescriber       | outeweight risks                                               |                                                    |
| determines benefits outeweight risks          |                                                                  |                                                    |
| **BEN POPULATION**                            | • Recommend hematology consultation                             |                                                    |
| • Interrupt treatment for suspected           | • Daily until ANC ≥ 1000/µL                                    |                                                    |
| clozapine-induced neutropenia                 | • Three times weekly until ANC ≥ 1500/µL                       |                                                    |
| • Do not rechallenge unless prescriber       | • If patient rechallenged, resume treatment as a new patient   |                                                    |
| determines benefits outeweight risks          | under “Normal Range” monitoring once ANC ≥1500/µL             |                                                    |
| **BEN POPULATION**                            | • Daily until ANC ≥ 500/µL                                     |                                                    |
| • If patient rechallenged, resume treatment   | • Three times weekly until ANC ≥ patient’s established baseline|                                                    |
| as a new patient under “Normal BEN Range”     | • If patient rechallenged, resume treatment as a new patient   |                                                    |
| *ANC monitoring interval**                    | monitoring once ANC ≥1500/µL or patient’s baseline              |                                                    |

* 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

---

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

- at least 1500/µL for the general population
- at least 1000/µL for patients diagnosed with BEN

During treatment, monitor ANC regularly as described in Table 1 below.
Can a patient continue clozapine treatment with an ANC less than 1000/μL?

For Patients in the General Population

Yes; prescribers may choose to continue clozapine treatment in patients with ANCs less than 1000/μL. 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/μL are at risk of developing complications of severe neutropenia including serious infection and death.

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

For Patients with documented BEN

Yes; the Prescribing Information for clozapine recommends interrupting clozapine treatment for patients with BEN only when the ANC is less than 500/μL. No interruption in treatment is recommended for ANC 500-999/μL, 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/μL, initiate appropriate neutropenia work-up 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 most recent ANC result. Abrupt treatment discontinuation is necessary for moderate to severe neutropenia that you suspect is caused by clozapine.
How is a patient monitored if clozapine treatment is discontinued for neutropenia?

After discontinuing clozapine, monitor ANC according to the recommendations in Table 2 as shown below.

Table 2: Recommended monitoring frequency when clozapine treatment is discontinued

<table>
<thead>
<tr>
<th>Moderate Neutropenia (500 to 999/µL)*</th>
<th>GENERAL POPULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Daily until ANC ≥ 1000/µL, then</td>
</tr>
<tr>
<td></td>
<td>Three times weekly until ANC ≥ 1500/µL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severe Neutropenia (less than 500/µL)*</th>
<th>GENERAL POPULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Daily until ANC ≥ 1000/µL, then</td>
</tr>
<tr>
<td></td>
<td>Three times weekly until ANC ≥ 1500/µL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BEN POPULATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Daily until ANC ≥ 500/µL</td>
</tr>
<tr>
<td></td>
<td>Three times weekly until ANC ≥ patient’s established baseline</td>
</tr>
</tbody>
</table>

* Confirm all initial reports of ANC less than 1500/µL (ANC < 1000/µL 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/µL and for patients with documented BEN until their ANC is greater than or equal to 1000/µL 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/μL) or severe clozapine-related neutropenia (ANC less than 500/μL), 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 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?

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Review the full Prescribing Information for clozapine</td>
</tr>
</tbody>
</table>
| Step 2 | Certify* in the Clozapine REMS Program by:  
- Passing the Clozapine REMS 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 which can lead to serious infection and death |
| Step 5 | Check the ANC for each patient according to the monitoring requirement |
| Step 6 | Submit each ANC for each patient to the Clozapine REMS Program within 7/15/31 days of the lab draw date according to the patient’s monitoring frequency on the file with 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 14 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.

*Prescribers who prescribe clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition) are not required to certify in the Clozapine REMS Program. Patients in this setting are required to be enrolled in the Clozapine REMS Program in order to receive clozapine. If a patient in this setting is not enrolled, he/she must be enrolled by a certified prescriber before being allowed to receive clozapine.

What do I tell my patients about clozapine?

Use the patient counseling tool entitled, A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia. 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 (Patient Counseling Information) of the clozapine Prescribing Information for additional important counseling messages for your clozapine patients.

You may choose not to provide A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia 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 in one of two ways:

1. By signing in to the Clozapine REMS Program Website at www.clozapinerems.com and enrolling the patient online
2. By downloading a Clozapine REMS Patient Enrollment Form from the Clozapine REMS Program Website at 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 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).

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 be able to access the patient’s ANC history.

If you cannot find the patient, contact the Clozapine REMS Program Contact Center 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 Contact Center 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/μL or an ANC less than 1,000/μL.

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.

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 Contact Center at 844-267-8678 for assistance.

How do I report ANC results for my patients?

For patients in an **outpatient** setting:

Prescribers or their designees are responsible for submitting ANC for each prescription to the Clozapine REMS Program before clozapine can be dispensed by a pharmacy to patients treated on an outpatient or chronic basis, including but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

**For patients in an inpatient setting:**

Pharmacists must verify the patient is enrolled in the Clozapine REMS Program before clozapine can be dispensed by a pharmacy within a facility that dispenses clozapine to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).

While you are not required to submit ANCs to the Clozapine REMS Program before clozapine can be dispensed to a patient in an inpatient setting, you (or the certified pharmacy responsible for the patient in the hospital) are encouraged to submit ANCs to the Clozapine REMS Program with a blood draw date within the patient’s monitoring frequency on file with the Clozapine REMS Program.

While the patient is hospitalized, remember to monitor ANC according to the patient’s ANC monitoring frequency on file with the Clozapine REMS Program.
For Prescribers in an Outpatient setting:

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
- 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

* When using the Clozapine REMS ANC Lab Reporting Form to submit patient ANC to the Clozapine REMS Program, prescribers can enter the Patient ID number found on the prescriber dashboard on the website. This is also known as the Patient Enrollment ID.

When should I submit a patient’s ANC to the Clozapine REMS Program?

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

<table>
<thead>
<tr>
<th>Monitoring Frequency</th>
<th>ANC Blood Draw Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekly</td>
<td>Labs must be within 7 days of the lab draw* date</td>
</tr>
<tr>
<td>Every two weeks</td>
<td>Labs must be within 15 days of the lab draw* date</td>
</tr>
<tr>
<td>Monthly after 12 months</td>
<td>Labs must be within 31 days of the lab draw* date</td>
</tr>
</tbody>
</table>

* Assumes the lab draw date is day 0.

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

How do I authorize continuation of clozapine when my patient’s ANC is less than 1000/µL (general population) or less than 500/µL (patients with BEN)?

When a patient’s ANC is less than 1000/µL (general population) or less than 500/µL (patients with documented BEN), a prescriber may provide a Treatment Rationale to authorize clozapine treatment to continue.

What is a Treatment Rationale?

An 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 can I provide a Treatment Rationale?

- The Clozapine REMS Program will alert the prescriber if an ANC is submitted 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 continuation of treatment.
- The Clozapine REMS Program will change the treatment status automatically of a patient with a low ANC to “interrupted” or “discontinued”, according to the recommendations in the Prescribing Information, found in Table 1 above.
Clozapine and the Risk of Neutropenia:
A Guide for Healthcare Providers

• 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., by providing a Treatment Rationale).

Prescribers must confirm treatment continuation one of two ways:

- By signing in to the Clozapine REMS Program Website at www.clozapinerems.com and providing a Treatment Rationale online
- By faxing a signed Clozapine REMS 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 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.
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 the section, “How do I verify the patient is authorized to receive clozapine?”

An **inpatient pharmacy** is a pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).

An **outpatient pharmacy** is a pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

The designated authorized representative for the pharmacy will complete the *Clozapine REMS Inpatient Pharmacy Enrollment Form* and/or the *Clozapine REMS Outpatient 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 completed online.

Who 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 the pharmacy authorized representative in the Clozapine REMS Program?"

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

- Pharmacy Manager; or
- 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:

- Director of Pharmacy Services, or
- Corporate Executive overseeing Pharmacy Services

What is a Predispose Authorization (PDA)?

Before clozapine can be dispensed to a patient by a pharmacy dispensing clozapine to patients treated on an outpatient or chronic basis, including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, the pharmacy must obtain a PDA each time 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 within acceptable range described in the Prescribing Information, or the prescriber has provided a Treatment Rationale
- ANC is current (i.e., submitted within 7/15/31 days prior to the PDA transaction date according to the patient’s monitoring frequency on file with the Clozapine REMS Program)

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 using the Clozapine REMS Program Website at www.clozapinerems.com
- By calling the Clozapine REMS Program Contact Center at 844-267-8678

Note: Inpatient pharmacies are not required to obtain a PDA. Inpatient pharmacies must complete an Eligibility Check for each patient before dispensing clozapine. For additional details about the Eligibility Check, please refer to the Clozapine REMS Eligibility Check Fact Sheet, or visit the Clozapine REMS Program Website at www.clozapinerems.com.
What is the role of the pharmacy authorized representative in the Clozapine REMS Program?

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

- **Step 1**: Review the 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 *Clozapine REMS Knowledge Assessment for Healthcare Providers*
  - Completing the *Clozapine REMS Inpatient Pharmacy Enrollment Form and/or the Clozapine REMS Outpatient 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 ensure pharmacy staff obtain a PDA (for outpatient pharmacies) or conduct an *Eligibility Check* (for inpatient pharmacies) to verify that it is safe to dispense clozapine
- **Step 5**: Renew certification in the Clozapine REMS Program every two years from initial enrollment to maintain certification to order and dispense clozapine

In addition, the authorized representative of a pharmacy that uses electronic telecommunication verification must:
- Ensure the pharmacy enables its pharmacy management system to support electronic communication with the Clozapine REMS Program
- Run the verification test transactions to ensure system connectivity

**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 (outpatient or inpatient) and your pharmacy’s telecommunication capabilities.
Dispensing Information for All Outpatient Pharmacies

- The amount of clozapine that can be dispensed depends on when the patient’s next blood draw is scheduled to occur according to the monitoring frequency 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.
- If a PDA is not received because a patient’s prescriber is not certified in the Clozapine REMS Program, certified pharmacies can apply clinical judgment and provide a Dispense Rationale to dispense clozapine.

Outpatient Pharmacies WITH 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 each time a clozapine prescription is dispensed.

Dispensing

Before you dispense clozapine to each patient, you must:

Step 1: Obtain a PDA using the pharmacy management system

All prescriptions require a PDA prior to dispensing, including those paid for in cash and/or not using insurance for reimbursement.

Step 2: Before issuing the PDA, the Clozapine REMS Program will verify the following:

- The prescriber is certified in the Clozapine REMS Program
- The patient is enrolled in the Clozapine REMS Program
- The outpatient pharmacy is certified in the Clozapine REMS Program
- The ANC is current according to the patient’s monitoring frequency on file (i.e., the most recent ANC submitted is within 7/15/31 days prior to the PDA transaction date) with the Clozapine REMS Program
- The ANC is within an acceptable range described in the Prescribing Information, or the prescriber has provided a Treatment Rationale

Step 3: Once a PDA is obtained, 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 provide a message to explain why you are not authorized to dispense clozapine to the patient
- The pharmacist is encouraged to submit the patient’s ANC to the Clozapine REMS Program at intervals consistent with the patient’s monitoring frequency, or if you have an ANC more current than the one reported in the PDA result, submit it to the Clozapine REMS Program by:
  - By signing in to the Clozapine REMS Program Website at 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
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 each time a clozapine prescription is dispensed.

Dispensing
Before you dispense clozapine to each patient, you must obtain a PDA by:

Step 1: Access the Clozapine REMS Program in one of two ways:

- Sign in to the Clozapine REMS Program Website at www.clozapinerems.com, or
- Call the Clozapine REMS Program Contact Center at 844-267-8678

Step 2: Provide the following information:
- Patient Name
- Patient Date of Birth
- Prescriber
- Dispense Date
- NDC
- Days’ Supply
- Quantity

Step 3: Before issuing the PDA, the Clozapine REMS Program will verify the following for you:
- The prescriber is certified in the Clozapine REMS Program
- The patient is enrolled in the Clozapine REMS Program
- The outpatient pharmacy is certified in the Clozapine REMS Program
- The ANC is current according to the patient’s monitoring frequency on file (i.e., the most recent ANC submitted is within 7/15/31 days prior to the PDA transaction date) with the Clozapine REMS Program
- The ANC is within an acceptable range described in the Prescribing Information, or the prescriber has provided a Treatment Rationale

Step 4: 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 provide a message to explain why you are not authorized to dispense clozapine to the patient
- The pharmacist is encouraged to submit the patient’s ANC to the Clozapine REMS Program at intervals consistent with the patient’s monitoring frequency.
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.

Obtaining a PDA is not required in an inpatient setting.

Dispensing

Before you dispense the first inpatient dose of clozapine to each patient, the inpatient pharmacist must complete an Eligibility Check as follows:

Step 1: Access the Clozapine REMS Program by:
- Signing in to the website at www.clozapinerems.com, or
- Calling the Clozapine REMS Program Contact Center at 844-267-8678

Step 2: Obtain an Eligibility Check to verify the patient is enrolled in the Clozapine REMS Program. To obtain an Eligibility Check, you must provide the following information:
- Pharmacy Location Information
- Patient Name
- Patient Date of Birth
- Prescriber
- Dispense Date
- NDC

Step 3: Verify the ANC is within acceptable range as described in the Prescribing Information, or the prescriber has authorized the continuation of clozapine treatment by either (a) completing an Eligibility Check or (b) reviewing the patient’s medical record in their hospital’s medical record system.

Step 4: Verify the ANC is current according to the patient’s ANC monitoring frequency on file (i.e., submitted within 7/15/31 days prior to the Eligibility Check transaction date) with the Clozapine REMS Program by either (a) completing an Eligibility Check or (b) reviewing the patient’s medical record in their hospital’s medical record system.

The pharmacist is encouraged to submit the patient’s ANC obtained at the inpatient facility to the Clozapine REMS Program at intervals consistent with the patient’s monitoring frequency. ANC results may be submitted:
- 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 does an outpatient pharmacy authorize continuation of clozapine when the patient’s physician is not certified in the Clozapine REMS Program?

Outpatient pharmacies may provide a *Dispense Rationale* to dispense clozapine to a patient.

**What is a Dispense Rationale?**

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

- The Clozapine REMS Program will alert the pharmacy if the prescriber is not certified in the Clozapine REMS Program when a PDA is requested. A PDA will not be issued for a clozapine dispense unless the pharmacy provides a *Dispense Rationale* to authorize a dispense.
- In order for a patient to be eligible for a *Dispense Rationale*, that patient must:
  - Be enrolled in the Clozapine REMS Program
  - Have an acceptable ANC value on file or, if the ANC on file is low indicating moderate or severe neutropenia, a *Treatment Rationale* must be on file
- The *Dispense Rationale* is valid for 72 hours (3 calendar days).
- The *Dispense Rationale* will be limited to no more than three (3) *Dispense Rationales* for an individual patient within a rolling six (6) month period.
- Pharmacies must fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.

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

Certified authorized representatives and enrolled pharmacy staff for certified pharmacies provide the *Dispense Rationale* electronically via one of two available processes, depending on whether your pharmacy requests a *Predispose Authorization* by using the Clozapine REMS Program Website (see section A. below) or by using the pharmacy network system, i.e., “switch” (see section B. below).
A. Pharmacies using the Clozapine REMS Program Website to request a **Predispose Authorization** should:

**Step 1:** Log in to the Clozapine REMS Program Website at www.clozapinerems.com.

**Step 2:** Access the dashboard.

**Step 3:** Select ‘Predispose Authorization’ from the drop-down menu and click the Go button.

**Step 4:** Enter the patient information on the ‘Predispose Authorization’ screen and click Submit. The ‘Predispose Authorization Result’ screen will appear with a reject message.

**Step 5:** Click the ‘Provide a Dispense Rationale for this patient’ check box at the bottom of the ‘Predispose Authorization Result’ screen and click the Submit button.

**Step 6:** If the Dispense Rationale was provided successfully, a success screen will appear.

B. Pharmacies using the using the pharmacy network system (i.e., “switch”) to request a **Predispose Authorization** should:

**Step 1:** Log in to the Clozapine REMS Program Website at www.clozapinerems.com.

**Step 2:** Access the dashboard.

**Step 3:** Select ‘Dispense Rationale’ from the drop-down menu and click the Go button.

**Step 4:** Enter the patient information on the Dispense Rationale screen and click Submit.

**Step 5:** The ‘Dispense Rationale Result’ screen will appear with a reject message similar to the switch reject message.

**Step 6:** Click on the ‘Provide a Dispense Rationale for this patient’ check box at the bottom of the ‘Dispense Rationale Result’ screen and click Submit.

**Step 7:** If the Dispense Rationale is provided successfully, a success screen will appear.

**Step 8:** Reprocess the claim transaction through the pharmacy switch system.

Note: Please wait approximately 2 minutes before going back to the switch to reprocess the claim transaction.

If you experience any issues, please call the Clozapine REMS Program Contact Center at 844-267-8678.
5 Reporting Adverse Events Associated with Clozapine

Report suspected adverse events directly to the Clozapine REMS Program Contact Center 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.

6 Clozapine REMS Program Information and Resources

Additional Clozapine REMS Program information and resources are available online at www.clozapinerems.com or by calling 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 single shared Clozapine REMS Program.

A. True  
B. False

**Question 2**

Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

A. True  
B. False

**Question 3**

Severe neutropenia is defined as:

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

**Question 4**

Before initiating treatment with clozapine:

A. A baseline absolute neutrophil count (ANC) must be at least 1000/µL for a patient with documented benign ethnic neutropenia (BEN)  
B. A baseline absolute neutrophil count (ANC) must be at least 1500/µL for a patient who is part of the general population (i.e., the patient does not have documented BEN)  
C. A baseline absolute neutrophil count (ANC) is not necessary  
D. Both A and B

Please fax this Clozapine REMS Knowledge Assessment for Healthcare Providers to the Clozapine REMS Program at 844-404-8876. Print your full name and NPI below to ensure it is associated with your program record.

Name: ______________________ NPI: ______________________ Fax: ______________________
Question 5
Before clozapine is dispensed to a patient, a certified prescriber must:
A. Determine if the patient has documented BEN
B. Enroll the patient in 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 submit it to the Clozapine REMS Program
F. All of the above

Question 6
In the outpatient setting, prescribers must submit the ANC to the single shared Clozapine REMS Program before the patient can be dispensed clozapine.
A. True
B. False

Question 7
Before clozapine can be dispensed, a pharmacist in an outpatient pharmacy must:
A. Verify the patient is enrolled in the single shared Clozapine REMS Program
B. Verify the prescriber is certified in the single shared Clozapine REMS Program
C. Verify the ANC is acceptable or verify the prescriber has authorized continuing treatment if the ANC is abnormal
D. Obtain a “Predispense Authorization” each time from the Clozapine REMS Program
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 documented BEN, which of the following statements are true?

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

B. Patients with BEN are healthy and do not suffer from repeated severe infections

C. Patients with BEN are NOT at increased risk for developing clozapine-induced neutropenia

D. Before starting clozapine, additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Hematology consultation may be necessary

E. All of the above statements are true

**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 ≥1500/μL if the patient is part of the general population (i.e., if the patient does not have documented BEN)

B. Mild neutropenia is within the normal range for a patient with documented BEN

C. If the patient has documented BEN, ANC monitoring should be conducted: weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months

D. All of the above
Question 12

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

A. Treatment should be continued regardless of whether the patient is part of the general population or has documented BEN
B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt therapy and conduct ANC monitoring: daily until ANC ≥ 1000/µL; three times weekly until ANC ≥ 1500/µL; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
C. The ANC monitoring schedule is the same regardless of whether the patient is part of the general population or has BEN
D. None of the above

Question 13

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

A. Treatment should be interrupted regardless of whether the patient is part of the general population or has BEN and a hematology consultation should be considered; resume treatment only if the prescriber determines that the benefits of clozapine therapy outweigh the risks
B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt treatment and conduct ANC monitoring: daily until ANC ≥ 1000/µL; three times weekly until ANC ≥ 1500/µL
C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
D. All of the above
Prescriber Enrollment Form

Instructions

For immediate certification, please go to 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 prescribe clozapine, you must:

2. Successfully complete the Clozapine REMS Knowledge Assessment for Healthcare Providers
3. Complete and submit this one-time Clozapine REMS Prescriber Enrollment Form along with the completed Clozapine REMS Knowledge Assessment for Healthcare Providers

If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

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

*Assumes the lab draw date is day 0

Prescriber Information (All Fields Required Unless Otherwise Indicated)

<table>
<thead>
<tr>
<th>First Name:</th>
<th>MI (opt):</th>
<th>Last Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI:</td>
<td>DEA:</td>
<td>Credentials (MD, DO, NP, PA):</td>
</tr>
<tr>
<td>Email:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinic/Practice Name:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>State:</td>
<td>Zip Code:</td>
</tr>
<tr>
<td>Phone:</td>
<td>Ext (opt):</td>
<td>Fax:</td>
</tr>
<tr>
<td>Contact Preference (please select one):</td>
<td>Email</td>
<td>Fax</td>
</tr>
</tbody>
</table>

Prescriber’s Signature: ____________________________ Date (MM/DD/YYYY): __________

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

Reference ID: 4376730
Instructions

For immediate online absolute neutrophil count (ANC) reporting, please go to www.clozapinerems.com.

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

Prescribers must:

• Order ANC according to the monitoring frequency described in the Prescribing Information.
• Submit ANC according to the patient’s monitoring frequency on file with the Clozapine REMS Program:
  • For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
  • For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
  • For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of the lab draw* date

*Assumes the lab draw date is day 0

---

Section 1: ANC Lab Reporting and Prescriber Information (All Fields Required)

Name: ___________________________ NPI or DEA: ___________________________

Phone: __________________________ Email: __________________________ Fax: __________________________

Submitter:  [ ] Prescriber  [ ] Prescriber Designee  [ ] Pharmacy

Patient Information (All Fields Required Unless Otherwise Indicated)

Name: ___________________________ Rems Patient ID (optional): ___________________________

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

ANC Monitoring (All Fields Required)

Blood Draw Date (MM/DD/YYYY): ___________________________ ANC (per μL): ___________________________

---

Section 2: Patient Treatment Status Update (If Applicable)

Complete this section 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: [ ] Active*  [ ] Interrupted  [ ] Discontinued

*Restarting or continuing clozapine requires a “Treatment Rationale” for patients with moderate or severe neutropenia. Please refer to Treatment Rationale section below.

---

Section 3: Prescriber or Designee Authorization: Patient Monitoring Frequency Update (If Applicable)

Complete this section to change the 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. By selecting ‘monthly,’ I attest that this patient: is eligible for monthly monitoring, has been on clozapine therapy continuously for one year, and all ANC results in the past 12 months have been within normal limits according to the Prescribing Information.

[ ] Weekly  [ ] Every 2 weeks  [ ] Monthly

Prescriber Name: ___________________________ NPI or DEA#: ___________________________

Prescriber or Designee Signature: ___________________________ Date (MM/DD/YYYY): ___________________________

---

Section 4: Prescriber Authorization: Treatment Rationale or Hospice Care (If Applicable)

Complete this section to continue treatment if the patient has moderate neutropenia (ANC 500-999/μL for the general population) or severe neutropenia (ANC<500/μL for general population and patients with benign ethnic neutropenia).

To provide a Treatment Rationale, check one and sign below:

[ ] Benefits of continuing clozapine treatment outweigh the risk of neutropenia
[ ] Until next ANC Lab
[ ] Until (MM/DD/YYYY) ________________ (not to exceed 6 months)
[ ] This is a patient with documented benign ethnic neutropenia (no expiration)

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.

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

Prescriber Name: ___________________________ NPI or DEA#: ___________________________

Prescriber Signature: ___________________________ Date (MM/DD/YYYY): ___________________________

---
General Information

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

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

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, and that you understand:

- Clozapine is only available through the Clozapine REMS Program and I must comply with the program requirements
- There is a risk of severe neutropenia associated with clozapine, which can lead to serious infection and death
- The ANC testing and monitoring requirements as described in the clozapine Prescribing Information

**Outpatient Settings**: An ANC must be submitted to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed and per the Monitoring Schedule described in the Prescribing Information:

- For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
- For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
- For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date

*Assumes the lab draw date is day 0

- A certified prescriber must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed to a patient
- Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program
- Personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine 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 in to the website using my credentials

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

**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 listed below.

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

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

---

**Designee Requirements**

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

I understand:

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

   *Assumes the lab draw date is day 0

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

---

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

<table>
<thead>
<tr>
<th>First Name:</th>
<th>Last Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>Ext (opt):</td>
</tr>
<tr>
<td>Contact Preference (please select one):</td>
<td>Email</td>
</tr>
</tbody>
</table>

**Prescriber Designee Signature:** Date (MM/DD/YYYY): 

---

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

<table>
<thead>
<tr>
<th>First Name:</th>
<th>Last Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>REMS Certification ID (opt):</td>
<td>DEA:</td>
</tr>
<tr>
<td>NPI:</td>
<td></td>
</tr>
</tbody>
</table>

**Prescriber’s Signature:** Date (MM/DD/YYYY):
Please select the best answer for the following question. This question must be answered correctly to become certified:

**Question 1**

I have reviewed the requirements of the Clozapine REMS Program.

A. Yes
B. No

Please fax this Clozapine REMS Knowledge Assessment for Prescriber Designees to the Clozapine REMS Program at 844-404-8876. Print your full name and NPI below so we can correctly associate your progress with your program record.

Name: ________________________  NPI: ________________________  Fax: ________________________
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, which can lead to serious infections and death.** 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 blood testing requirements for clozapine?

<table>
<thead>
<tr>
<th>Get your Blood Tested</th>
<th>Your doctor will give you an order to have blood tests done.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>You will need to get your blood tested on the following schedule or as directed by your doctor:</td>
</tr>
<tr>
<td></td>
<td>- Weekly blood tests for the first 6 months you are taking clozapine</td>
</tr>
<tr>
<td></td>
<td>- Every 2 weeks for the next 6 months if your ANC stays normal</td>
</tr>
<tr>
<td></td>
<td>- Monthly after the first year if your ANC stays normal</td>
</tr>
</tbody>
</table>

| 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.

Report any side effects directly to the Clozapine REMS Program at 844-267-8678. You can also report negative side effects to the FDA at www.fda.gov/medwatch, or call 800-FDA-1088.
For immediate enrollment, please go to www.clozapinerems.com.

For enrollment via fax, please complete all required fields below and fax to 844-404-8876. For enrollment via the Clozapine REMS Program 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:

- The 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 single shared Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. In order to treat a patient with clozapine, the patient MUST be enrolled in the Clozapine REMS Program. To enroll a patient, you must:

1. Provide the patient or caregiver with A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia
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 A Guide for Patients and Caregivers: What You Need to Know about Clozapine and Neutropenia 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 copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

### Patient Information (All Fields Required)

<table>
<thead>
<tr>
<th>Field</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td>Yes</td>
</tr>
<tr>
<td>Last Name:</td>
<td>Yes</td>
</tr>
<tr>
<td>Gender: Male</td>
<td>Yes</td>
</tr>
<tr>
<td>Gender: Female</td>
<td>Yes</td>
</tr>
<tr>
<td>Race: Caucasian</td>
<td>Yes</td>
</tr>
<tr>
<td>Race: African American</td>
<td>Yes</td>
</tr>
<tr>
<td>Race: Asian</td>
<td>Yes</td>
</tr>
<tr>
<td>Race: Hispanic</td>
<td>Yes</td>
</tr>
<tr>
<td>Race: Other</td>
<td>Yes</td>
</tr>
<tr>
<td>Date of Birth (MM/DD/YYYY)</td>
<td>Yes</td>
</tr>
<tr>
<td>Zip Code:</td>
<td>Yes</td>
</tr>
<tr>
<td>Is this patient actively on clozapine therapy?</td>
<td>Yes, No, Unknown</td>
</tr>
</tbody>
</table>

### Lab Information (Not Required for Enrollment, Required for Dispense)

<table>
<thead>
<tr>
<th>Field</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Draw Date (MM/DD/YYYY):</td>
<td>No</td>
</tr>
<tr>
<td>ANC (per μL):</td>
<td>No</td>
</tr>
</tbody>
</table>

### Prescriber Information (All Fields Required)

<table>
<thead>
<tr>
<th>Field</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Yes</td>
</tr>
<tr>
<td>NPI or DEA:</td>
<td>Yes</td>
</tr>
<tr>
<td>Phone:</td>
<td>Yes</td>
</tr>
<tr>
<td>Email:</td>
<td>No</td>
</tr>
<tr>
<td>Fax:</td>
<td>No</td>
</tr>
<tr>
<td>Submitter: Prescriber</td>
<td>Yes</td>
</tr>
<tr>
<td>Submitter: Prescriber Designee</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Benign Ethnic Neutropenia (BEN) Patient Attestation* (Signature required only for attestation of BEN diagnosis)

By signing below, I attest that the above is a patient with documented benign ethnic neutropenia.

<table>
<thead>
<tr>
<th>Prescriber Signature:</th>
<th>Date (MM/DD/YYYY):</th>
</tr>
</thead>
</table>

*Enrollment for patients with documented 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.
Instructions

Complete this form if your pharmacy is within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).

If your pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, please complete the Clozapine REMS Outpatient Pharmacy Enrollment Form.

For immediate certification, please go to www.clozapinerems.com.

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. A confirmation will be sent via the contact preference chosen below.

Use this form to enroll a SINGLE pharmacy location. To enroll MULTIPLE pharmacy locations, you must go to 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:

2. Successfully complete the Clozapine REMS Knowledge Assessment for Healthcare Providers
3. Complete and submit this Clozapine REMS Inpatient Pharmacy Enrollment Form along with the completed Clozapine REMS 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 copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

---

Inpatient Pharmacy 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 absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. Establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
   a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
   b. Verify the patient is enrolled in the Clozapine REMS Program by:
      - Signing in to the Clozapine REMS Program Website at www.clozapinerems.com to complete an “Eligibility Check”, or
      - Calling the Clozapine REMS Program Contact Center at 844-267-8678
   c. Verify the ANC is current based on the patient’s monitoring frequency (within 7 days of the Eligibility Check date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
   d. Verify the last ANC is acceptable or verify the certified prescriber’s authorization for clozapine treatment if the ANC is low indicating moderate or severe neutropenia
   e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber

2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit

3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine

Continued on Page 2
### Inpatient Pharmacy Authorized Representative Responsibilities (continued)

4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program

5. Clozapine REMS Program personnel may contact my pharmacists to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program

6. Inpatient pharmacies must complete an Eligibility Check and verify ANC/prescriber authorization before dispensing clozapine products to a patient to ensure compliance with the required safe-use conditions

7. Provide dispensing location information to the Clozapine REMS Program

8. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials

9. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program

Note: Inpatient pharmacies are **not** required to obtain a “Predispense Authorization” (PDA) prior to dispensing clozapine.

### Inpatient Pharmacy Information (All Fields Required)

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Name:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Address:</td>
<td>[ ]</td>
</tr>
<tr>
<td>City:</td>
<td>[ ]</td>
</tr>
<tr>
<td>State:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Zip Code:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### Inpatient Pharmacy Identifiers (At Least One Required)

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCPDP:</td>
<td>[ ]</td>
</tr>
<tr>
<td>NPI:</td>
<td>[ ]</td>
</tr>
<tr>
<td>DEA:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### Authorized Representative Information (All Fields Required)

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Last Name:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Credentials:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Phone:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Fax:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Email:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Contact Preference (please select one):</td>
<td>[ ]</td>
</tr>
<tr>
<td>Authorized Representative Signature:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Date:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
Outpatient Pharmacy Enrollment Form

Instructions

Complete this form if your pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

If your pharmacy is within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition), please complete the Clozapine REMS Inpatient Pharmacy Enrollment Form.

For immediate certification, please go to www.clozapinerems.com.

To submit this form via fax, please complete all required fields below and fax to 844-404-8876. A confirmation will be sent via the contact preference chosen below.

Use this form to enroll a SINGLE pharmacy location. To enroll MULTIPLE pharmacy locations, you must go to 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:

2. Successfully complete the Clozapine REMS Knowledge Assessment for Healthcare Providers
3. Complete and submit this Clozapine REMS Outpatient Pharmacy Enrollment Form along with the completed Clozapine REMS 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 copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

Outpatient Pharmacy 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 absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. My pharmacy will establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
   a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
   b. Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
   c. Verify the ANC is current based on the patient’s monitoring frequency (within 7 days of the “Predispense Authorization” (PDA) transaction date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
   d. Verify the last ANC is acceptable or verify the certified prescriber’s authorization for continuing clozapine treatment if the ANC is low indicating moderate or severe neutropenia
   e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy, institution, or prescriber who is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact my pharmacists to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. Provide dispensing location information to the Clozapine REMS Program
7. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials
8. Outpatient pharmacies must obtain a PDA each time before dispensing clozapine products to a patient to ensure compliance with the required safe-use conditions
9. Report dosing information for each clozapine prescription/fill to the Clozapine REMS Program
10. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program

Can your outpatient pharmacy management system adjudicate claims online?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 below 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.</td>
<td></td>
</tr>
<tr>
<td>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 <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or call the Clozapine REMS Program Contact Center to confirm safe-use conditions (as outlined in attestation #8) before dispensing each clozapine prescription. A complete PDA request requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber’s NPI or DEA.</td>
<td></td>
</tr>
</tbody>
</table>

Outpatient Pharmacy Information (All Fields Required)

- **Pharmacy Name:**
- **Address:**
- **City:**
- **State:**
- **Zip Code:**

Outpatient Pharmacy Identifiers (NCPDP and NPI Required)

- **NCPDP:**
- **NPI:**
- **DEA:**

Authorized Representative Information (All Fields Required)

- **First Name:**
- **Last Name:**

- **Credentials:**
  - [ ] RPh
  - [ ] PharmD
  - [ ] BCPS
  - [ ] Other

- **Phone:**
- **Fax:**
- **Email:**

- **Contact Preference (please select one):**
  - [ ] Email
  - [ ] Fax

- **Authorized Representative Signature:**
- **Date:**
Instructions

Contact your Pharmacy Network Account Manager to submit this form to the Clozapine REMS Program.

Please complete all required fields below. 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
3. Successfully complete the Clozapine REMS Knowledge Assessment for Healthcare Providers
4. Complete and submit this Clozapine REMS Chain Headquarters Pharmacy Enrollment Form along with the completed Clozapine REMS Knowledge Assessment for Healthcare Providers
5. Implement the necessary staff training and processes at both a headquarters level and at each dispensing location to comply with the Clozapine REMS Program requirements

If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

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 absolute neutrophil count (ANC) monitoring
3. There is a different ANC monitoring algorithm for patients with documented benign ethnic neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to 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 chain headquarters pharmacy, I agree to comply with the following program requirements:

1. My chain headquarters 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 based on the patient’s monitoring frequency (within 7 days prior to the PDA transaction date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring)
     • The last ANC is acceptable or the certified prescriber has authorized clozapine treatment if the ANC is low indicating moderate or severe neutropenia
   – This information will be verified each time 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, or prescriber who is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit.
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine.
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program.
5. Clozapine REMS Program personnel may contact pharmacists in my pharmacies 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 in to the website using my credentials.
**Chain Headquarters Pharmacy Information (All Fields Required)**

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Chain ID:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>City:</td>
<td>State:</td>
</tr>
<tr>
<td>Phone:</td>
<td>Fax:</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td>Last Name:</td>
</tr>
<tr>
<td>Credentials:</td>
<td></td>
</tr>
<tr>
<td>RPh</td>
<td>PharmD</td>
</tr>
<tr>
<td>BCPS</td>
<td>Other</td>
</tr>
<tr>
<td>Phone:</td>
<td>Fax:</td>
</tr>
<tr>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td>Contact Preference</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td>Fax</td>
</tr>
</tbody>
</table>

**Authorized Representative Signature:**

**Date (MM/DD/YYYY):**

**Next Steps**

1. Once this form is processed, you will receive instructions about submitting test transaction(s) to the Clozapine REMS Program to ensure that your pharmacy management system is 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 training.

3. Once each dispensing location is trained, it is your responsibility to report documentation of training to the Clozapine REMS Program online via [www.clozapinerems.com](http://www.clozapinerems.com), or by calling 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, the dispensing location will be certified and permitted to purchase, receive, and dispense clozapine.
Pharmacy Staff Enrollment Attestation Language – Web Only

Pharmacy staff can access the Clozapine REMS Program online at www.clozapinerems.com to complete the following:

- Enter an absolute neutrophil count (ANC) result for a patient
- Verify a patient is enrolled in the Clozapine REMS Program
- In an outpatient pharmacy:
  - Obtain a “Predispense Authorization” (PDA)\(^1,2\) or
  - Provide a “Dispense Rationale”
- In an inpatient pharmacy:
  - Complete an “Eligibility Check”

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

\(^1\) Inpatient pharmacies do not need to obtain a PDA.
\(^2\) Outpatient pharmacies with a pharmacy management system that supports electronic communication with the Clozapine REMS Program using established telecommunications standards do not obtain a PDA via the Clozapine REMS Program Website.

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

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

1. What is a REMS?

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

2. What is the Clozapine REMS Program?

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

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

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

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

Download program enrollment forms here

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

For current Prescribing Information for clozapine, visit the Resources page on the Clozapine REMS Program Website at www.clozapinerems.com.
5. What are the different roles of healthcare staff in the Clozapine REMS Program?

There are 4 different roles in the Clozapine REMS Program:

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

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

<table>
<thead>
<tr>
<th>Role</th>
<th>Certify or Enroll?</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber</td>
<td>Certify</td>
<td>Prescriber Certification Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Complete the Clozapine REMS Prescriber Enrollment Form online at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pass the Clozapine REMS Knowledge Assessment for Healthcare Providers via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center</td>
</tr>
<tr>
<td>Prescriber Designee</td>
<td>Enroll</td>
<td>Prescriber Designee Enrollment Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Complete the Clozapine REMS Prescriber Designee Enrollment Form online at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Become associated in the system with a certified prescriber</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Be approved by a certified prescriber</td>
</tr>
<tr>
<td>Role</td>
<td>Certify or Enroll?</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>--------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Authorized Representative (Non-chain Pharmacy)</td>
<td>Certify</td>
<td><strong>Authorized Representative Certification Process</strong>  &lt;br&gt;- Complete the <em>Clozapine REMS Outpatient Pharmacy Enrollment Form</em> or the <em>Clozapine REMS Inpatient Pharmacy Enrollment Form</em> online at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876  &lt;br&gt;- Pass the <em>Clozapine REMS Knowledge Assessment for Healthcare Providers</em> via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center  &lt;br&gt;- Renew certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment</td>
</tr>
<tr>
<td>Authorized Representative (Chain Pharmacy)</td>
<td>Certify</td>
<td><strong>Chain Pharmacy Authorized Representative Certification Process</strong>  &lt;br&gt;- Work with an account manager from your pharmacy network system (i.e., the “switch”) provider to complete the certification process  &lt;br&gt;- Pass the <em>Clozapine REMS Knowledge Assessment for Healthcare Providers</em> via the Clozapine REMS Program Website, or by completing and faxing it to the Clozapine REMS Program Contact Center at 844-404-8876  &lt;br&gt;- Renew certification of their pharmacies in the Clozapine REMS Program every two years from initial enrollment</td>
</tr>
<tr>
<td>Pharmacy Staff</td>
<td>Enroll</td>
<td><strong>Pharmacy Staff Enrollment Process</strong>  &lt;br&gt;- Enroll online as pharmacy staff at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a>  &lt;br&gt;- Become associated in the system with a pharmacy</td>
</tr>
</tbody>
</table>
### Prescriber

<table>
<thead>
<tr>
<th><strong>Definition</strong></th>
<th><strong>Responsibilities</strong></th>
</tr>
</thead>
</table>
| A prescriber is any healthcare professional who prescribes clozapine to a patient. **An inpatient pharmacy operates within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).** | **Certification Process**
- A prescriber must certify in the Clozapine REMS Program:
  - Review the Prescribing Information for clozapine
  - Complete the *Clozapine REMS Prescriber Enrollment Form*
  - Pass the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
- Prescribers who order clozapine to be dispensed from an inpatient pharmacy** are not required to become certified in the Clozapine REMS Program.

**Responsibilities**
- Prescribers who order clozapine to be dispensed from an outpatient pharmacy are required to become certified in the Clozapine REMS Program and must adhere to the following requirements:
  - Enroll every new patient in the Clozapine REMS Program
  - Counsel each patient (or their caregiver) about the risk of severe neutropenia which can lead to serious infection and death
  - Check the ANC for each patient according to the monitoring requirements
  - Submit and verify ANC according to the patient’s monitoring frequency on file with the Clozapine REMS Program:
    - For weekly monitoring frequency, ANC must be submitted within 7 days of the lab draw* date
    - For every two weeks monitoring frequency, ANC must be submitted within 15 days of the lab draw* date
    - For monthly monitoring frequency, ANC must be submitted within 31 days of the lab draw* date
  - *Assumes the lab draw date is day 0*

In the future¹, a lab that is not current according to the patient’s monitoring frequency will prevent a patient from receiving clozapine. The Clozapine REMS Program will then require the ANC to be aligned with the patient’s monitoring frequency. In the interim, warning messages will alert the pharmacy if the ANC is overdue.

---

¹Reference ID: 4376730
Definition | Responsibilities
--- | ---
 | • Provide a “Treatment Rationale” to authorize the continuation of clozapine therapy for patients with moderate or severe neutropenia if it is determined that:
  o The benefits of clozapine therapy outweigh the risks
  o The patient has documented benign ethnic neutropenia (BEN)

1Once the date for full program implementation has been confirmed, updated information will be provided to prescribers and pharmacies and will also be available on the Clozapine REMS Program Website.

Prescriber Designee

| Definition | Responsibilities
--- | ---
A Healthcare Provider, office staff member, or pharmacist designated by a certified prescriber to act on their behalf | **Enrollment Process**
|  | • Complete the Clozapine REMS Prescriber Designee Enrollment Form online at www.clozapinerems.com or by faxing it to the Clozapine REMS Program Contact Center at 844-404-8876
|  | • Become associated in the system with a certified prescriber
|  | • Be approved by the associated prescriber

**Responsibilities**

• A prescriber designee can:
  o Enroll general population patients
  o Counsel patients
  o Check ANCs
  o Submit ANCs on the prescriber’s behalf
  o Change a patient’s monitoring frequency

• A prescriber designee cannot:
  o Enroll a patient with benign ethnic neutropenia (BEN)
  o Provide a Treatment Rationale for a patient
  o Designate a patient as a hospice patient
# Authorized Representative for Outpatient Pharmacy

<table>
<thead>
<tr>
<th>Definition</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>For outpatient pharmacies with a single location, the authorized representative may be a:</td>
<td>Certification Process</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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, or  
- Corporate Executive over-seeing Pharmacy Service  

The authorized representative represents the pharmacy and is responsible for ensuring the processes and procedures within the pharmacy are in place to comply with the Clozapine REMS Program requirements
### Definition

**Responsibilities**

- Renewing certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment

### Responsibilities

- Coordinate the activities required in the Clozapine REMS Program
- Establish and implement processes and procedures to ensure compliance with the safe-use conditions required in the Clozapine REMS Program

---

**Authorized Representative for Inpatient Pharmacy**

<table>
<thead>
<tr>
<th>Definition</th>
<th>Responsibilities</th>
</tr>
</thead>
</table>
| For inpatient pharmacies with a single location, the authorized representative may be a:  
- Pharmacy Manager, or  
- Staff Pharmacist  
If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement process for all the pharmacies in your organization, the authorized representative may be a:  
- Director of Pharmacy Services, or  
- Corporate Executive overseeing Pharmacy Service  
The authorized representative represents the pharmacy and is responsible for ensuring the processes and procedures within the pharmacy are in place to comply with the Clozapine REMS Program | Certification Process

- An authorized representative for a pharmacy must certify in the Clozapine REMS Program by:
  - Reviewing the Prescribing Information for clozapine
  - Certifying their pharmacy in the Clozapine REMS Program by:
    - Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
    - Completing the *Clozapine REMS Inpatient Pharmacy Enrollment Form*
    - Passing the *Clozapine REMS Knowledge Assessment for Healthcare Providers*
  - Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements
  - Putting processes and procedures in place to verify the patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine
  - Renewing certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment

<table>
<thead>
<tr>
<th>Certification Process</th>
<th>Responsibilities</th>
</tr>
</thead>
</table>
| - An authorized representative for a pharmacy must certify in the Clozapine REMS Program by:  
  - Reviewing the Prescribing Information for clozapine  
  - Certifying their pharmacy in the Clozapine REMS Program by:  
    - Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*  
    - Completing the *Clozapine REMS Inpatient Pharmacy Enrollment Form*  
    - Passing the *Clozapine REMS Knowledge Assessment for Healthcare Providers*  
  - Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements  
  - Putting processes and procedures in place to verify the patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine  
  - Renewing certification of their pharmacy in the Clozapine REMS Program every two years from initial enrollment | Coordinate the activities required in the Clozapine REMS Program  
Establish and implement processes and procedures to ensure compliance with the safe-use conditions required in the Clozapine REMS Program  
Verify every patient receiving clozapine is enrolled in the Clozapine REMS Program prior to dispensing |
### REMS Program requirements

<table>
<thead>
<tr>
<th>Definition</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before dispensing clozapine, inpatient pharmacies can:</td>
<td></td>
</tr>
<tr>
<td>o Verify the ANC is current (within 7 days of the “Eligibility Check” date for weekly monitoring, 15 days for every 2 weeks monitoring, and 31 days for monthly monitoring)</td>
<td></td>
</tr>
<tr>
<td>o Verify ANC is within the acceptable range or a certified prescriber has provided a <em>Treatment Rationale</em> to authorize the continuation of clozapine treatment</td>
<td></td>
</tr>
<tr>
<td>o Inpatient pharmacists are encouraged to submit the patient's ANC to the Clozapine REMS Program at intervals consistent with the patient's monitoring frequency.</td>
<td></td>
</tr>
</tbody>
</table>

### Pharmacy Staff

<table>
<thead>
<tr>
<th>Definition</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any pharmacist or pharmacy employee may assume the role of pharmacy staff member associated with a pharmacy to conduct basic program functions</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enrollment Process</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>o Enroll online as pharmacy staff</td>
<td></td>
</tr>
<tr>
<td>o Associate with a pharmacy</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient pharmacy staff must:</td>
<td></td>
</tr>
<tr>
<td>o Verify a prescriber is certified in the Clozapine REMS Program</td>
<td></td>
</tr>
<tr>
<td>o Verify the pharmacy is certified</td>
<td></td>
</tr>
<tr>
<td>o Verify a patient is enrolled in the Clozapine REMS Program</td>
<td></td>
</tr>
<tr>
<td>o Obtain a PDA before dispensing clozapine to a patient</td>
<td></td>
</tr>
<tr>
<td>o May submit an ANC for a patient</td>
<td></td>
</tr>
</tbody>
</table>

| Inpatient pharmacy staff must: |                                                                       |
| o Verify a patient is enrolled in the Clozapine REMS Program using the *Eligibility Check* |                                                                       |
| o Verify patient has an ANC on file and the ANC is current and within acceptable range via an *Eligibility Check* and/or review of the patient’s medical record |                                                                       |
| o Dispense clozapine to patients only after verifying safe-use conditions have been met |                                                                       |
| o May submit an ANC for a patient                                        |                                                                       |
6. Can a Healthcare Provider fulfill multiple roles in the Clozapine REMS Program?

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

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

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

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

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

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

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

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

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

The ANC Monitoring Table can be found on the Clozapine REMS Program Website:

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

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

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

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

*Assumes the lab draw date is day 0

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

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

11. How do I contact the Clozapine REMS Program?

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

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

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

To report a product complaint, or if you require medical information, you may also call the Clozapine REMS Program Contact Center at 844-267-8678.
13. What is the new certification deadline for prescribers and outpatient pharmacies?

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

Pharmacies

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

Outpatient Prescribers

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

Inpatient Prescribers

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

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

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

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

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

Note: A pharmacy cannot update a patient’s monitoring frequency. Pharmacies should work with the patient’s prescriber to update a patient’s monitoring frequency.
The ANC Monitoring Table can be found on the Clozapine REMS Program Website:

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

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

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

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

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

The guidelines outlined above for assigning a new monitoring frequency are consistent with the clozapine Prescribing Information.

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

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

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

If a prescriber needs to change a patient’s monitoring frequency, the prescriber can do so on the prescriber dashboard on the Clozapine REMS Program Website. The prescriber or the prescriber designee can also update a patient’s monitoring frequency by calling the Clozapine REMS Program Contact Center at 844-267-8678.
Clozapine REMS Program Contact Center at 844-267-8678, or by faxing the update via the *Clozapine REMS ANC Lab Reporting Form* to the Clozapine REMS Program Contact Center for processing.
17. How can a prescriber become certified in the single shared Clozapine REMS Program?

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

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

To complete certification on the Clozapine REMS Program Website:

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

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

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

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

18. When do I need to complete certification?

The new deadline for prescriber certification is February 28, 2019. If you are not certified by this date your patient may not be eligible to receive clozapine. Prescribers are highly encouraged to certify in the Clozapine REMS Program as soon as possible.
For further information on this change for prescribers who prescribe clozapine in an inpatient setting, please visit the Clozapine REMS Program Website at www.clozapinerems.com or call the Clozapine REMS Program Contact Center at 844-267-8678.

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

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

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

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

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

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

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

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

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

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

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

Yes; the Clozapine REMS Program allows a certified prescriber to identify a prescriber designee to perform some duties or functions on behalf of the prescriber. The prescriber’s designee(s) will need to enroll in the Clozapine REMS Program and become certified
before they can perform any duties or functions for their associated prescriber(s). A prescriber may have more than one prescriber designee.

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

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

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

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

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

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

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

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

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

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

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

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

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

Download program enrollment forms here
Patient Management

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

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

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

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

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

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

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

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

Download program enrollment forms here.

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

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

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

For organizations with high laboratory volumes, a simple automated interface can be implemented to electronically send ANC data for entry into the Clozapine REMS Program.
Please call the Clozapine REMS Program Contact Center at 844-267-8678 for more information on this process.

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

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

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

31. What is a Treatment Status?

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

There are four Treatment Statuses in the Clozapine REMS Program:

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

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

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

A Treatment Status of **Interrupted** or **Discontinued** will prevent a PDA from being provided and could result in a disruption of a patient’s clozapine therapy. If a prescriber determines that the benefits of continuing clozapine outweigh the risks when a patient’s Treatment Status was changed to **Interrupted**, the prescriber can provide a **Treatment Rationale** into the system and change the patient’s Treatment Status back to **Active** thereby allowing clozapine to be dispensed.
If a patient’s Treatment Status was changed to *Discontinued* because of a low ANC value, the Treatment Status will automatically return to *Active* only when a new/current lab is submitted with the patient’s ANC value within acceptable range.

**32. What is a Treatment Rationale?**

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

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

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

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

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

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

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

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

1. Faxing a signed *Clozapine REMS ANC Lab Reporting Form* to 844-404-8876 containing a completed *Treatment Rationale* section, or
2. Accessing the Clozapine REMS Program Website to provide a *Treatment Rationale* online. To do so, perform the following steps:
   a. **Log in** to the Clozapine REMS Program Website at [www.clozapinerems.com](http://www.clozapinerems.com).
   b. **Access** the dashboard.
c. Select ‘Change Treatment Rationale’ from the drop-down menu and click the GO button.
d. Enter the lab information on the ‘Lab Information’ screen and click Next. The user will be redirected back to the Dashboard after this step is complete.

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

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

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

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

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

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

Download Clozapine REMS ANC Lab Reporting Form

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

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

If a prescriber wishes to remove a patient from their list, they can deactivate the patient via their dashboard.
37. When discontinuing treatment, does the patient’s ANC need to be monitored for 4 weeks?

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

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

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

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

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

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

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Definition</th>
</tr>
</thead>
</table>
| Chain Pharmacy          | - A chain of retail pharmacies has an authorized representative located at a chain headquarters who is responsible for ensuring certification and training in the Clozapine REMS Program across all stores in the chain.  
- A chain pharmacy is contracted to participate with a pharmacy network provider.  
- Chain pharmacies must adjudicate claims through their Pharmacy Benefit Management System (PBMS) via electronic communication with the Clozapine REMS Program using established telecommunications standards (i.e., “the switch”).                                                                                                                                                  |
| Outpatient Pharmacy     | - Pharmacies are considered outpatient if the pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.  
- An outpatient pharmacy is an individual location or multiple stores with an authorized representative associated to the independent stores. The authorized representative is responsible for ensuring certification and training in the Clozapine REMS Program within the individual or multiple stores.  
- Even if a pharmacy has multiple locations, it is not considered a chain for the purposes of the REMS unless it has a single authorized representative at a corporate headquarters that is responsible for ensuring certification and training in the Clozapine REMS Program across all stores in the chain.  
- An outpatient pharmacy *may* be able to adjudicate claims via electronic communication with the Clozapine REMS Program using established telecommunications standards (i.e., “the switch”).  
- Outpatient pharmacies that cannot adjudicate claims via the switch must obtain a PDA via the Clozapine
<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Definition</th>
</tr>
</thead>
</table>
| Inpatient Pharmacy | - Pharmacies are considered inpatient if the pharmacy is within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).
- Inpatient pharmacies are required to perform an **Eligibility Check** to verify a patient is eligible to receive clozapine before dispensing. If the patient is found to not yet have been enrolled in the Clozapine REMS Program, he/she must be enrolled by a certified prescriber before being allowed to receive clozapine. |

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

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

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

In addition, PDA responses provide the dispensing pharmacy with the following information:
- The most recent ANC value and the associated blood draw date
- Patient monitoring frequency

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

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

Click here to access the **Clozapine REMS PDA Fact Sheet**.
43. What is an Eligibility Check?

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

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

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

All EC responses will provide the following information:
- The most recent ANC value and the associated blood draw date
- Patient monitoring frequency

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

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

Click here to access a Clozapine REMS Eligibility Check Fact Sheet.

44. How is an Eligibility Check different from a Predis pense Authorization?

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

45. What is a “Dispense Rationale”? 

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

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

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

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

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

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

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

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

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

1. **Log in to** the Clozapine REMS Program Website.
   
   Note: You must be enrolled as a pharmacy staff or certified as an authorized representative for the pharmacy.

2. **Access** the dashboard.

3. **Select** ‘*Predispense Authorization*’ from the drop-down menu and **click** the Go button.

4. **Enter the patient information** on the ‘*Predispense Authorization*’ screen and **click** Submit (see screenshot below.) The ‘*Predispense Authorization Result*’ screen will appear with a reject message.
Predispose Authorization

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

Patient Information
- First Name
- Last Name
- Date of Birth
- Zip Code

Add Patient Lab (optional)
- AMC value per millimeter (opt)
- Bleed Draw Date (opt)

Predispose Authorization Request
- Date of Service
- Manufacturer
- NDC Code Number
- Days Supply
- Quantity
- At least one identifier is required
  - Prescriber DEA
  - Prescriber NPI

For additional information about the Clozapine REMS Program, please call 844-267-8078.
5. Click on the ‘Provide a Dispense Rationale for this patient’ check box at the bottom of the ‘Predispense Authorization Result’ screen and click the Submit button. (see screenshot below)

![Provide Dispense Rationale for this patient](image)

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

6. If the Dispense Rationale was provided successfully, you will be taken to a success screen. (see screenshot below)
B. A pharmacy using the pharmacy network system (i.e., “switch”) to request a PDA should:

1. **Log in** to the Clozapine REMS Program Website.
   Note: You must be enrolled as a pharmacy staff or certified as an authorized representative for the switch pharmacy.

2. **Access** the dashboard.

3. **Select** ‘Dispense Rationale’ from the drop-down menu and **click** the Go button. (see screenshot below)
### Pharmacies

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

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Address</th>
<th>Pharmacy Type</th>
<th>Certification ID</th>
<th>Certification Status</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>aali shay ku</td>
<td>4343 n scottsdale rd. BURKEVILLE, Virginia 23922</td>
<td>Inpatient</td>
<td>FAC5413173002</td>
<td>Certified</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>Test Pharma</td>
<td>4343 n scottsdale rd. PHOENIX, Arizona 85054</td>
<td>Inpatient</td>
<td>FAC5413315247</td>
<td>Certified</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>Jea Inc</td>
<td>4343 n scottsdale rd. PhoENAIX, Arizona 85054</td>
<td>Outpatient</td>
<td>FAC5413637605</td>
<td>Certified</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>JC Pauny</td>
<td>4343 n richtard, PHOENAIX, Arizona 85054</td>
<td>Outpatient</td>
<td>FAC5413634942</td>
<td>Certified</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>Tata Pharma</td>
<td>4343 n scottsdale rd. LANSING, Michigan 48915</td>
<td>Outpatient</td>
<td>FAC5414118715</td>
<td>Incomplete</td>
<td>View/Update Pharmacy Profile Add Lab Dispense Authorization Dispense Rationale Recently Dispensed</td>
</tr>
<tr>
<td>Sharma Pharma</td>
<td>4343 N scottsdale rd. LANSING, Michigan 48912</td>
<td>Outpatient</td>
<td>FAC5414119840</td>
<td>Incomplete</td>
<td>— Please Select —</td>
</tr>
<tr>
<td>Inpatient</td>
<td>Address, SCOTTSDALE, Arizona 85250</td>
<td>Inpatient</td>
<td>FAC5414782350</td>
<td>Incomplete</td>
<td>— Please Select —</td>
</tr>
</tbody>
</table>

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

![Dispense Rationale](image)

**Dispense Rationale**

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

**Patient Information**

- First Name
- Last Name
- Date of Birth
- Zip Code

**Add Patient Lab (optional)**

- ANC value per micro litre (opt)
- Blood Draw Date (opt)

**Dispensation Information**

- Date of Service
- Manufacturer
- NDC# Number
- Days Supply
- Quantity

**At least one identifier is required**

- Prescriber DEA
- Prescriber NPI

---

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

---

Reference ID: 4376730
6. Click on the ‘Provide a Dispense Rationale for this patient’ check box at the bottom of the ‘Dispense Rationale Result’ screen and click the Submit button (see screenshot below).

7. If the Dispense Rationale is provided successfully, you will be taken to a success screen. (see screenshot below)
8. **Reprocess the claim transaction** through the pharmacy switch system. 
Note: **Please wait approximately 2 minutes** before going back to the switch to reprocess the claim transaction.

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

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

To certify in the Clozapine REMS Program, the authorized representative of a pharmacy must:
- Complete the *Clozapine REMS Inpatient Pharmacy Enrollment Form* or the *Clozapine REMS Outpatient Pharmacy Enrollment Form*
Complete the *Clozapine REMS Knowledge Assessment for Healthcare Providers*

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

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

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

48. **How often must pharmacies recertify?**

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

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

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

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

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

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

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

51. **What happens if a pharmacy is deactivated?**
Deactivated pharmacies will be unable to order or dispense clozapine. Previously certified pharmacies will be unable to obtain a *Predispense Authorization* from the Clozapine REMS Program until recertified.

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

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

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

53. What is an authorized representative?

Please refer to the FAQ on different roles of healthcare staff in the Clozapine REMS Program in the General Section of the FAQs.

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

Please refer to the FAQ on different roles of healthcare staff in the Clozapine REMS Program in the General Section of the FAQs.

55. When does certification need to be completed?

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

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

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

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

- A pharmacy that dispenses clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition), the pharmacy will be classified as an “inpatient pharmacy.”

- A pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, the pharmacy will be classified as an “outpatient pharmacy.”

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

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

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

Reference ID: 4376730
Pharmacy Enrollment Form and faxing them to the Clozapine REMS Program at 844-404-8876.

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

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

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

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

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

Access the pharmacy certification procedure here

61. The pharmacy has been certified but the system is reporting that the pharmacy is not certified. What are the next steps?
Please ensure you have completed the steps listed on the certification page. If you are still experiencing issues, please call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

62. Will patients still need to have blood draws?
Yes; blood draws for ANC monitoring are required prior to dispensing. Monitoring frequency (i.e., weekly, every 2 weeks, or monthly) is determined by the patient’s prescriber based on criteria in the clozapine Prescribing Information.
63. Can clozapine be dispensed to a patient without bloodwork?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Outpatient Pharmacy using the pharmacy management system:

“*REMS* - ANC results out of range. Results Last ANC: 400 01/12/16; MF=7d
“*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient.”
“*REMS* - ANC results not on file. Contact prescriber”

Outpatient Pharmacy using web-based PDA:

“*REMS* - ANC results out of acceptable range”
“*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient.”
“*REMS* - ANC results not on file. Contact prescriber”

Inpatient Pharmacy:

“*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient.”
69. Does a distributor have to enroll in the Clozapine REMS Program?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

You can create a user account for the Clozapine REMS Program Website. You will be asked to provide your contact information and create a username and password. Once the information is submitted online, you will be sent an email with a link to use in order to verify your account.
81. What if I do not receive the verification email after I created my account?

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

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

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

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

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

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

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

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

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

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

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

- In the Create an Account screen, you may enter the same email address in the My Information section for each account being set up. (see screenshot below)
In the Sign In section, do not use your email address as the username or select the checkbox to use email address as username. Please create a unique username for each account you create.

- You will need to log in to each account separately in order to access applicable role functionality.
  - For example, if you have an account as a prescriber designee and an account as a pharmacy staff, you would have to log out of one in order to access the other.
A single log in for multiple roles is not available at this time.

- You will receive Clozapine REMS Program communications to a single email address if these steps are followed.

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

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

You may change your username by signing in to your account on the Clozapine REMS Program Website and selecting the Change Username option from the links below your account link in the upper right corner of the website. (see screenshot below)
88. How does a Healthcare Provider change the email address on their REMS profile if they previously created an account with an email address they no longer wish to use?

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

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

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

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

Your Healthcare Provider can help you find a participating pharmacy. Please contact your Healthcare Provider for additional information about the Clozapine REMS Program.
The “Eligibility Check” (EC) evaluates criteria established by the Clozapine REMS Program to determine if it is safe to dispense clozapine to patients receiving inpatient medical care. This includes absolute neutrophil count (ANC) values.

An EC must be completed before dispensing an inpatient’s first dose of clozapine by using the Clozapine REMS Program Website at www.clozapinerems.com, or by calling the Clozapine REMS Program Contact Center at 844-267-8678.

An EC requires an ANC value which may be obtained through the Clozapine REMS Program, or by checking the patient’s medical records.

Inpatient pharmacies are encouraged to submit the patient’s ANC via the Clozapine REMS Program Website, by phone, or by fax according to the patient’s monitoring frequency (i.e., within 7 days of the EC date for weekly monitoring, within 15 days for every two weeks monitoring and within 31 days for monthly monitoring).

**HOW CAN I PERFORM AN ELIGIBILITY CHECK?**

**Option 1:** Use the Clozapine REMS Program Website:
- Log in to your account at www.clozapinerems.com
- Access the dashboard
- Select ‘Eligibility Check’ from the drop-down menu and click the GO button
- Enter the patient information on the ‘Eligibility Check’ screen and click Submit
  - A success message will appear or you will receive a warning message that will inform you of next steps to take. Refer to page 2 of this Clozapine REMS Eligibility Check Fact Sheet for further guidance.

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

**HOW CAN I SUBMIT ANC VALUES?**

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

**Option 1:** Submit via the Clozapine REMS Program Website:
- Log in to your account at www.clozapinerems.com
- Access the dashboard
- Select ‘Add Lab’ from the drop-down menu and click the GO button
- Enter the patient information and ANC results on the ‘Add Lab’ screen and click Submit
  - User will be returned to the dashboard when complete

**Option 2:** Fax to the Clozapine REMS Program:
- Visit www.clozapinerems.com
- Choose the Resources tab
- Click on Program Materials
- Select ‘Clozapine REMS ANC Lab Reporting Form’ from the list
- Print and complete the form
- Fax the completed form to 844-404-8876

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

**Option 3:** Call the Clozapine REMS Program Contact Center at 844-267-8678.
<table>
<thead>
<tr>
<th>REMS PROGRAM ELEMENT EVALUATED BY THE ELIGIBILITY CHECK</th>
<th>POSSIBLE OUTCOMES</th>
<th>ELIGIBILITY TO RECEIVE CLOZAPINE</th>
<th>ACTION BY PHARMACY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient enrollment in the Clozapine REMS Program</td>
<td>Patient is enrolled.</td>
<td>Eligibility Check Successful.</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td></td>
<td>Patient is not enrolled.</td>
<td>Eligibility Check Unsuccessful.</td>
<td>Do not dispense. Contact a certified prescriber (or his designee) to enroll new patient.</td>
</tr>
<tr>
<td>Patient absolute neutrophil count (ANC) is on file</td>
<td>ANC on file.</td>
<td>Eligibility Check Successful.</td>
<td>Check if ANC is acceptable. Dispense.</td>
</tr>
<tr>
<td></td>
<td>No ANC on file.</td>
<td>A warning message will be displayed but patient will remain eligible to receive clozapine.</td>
<td>Check inpatient's medical record to verify ANC. Apply clinical judgement whether to dispense.2 Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency.1</td>
</tr>
<tr>
<td>Last ANC value on file is acceptable</td>
<td>ANC on file.</td>
<td>Eligibility Check Successful.</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td></td>
<td>ANC on file for patient indicates moderate or severe neutropenia; and a &quot;Treatment Rationale&quot;3 is on file.</td>
<td>Eligibility Check Successful.</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td></td>
<td>ANC on file for patient indicates moderate or severe neutropenia; and a Treatment Rationale3 is not on file.</td>
<td>A warning message will be displayed but patient will remain eligible to receive clozapine.</td>
<td>Check patient's inpatient medical record to verify ANC is acceptable. Apply clinical judgement whether to dispense.2</td>
</tr>
<tr>
<td>ANC is current according to the patient's monitoring frequency1</td>
<td>ANC is current.</td>
<td>Eligibility Check Successful.</td>
<td>No action necessary. Dispense.</td>
</tr>
<tr>
<td></td>
<td>ANC is not current.</td>
<td>A warning message will be displayed but patient will remain eligible to receive clozapine.</td>
<td>Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency.1 Apply clinical judgement whether to dispense.2</td>
</tr>
</tbody>
</table>

1Monitoring frequency:
- For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the Eligibility Check date.
- For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the Eligibility Check date.
- For monthly monitoring frequency, the ANC submitted to the Clozapine REMS must be drawn* within 31 days prior to the Eligibility Check date.

*AAssumes lab draw date is day 0

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

3Treatment Rationale: a justification provided by a certified prescriber which allows a patient having moderate or severe neutropenia to continue treatment with clozapine.
# How to Start Clozapine and Monitor Patients

## Before Starting Clozapine Treatment

> Before starting treatment with clozapine, the baseline absolute neutrophil count (ANC) must be:

- At least 1500/µL for the general population, or
- At least 1000/µL for patients with documented benign ethnic neutropenia (BEN)

> It is no longer necessary to check the National Non-Rechallenge Master File (NNRMF) before starting treatment.

- The NNRMF is no longer available. All patients who were listed in the NNRMF were transferred into the Clozapine REMS Program. These patients are identified with a red flag in the Clozapine REMS Program.

## Monitoring and During Treatment

### Labs

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

  *Assumes the lab draw date is day 0*

- White blood cell (WBC) counts are not accepted. If you have a WBC count and differential, you may use the ANC calculator on the Clozapine REMS Program Website at [www.clozapinerems.com](http://www.clozapinerems.com) to determine the ANC.

- An ANC is normal if it is greater than or equal to 1000/µL for patients with BEN.

### Monitoring Frequency

- Patients may transition to less frequent ANC monitoring based on their history of continuous clozapine therapy and normal ANCs:
  - Weekly ANC monitoring is required for all patients during the first six months of treatment.
  - If the patient’s ANC remains in the normal range for the first six months of therapy, MF may be reduced to once every two weeks.
  - If the patient’s ANC continues to remain in the normal range for the second six months of treatment, ANC MF may be reduced to once monthly.

> Monitoring frequency is calculated based on the patient’s lab history in the Clozapine REMS Program. It is critical that all labs be submitted to the Clozapine REMS Program according to the patient’s MF to ensure that the patient’s monitoring frequency does not revert to a more frequent schedule.

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

  - In accordance with the clozapine Prescribing Information, if the patient had consistent ANCs submitted over the previous 12-month period, the patient was migrated with a monthly MF.
  - If a patient’s ANCs were inconsistently submitted to the registries in the previous 12-month period and there was a timeframe longer than 56 days between blood draw dates, the patient was migrated with a weekly MF.

- The guidelines outlined above for assigning a new MF are consistent with the Prescribing Information.

- If a prescriber needs to change a patient’s MF, the prescriber may do so via the Prescriber Dashboard on the Clozapine REMS Program Website. The prescriber or prescriber designee may also update a patient’s MF by calling the Clozapine REMS Program Contact Center at 844-267-8678.

- During the phased implementation period, the Clozapine REMS Program will not deny clozapine dispensing based on MF data. However, once the REMS Program is fully implemented, the MF is utilized to determine if a patient’s ANC is current. Therefore, accuracy of the MF is important as a factor in determining if a pharmacy will be authorized to dispense clozapine to the patient.

### Treatment Interruptions

- Treatment interruptions are now recommended at lower ANC thresholds than in previous versions of the Prescribing Information.
  - For general population patients, interrupt treatment if neutropenia is suspected to be clozapine-induced for ANC less than 1000/µL.
  - For patients with documented BEN, interrupt treatment if neutropenia is suspected to be clozapine-induced for ANC less than 500/µL.

- See Table 1 in the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* or Tables 2 and 3 in the clozapine Prescribing Information for more detailed treatment guidance.

### Ben Patients

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

### Hospice Patients

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

### Discontinuing Clozapine Treatment

- Four weeks of weekly monitoring for patients who are discontinuing clozapine treatment is no longer required.

- The duration and frequency of ANC monitoring is dependent on that patient’s last ANC and clinical status (see Section 2.4 in the clozapine Prescribing Information for more details).
A “Predispense Authorization” (PDA) determines if a patient is eligible to receive clozapine and provides an authorization for an outpatient pharmacy to dispense. An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis, including but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

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

### CLOZAPINE REMS PROGRAM ELEMENT EVALUATED BY THE PREDISPENSE AUTHORIZATION

<table>
<thead>
<tr>
<th>POSSIBILITY TO RECEIVE CLOZAPINE</th>
<th>ACTION BY PHARMACY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POSSIBLE OUTCOMES</strong></td>
<td><strong>All PDA responses will provide the dispensing pharmacy with the most recent absolute neutrophil count (ANC) value, the associated blood draw date, and the patient’s monitoring frequency.</strong></td>
</tr>
<tr>
<td><strong>ACTION BY PHARMACY</strong></td>
<td><strong>Pharmacies are encouraged to submit the patient’s ANCs through the Clozapine REMS Program Website, by phone, or by fax according to the patient’s monitoring frequency.</strong></td>
</tr>
</tbody>
</table>

### Patient enrollment in the Clozapine REMS Program

<table>
<thead>
<tr>
<th>Patient is enrolled</th>
<th>PDA Successful</th>
<th>No action necessary. Dispense.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient is not enrolled</td>
<td>PDA Unsuccessful</td>
<td>Contact a certified prescriber (or his designee) to enroll new patient. Do not dispense.</td>
</tr>
</tbody>
</table>

### Prescriber Certification

<table>
<thead>
<tr>
<th>Prescriber is certified</th>
<th>PDA Successful</th>
<th>No action necessary. Dispense.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber is not certified</td>
<td>PDA Unsuccessful</td>
<td>Contact prescriber to inform them they must be certified. Pharmacy can provide a “Dispense Rationale” and reattempt PDA.</td>
</tr>
</tbody>
</table>

### Pharmacy Certification

<table>
<thead>
<tr>
<th>Pharmacy is certified</th>
<th>PDA Successful</th>
<th>No action necessary. Dispense.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy is not certified</td>
<td>PDA Unsuccessful</td>
<td>Contact Pharmacy Manager to inform them the pharmacy must be certified to order, purchase, and dispense clozapine. Do not dispense.</td>
</tr>
</tbody>
</table>

### Patient ANC is on file

<table>
<thead>
<tr>
<th>ANC is on file</th>
<th>PDA Successful</th>
<th>No action necessary. Dispense.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No ANC on file</td>
<td>PDA Unsuccessful: A warning message will be displayed, reattempt PDA after ANC is obtained</td>
<td>If the pharmacist is in possession of an ANC, they are encouraged to submit the ANC to the Clozapine REMS Program; if not, contact the patient’s certified prescriber. Reattempt PDA after ANC is obtained.</td>
</tr>
</tbody>
</table>

### Last ANC value on file is acceptable

<table>
<thead>
<tr>
<th>ANC indicates moderate or severe neutropenia; and a “Treatment Rationale” is on file</th>
<th>PDA Successful</th>
<th>No action necessary. Dispense.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC on file for patient indicates moderate or severe neutropenia; and a Treatment Rationale is not on file</td>
<td>PDA Unsuccessful: A warning message will be displayed</td>
<td>Do not dispense, unless one of these two possible follow-up actions are successful:</td>
</tr>
<tr>
<td>• If the pharmacist is in possession of an ANC that is more current and acceptable, the pharmacist is encouraged to submit the ANC to the Clozapine REMS Program and reattempt PDA.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Contact the prescriber to provide a Treatment Rationale or current acceptable ANC, reattempt the PDA.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### ANC is current according to the patient’s monitoring frequency:1

<table>
<thead>
<tr>
<th>ANC is current</th>
<th>PDA Successful</th>
<th>No action necessary. Dispense.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC is not current</td>
<td>PDA Successful: a warning message will be displayed</td>
<td>Dispense clozapine; and:</td>
</tr>
<tr>
<td>• Submit current ANC results to the Clozapine REMS Program according to the patient’s monitoring frequency.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Contact Prescriber to inform them that the ANC is not current according to the patient’s monitoring frequency.1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

1**Monitoring frequency:**

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

2Assumes lab draw date is day 0

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

Please refer to page 2 for step-by-step instructions for requesting a PDA and submitting a Dispense Rationale or patient ANC values.
HOW DO I REQUEST A PREDISPENSE AUTHORIZATION?

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

Pharmacies that do not use an electronic pharmacy management system (without switch network access):
Option 1: Use the Clozapine REMS Program Website to:
1. Log in to your account at www.clozapinerems.com
2. Access the dashboard
3. Select ‘Predispense Authorization’ from the drop-down menu and click the GO button
4. Enter the patient information on the ‘Predispense Authorization’ screen and click Submit
5. The ‘Predispense Authorization Result’ screen will appear with a success or warning message. Refer to page 1 of this Fact Sheet for further guidance.
Option 2: Call the Clozapine REMS Program Contact Center at 844-267-8678.

HOW CAN I PROVIDE A DISPENSE RATIONALE?

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

Option 1: Pharmacies using the Clozapine REMS Program Website to request a PDA should:
1. Continue from Step 2b above at the PDA Result reject message screen.
2. Click the ‘Provide a Dispense Rationale for this patient’ check box at the bottom of the ‘PDA Result’ screen and click the Submit button.
3. If the Dispense Rationale was provided successfully, a success screen will appear.

Option 2: Pharmacies using the pharmacy network system (i.e., “switch”) to request a PDA should:
2. Access the dashboard.
3. Select ‘Dispense Rationale’ from the drop-down menu and click the Go button. Enter the patient information on the Dispense Rationale screen and click Submit.
4. The ‘Dispense Rationale Result’ screen will appear with a reject message similar to the switch reject message.
5. Click on the ‘Provide a Dispense Rationale for this patient’ check box at the bottom of the ‘Dispense Rationale Result’ screen and click Submit.
6. If the Dispense Rationale is provided successfully, a success screen will appear.
7. Wait approximately 2 minutes to reprocess the claim transaction through the pharmacy switch system.

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

HOW DO I SUBMIT ANC VALUES?

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

Option 1: Submit via the Clozapine REMS Program Website by:
1. Logging in at www.clozapinerems.com
2. Accessing the dashboard
3. Selecting ‘Add Lab’ from the drop-down menu and click the GO button
4. Entering the patient information and ANC results on the ‘Add Lab’ screen and click Submit
5. User will be returned to the dashboard when completed.

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

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

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

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

Clozapine REMS Program

November 2018
# Table of Contents

1. Static Pages
   1.1 Home Page ................................................................. 10
   1.2 Site Guide – Prescriber Tab .............................................. 11
   1.3 Site Guide – Pharmacy Tab .............................................. 12
   1.4 Site Guide – Patient Tab .................................................. 13
   1.5 Site Guide – Designee Tab ............................................... 14
   1.6 Site Guide – Pharmacy Staff Tab ...................................... 15
   1.7 Prescriber Certification .................................................. 16
   1.8 Prescriber Designee Certification .................................... 17
   1.9 Pharmacy Certification .................................................. 18
   1.10 Pharmacy Staff Enrollment ............................................ 19
   1.11 Patient Information – Home Page .................................... 20
   1.12 Program Materials ....................................................... 21
   1.13 Prescribing Information ............................................... 23
   1.14 Certification Lookup .................................................... 24
   1.15 Certification Lookup Results ......................................... 25
   1.16 Site Map ....................................................................... 26
   1.17 FAQs ........................................................................... 27
   1.18 FAQ – Pharmacy Authorized Representative .................... 30
   1.19 Contact Us .................................................................... 31

2. User Identification and Record Search
   2.1 User Identification .......................................................... 32
   2.2 Phone/Fax User Prescriber Search .................................... 33
   2.3 Phone/Fax User Prescriber Search with Results ................. 34
   2.4 Phone/Fax User Prescriber Designee Search ....................... 35
   2.5 Phone/Fax User Prescriber Designee Search with Results ... 36
   2.6 Phone/Fax User Pharmacy Search .................................... 37
   2.7 Phone/Fax User Pharmacy Search with Results ................. 38
   2.8 Phone/Fax User .............................................................. 39
   2.9 Phone/Fax User with Results ......................................... 40

3. Web Account ................................................................. 41
3.1 Create Account ................................................................................. 41
3.2 Account Verification .......................................................................... 42
3.3 Account Confirmation ........................................................................ 43
4. Prescriber Certification ............................................................................... 44
4.1 Prescriber Intake .............................................................................. 44
4.2 Prescriber Education Program ............................................................. 45
4.3 Prescriber Education Confirmation ....................................................... 46
4.4 Prescriber Intake Review ................................................................. 47
4.5 Prescriber Attestation ........................................................................ 48
4.6 Prescriber Confirmation ..................................................................... 49
5. Prescriber Designee Certification............................................................... 50
5.1 Prescriber Designee Intake ................................................................. 51
5.2 Prescriber Designee Education Program Page 1 ..................................... 52
5.3 Prescriber Designee Education Program Page 2 ..................................... 53
5.4 Prescriber Designee Knowledge Assessment ......................................... 54
5.5 Prescriber Designee Knowledge Assessment Confirmation – Success ...... 55
5.6 Prescriber Designee Knowledge Assessment Confirmation – Not Successful ................................................................................................ 56
5.7 Prescriber Designee Intake Review........................................................ 57
5.8 Prescriber Designee Attestation .......................................................... 58
5.9 Prescriber Designee Confirmation ........................................................ 59
6. Pharmacy Certification ............................................................................... 60
6.1 Pharmacy Certification – Home Page ................................................... 60
6.2 Role Selection – New User ................................................................. 61
6.3 Role Selection – Phone/Fax User .......................................................... 62
6.4 Role Selection Confirmation – Inpatient Pharmacy ................................ 63
6.5 Role Selection Confirmation – Outpatient Pharmacy .............................. 64
6.6 Role Selection Confirmation – Chain Headquarters Pharmacy ................. 65
6.7 Authorized Representative Intake ....................................................... 66
6.8 Authorized Representative Confirmation ............................................. 67
6.9 Pharmacy Intake .............................................................................. 68
6.10 Pharmacy Re-classification .................................................................. 70
6.11 Pharmacy Education Program ............................................................. 76
6.12 Pharmacy Education Confirmation....................................................... 77
6.13 Pharmacy Attestation – Inpatient Pharmacy ......................................... 78
6.14 Pharmacy Attestation – Outpatient Pharmacy ....................................... 79
6.15 Pharmacy Confirmation...................................................................... 80
6.16 Pharmacy Test Transactions ............................................................... 81

7. Chain Pharmacy Certification ....................................................................... 82
7.1 Chain Pharmacy Store Intake ............................................................. 82
7.2 Chain Pharmacy Store Confirmation .................................................... 83

8. Pharmacy Staff Enrollment .......................................................................... 84
8.1 Enrollment Home Page ...................................................................... 84
8.2 Pharmacy Search............................................................................... 85
8.3 Pharmacy Search Results................................................................. 86
8.4 Pharmacy Staff Intake ................................................................ 87
8.5 Pharmacy Staff Attestation ............................................................... 88
8.6 Pharmacy Staff Confirmation .............................................................. 89

9. Knowledge Assessment for Healthcare Providers ............................................ 90
9.1 Knowledge Assessment for Healthcare Providers Landing Page ............... 90
9.2 Knowledge Assessment Question 1 ..................................................... 91
9.3 Knowledge Assessment Question 2 ..................................................... 92
9.4 Knowledge Assessment Question 3 ..................................................... 93
9.5 Knowledge Assessment Question 4 ..................................................... 94
9.6 Knowledge Assessment Question 5 ..................................................... 95
9.7 Knowledge Assessment Question 6 ..................................................... 96
9.8 Knowledge Assessment Question 7 ..................................................... 97
9.9 Knowledge Assessment Question 8 ..................................................... 98
9.10 Knowledge Assessment Question 9 ..................................................... 99
9.11 Knowledge Assessment Question 10 .................................................. 100
9.12 Knowledge Assessment Question 11 .................................................. 101
9.13 Knowledge Assessment Question 12 .................................................. 102
9.14 Knowledge Assessment Question 13 .................................................. 103
9.15 Knowledge Assessment Confirmation – Success................................. 104
9.16 Knowledge Assessment Confirmation – Not Successful .......................... 105
10. Patient Enrollment ................................................................................... 106
  10.1 Patient Intake ..................................................................................... 106
  10.2 Patient Lab Intake ............................................................................. 107
  10.3 Patient Lab Intake with Treatment Rationale ...................................... 108
  10.4 ANC Calculator ............................................................................... 109
11. Stakeholder Profiles ............................................................................... 110
  11.1 Prescriber Profile ............................................................................. 110
  11.2 Prescriber Designee Profile ............................................................... 111
  11.3 Authorized Representative Profile ...................................................... 112
  11.4 Chain Headquarters Pharmacy Authorized Representative Profile ........ 113
  11.5 Chain Headquarters Pharmacy Profile ............................................ 114
  11.6 Pharmacy Staff Profile ..................................................................... 115
12. My Account ............................................................................................. 116
  12.1 Forgot Username ............................................................................ 116
  12.2 Change Username ........................................................................... 117
  12.3 Change Username Confirmation ........................................................ 118
  12.4 Change Password ............................................................................ 119
  12.5 Change Password Notification ........................................................... 120
  12.6 Change Password Confirmation ......................................................... 121
  12.7 Change Email Address ..................................................................... 122
  12.8 Change Email Address Confirmation .................................................. 123
13. Patient Groups ........................................................................................ 124
  13.1 Manage Groups .............................................................................. 124
  13.2 Add Group ..................................................................................... 125
  13.3 Change Group Name ....................................................................... 126
  13.4 Remove Group ............................................................................... 127
  13.5 Remove Group Warning ................................................................... 128
  13.6 Reassign Patients ............................................................................ 129
14. Dashboard .............................................................................................. 130
  14.1 Dashboard Alerts and Notifications .................................................... 130
    14.1.1 Dashboard Alerts ........................................................................ 130
14.1.2 Dashboard Notifications ................................................................. 131
14.2 Prescriber Dashboard ........................................................................ 132
  14.2.1 Prescriber Dashboard Patient Tab Collapsed............................. 132
  14.2.2 Prescriber Dashboard Patient Tab Expanded ............................. 133
  14.2.3 Definitions of Terms Pop-up ....................................................... 135
  14.2.4 Add Lab, Change Treatment Status, and Change Monitoring Frequency for Prescribers ........................................... 136
  14.2.5 View Patient History Lab History Tab ....................................... 137
  14.2.6 View Patient History Treatment Status Tab ............................. 138
  14.2.7 View Patient History Monitoring Frequency Tab ................... 139
  14.2.8 View Patient History Dispense Rationale Tab .......................... 140
  14.2.9 View Patient Profile ................................................................. 141
  14.2.10 Prescriber Dashboard Designees Tab ...................................... 142
  14.2.11 Add Designee with Results ..................................................... 143
  14.2.12 Remove Designee ................................................................. 144
  14.2.13 Approve Designee ............................................................... 145
14.3 Prescriber Designee Dashboard ....................................................... 146
  14.3.1 Prescriber Designee Dashboard Patient Tab Collapsed ............ 146
  14.3.2 Prescriber Designee Dashboard Patient Tab Expanded .......... 147
  14.3.3 Definitions of Terms Pop-up ....................................................... 148
  14.3.4 Add Lab and Change Treatment Status for Prescriber Designees .... 149
  14.3.5 View Patient History: Lab History Tab .................................. 150
  14.3.6 View Patient History: Treatment Status Tab ......................... 151
  14.3.7 View Patient History: Monitoring Frequency Tab ................... 152
  14.3.8 View Patient History: Dispense Rationale Tab ....................... 153
  14.3.9 View Patient Profile ............................................................... 154
  14.3.10 Prescriber Designee Dashboard Prescribers Tab .................... 155
  14.3.11 Associate to Prescriber ......................................................... 156
  14.3.12 Remove Designee Relationship ............................................ 157
  14.3.13 Cancel Designee Request ..................................................... 158
14.4 Pharmacy Dashboard – Inpatient Pharmacies ................................ 159
  14.4.1 Inpatient Pharmacy Dashboard Pharmacies Tab ..................... 159
14.4.2 Add Lab ........................................................................................................ 161
14.4.3 Add Lab – Successful .................................................................................. 162
14.4.4 Add Lab – Unsuccessful .............................................................................. 163
14.4.5 Eligibility Check .......................................................................................... 164
14.4.6 Eligibility Check Result – Successful ......................................................... 165
14.4.7 Eligibility Check Result – Successful with warning message ................. 167
14.4.8 Eligibility Check Result – Unsuccessful ..................................................... 168

14.5 Pharmacy Dashboard – Outpatient Pharmacies ........................................ 169

14.5.1 Dispense Rationale ...................................................................................... 171
14.5.2 Dispense Rationale Result Screen – Success .............................................. 172
14.5.3 Dispense Rationale Result Screen – Success (After DR is issued) ............ 173
14.5.4 Dispense Rationale Result Screen – Unsuccessful ................................... 174

14.6 Pharmacy Dashboard – Outpatient Pharmacies on switch .................... 175

14.6.1 Predispense Authorization ........................................................................ 177
14.6.2 Predispense Authorization Result – Successful .......................................... 178
14.6.3 Predispense Authorization Result – Unsuccessful ...................................... 179
14.6.4 Predispense Authorization Result – Success (After DR is issued) ............. 180
14.6.5 View Pharmacy Profile .............................................................................. 181
14.6.6 Remove Pharmacy ..................................................................................... 182
14.6.7 Recertify Pharmacy ................................................................................... 183
14.6.8 Pharmacy Dashboard Pharmacy Staff Tab .............................................. 192
14.6.9 Remove Pharmacy Staff .......................................................................... 193

14.7 Chain Pharmacy Dashboard ......................................................................... 194

14.7.1 Chain Pharmacy Dashboard Pharmacies Tab ......................................... 194
14.7.2 View Pharmacy Profile .............................................................................. 195
14.7.3 Remove Pharmacy ..................................................................................... 196
14.7.4 Chain Pharmacy Dashboard Pharmacy Staff Tab .................................... 197
14.7.5 Remove Pharmacy Staff .......................................................................... 198

14.8 Pharmacy Staff Dashboard .......................................................................... 199

14.8.1 Pharmacy Staff Dashboard Pharmacies Tab ............................................ 199
14.8.2 Associate to Pharmacy ............................................................................. 200
14.8.3 Eligibility Check ......................................................................................... 201
14.8.4 Eligibility Check Result – Unsuccessful ........................................... 202
14.8.5 Predispose Authorization ................................................................. 203
14.8.6 Predispose Authorization Result – Unsuccessful ......................... 204
15. Dispense Rationale – Static Pages ......................................................... 205
  15.1 Home Page ..................................................................................... 205
16. Dispense Rationale – Pharmacy Authorized Representative (Non-Switch)...... 206
  16.1 Pharmacy – Authorized Representative Dashboard ......................... 206
  16.2 Pharmacy – Authorized Representative Predispose Authorization ........ 207
  16.3 Pharmacy – Authorized Representative Predispose Authorization Result - Successful ................................................................. 208
  16.4 Pharmacy – Authorized Representative Predispose Authorization Result - Unsuccessful ................................................................. 209
  16.5 Pharmacy – Authorized Representative Predispose Authorization Result – Successful ................................................................. 210
  16.6 Pharmacy – Authorized Representative Predispose Authorization Result- Successful (After the Dispense Rationale is issued) ......................... 211
  16.7 Pharmacy – Authorized Representative Predispose Authorization Result – Unsuccessful ................................................................. 212
17. Dispense Rationale – Pharmacy Staff (Non-Switch) ................................... 213
  Pharmacy Staff Dashboard ..................................................................... 213
  17.1 Pharmacy Staff Predispose Authorization ........................................ 214
  17.2 Pharmacy Staff Predispose Authorization Result- Successful .......... 215
  17.3 Pharmacy Staff Predispose Authorization Result- Unsuccessful ....... 216
  17.4 Pharmacy Staff Predispose Authorization Result – Successful ........ 217
  17.5 Pharmacy Staff Predispose Authorization Result- Successful (After the Dispense Rationale is issued) ......................................................... 218
  17.6 Pharmacy Staff Predispose Authorization Result – Unsuccessful ...... 219
18. Dispense Rationale – Pharmacy Authorized Representative (Switch) .......... 220
  18.1 Pharmacy – Authorized Representative Dashboard ........................... 220
  18.2 Pharmacy – Authorized Representative Dispense Rationale ............... 221
  18.3 Pharmacy – Authorized Representative Dispense Rationale Result Screen-Success ............................................................................... 222
  18.4 Pharmacy – Authorized Representative Dispense Rationale Result Screen-Success (After DR is issued) ................................................................. 223
18.5 Pharmacy – Authorized Representative Dispense Rationale Result Screen - Unsuccessful

18.6 Pharmacy – Authorized Representative Eligibility Check Result- Successful

18.7 Pharmacy – Authorized Representative Eligibility Check Result- Unsuccessful

19. Dispense Rationale – Pharmacy Staff (Inpatient Pharmacy)

19.1 Pharmacy Staff Dashboard

19.2 Pharmacy Staff Eligibility Check

19.3 Pharmacy Staff Eligibility Check Result- Successful

19.4 Pharmacy Staff Eligibility Check Result

20. Dispense Rationale – Pharmacy Staff (Switch)

20.1 Pharmacy Staff Dashboard

20.2 Pharmacy Staff Dispense Rationale

20.3 Pharmacy Staff Dispense Rationale Result- Success

20.4 Pharmacy Staff Dispense Rationale Result- Success (After DR is issued)

20.5 Pharmacy Staff Dispense Rationale Result- Unsuccessful

21. Dispense Rationale – Prescriber and Prescriber Designee

21.1 Prescriber and Prescriber Designee Dashboard

21.2 Prescriber and Prescriber Designee Dispense Rationale History
1. Static Pages

1.1 Home Page

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

Please click to open the IPU

What is the Clozapine REMS Program?

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

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

Site Guide

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

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

Prescriber | Pharmacy | Patient | Designee | Pharmacy Staff

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

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

Once signed 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 new patients and adding ANC values. The My Dashboard page is the main portal for all activities performed on this site.

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

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

Site Guide

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

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

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

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

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

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

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

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values. The links located at the top and bottom of every page offer information for prescribers, pharmacists, and patients. Additional information about the program is also available under Resources and through the FAQs, Site Map, and Contact Us links.

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

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

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

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

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

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

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

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

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

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

Site Guide

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

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

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

The Pharmacy Staff page provides specific steps that must be completed to dispense clozapine.

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

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

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

Prescriber Certification

Steps for Prescriber Certification

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

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

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

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


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

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

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

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

Prescriber Designee Certification

Steps for Prescriber Designee Certification

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

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

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

1. Enroll: Complete the Enrollment Form (name, address)
2. Educate: Review the REMS requirements
3. Confirm: Understanding of the requirements of the REMS

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

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

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

Pharmacy Certification

Steps for Pharmacy Certification

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

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

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

1. Enroll: Complete the Enrollment Form (name, address, NPI, DEA)
3. Assess: Successfully complete the Clozapine REMS Knowledge Assessment for Healthcare Providers
4. Implement: Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

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

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

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

Pharmacy Staff Enrollment

Steps for Pharmacy Staff Enrollment

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

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

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

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

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

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

2. Attest: Complete and sign the Pharmacy Staff Attestation

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

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

Patient Information

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

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

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

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

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

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

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

- **Pharmacy**
  - Clozapine REMS Eligibility Fact Check Sheet
  - Clozapine REMS PDA Fact Sheet
  - A Guide for Patients and Caregivers: What You Need to Know About Clozapine and Neutropenia
  - Dear Inpatient Pharmacy Letter
  - Dear Outpatient Pharmacy Using Web PDA Letter
  - Dear Outpatient Pharmacy Using Switch Letter
  - Clozapine REMS Inpatient Pharmacy Enrollment Form
  - Clozapine REMS Outpatient Pharmacy Enrollment Form
  - Clozapine REMS Chain Headquarters Pharmacy Enrollment Form
• Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers (Education Program and Knowledge Assessment)
• Clozapine REMS Patient Enrollment Form
• Clozapine REMS ANC Lab Reporting Form
• ANC Calculator
• ANC Monitoring Table

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

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

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

**Products covered under the Clozapine REMS Program**

**Brand Name Products**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Company</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clozaril</td>
<td>Clozapine</td>
<td>HLS Therapeutics (USA) Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>FazaCloz</td>
<td>Clozapine, USP</td>
<td>Jazz Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Voselecz</td>
<td>Clozapine, USP</td>
<td>Jazz Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
</tbody>
</table>

**Generic Products**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Company</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clozapine</td>
<td>Clozapine Tablets, USP</td>
<td>Accord Healthcare Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Tablets, USP</td>
<td>Aurobindo Pharma USA Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine, USP ODT</td>
<td>Jazz Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Tablets, USP</td>
<td>Mayne Pharma Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Tablets, USP</td>
<td>Mayne Pharma Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Tablets, USP</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Daily Disintegrating Tablets</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Tablets, USP</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Daily Disintegrating Tablets</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Tablets, USP</td>
<td>Sun Pharmaceutical Industries Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine Tablets, USP</td>
<td>Teva Pharmaceuticals USA Inc.</td>
<td>Full Prescribing Information</td>
</tr>
<tr>
<td>Clozapine</td>
<td>Clozapine, USP ODT</td>
<td>Teva Pharmaceuticals USA Inc.</td>
<td>Full Prescribing Information</td>
</tr>
</tbody>
</table>

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

Certification Lookup

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

Pharmacy Information (at least one identifier is required):

Certification ID (opt) or Zip Code (opt) or City and State

and

DEA or NPI or NCPDP

Search

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

Certification Lookup

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

![Certification Lookup Form](image)

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

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

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

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

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

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

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

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

What is a “Dispense Rationale?”

How can I provide a Dispense Rationale?

How does a pharmacy certify in the Clozapine REMS Program?

How often must pharmacies recertify?

How does a pharmacy recertify in the Clozapine REMS Program?

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

What happens if a pharmacy is deactivated?

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

• Wholesaler/Distributor

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

How can a distributor enroll in the Clozapine REMS Program?

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

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

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

• Technical Support

What if I need help using the Clozapine REMS Program website?

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

How does the Clozapine REMS Program Website use cookies?

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

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

Why does the Clozapine REMS Program Website use Captcha?

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

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

What do I do if I forgot my password?

What do I do if I forgot my username?

What do I do if my user account is locked?

How do I change my username and/or password?

How does a healthcare provider create multiple accounts with the same email address?

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

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

• Patient

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

Where do I find a list of local pharmacies that participate in the Clozapine REMS Program?
1.18 FAQ – Pharmacy Authorized Representative

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

Contact Us

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

Phone Number
844-267-8678

Fax Number
844-404-8876

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

Program Manufacturers

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

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

2.1 User Identification

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

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

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

2 – The options for role are Prescriber, authorized representative for pharmacy, Prescriber Designee, and Pharmacy Staff.
2.2 Phone/Fax User Prescriber Search

Phone/Fax User

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

At least one identifier is required:

- DEA (opt) or NPI
- First Name
- Last Name
- Certification ID (opt)
- Phone (opt)
- Fax (opt)
- Email (opt)

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

Phone/Fax User

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

A least one identifier below is required:

| AB1234567 | NPI |
| Summer | Hogan |
| Phone (opt) | Fax (opt) | Email (opt) |

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

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

Showing 1 of 1 entries

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

Phone/Fax User

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

At least one identifier is required:

DEA (opt) or NPI

First Name  Last Name  Certification ID (opt)

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

Search

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

Phone/Fax User

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

Prescriber Information

AB1234567

Designee Information

Summer

Hogan

Certification ID (opt)

Phone (opt)

Fax (opt)

Email (opt)

Search

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

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

Phone/Fax User

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

Pharmacy Information (at least one identifier is required):

- Zip Code
- DEA
- NPI
- NCPDP

Authorized Representative Information

- First Name
- Last Name
- Certification ID (opt)
- Phone (opt)
- Fax (opt)
- Email (opt)

Search

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

Phone/Fax User

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

Pharmacy Information (at least one identifier is required):

10001 and AB1234567890 NPI NCPDP

Authorized Representative Information

First Name Last Name Certification ID (opt)
Phone (opt) Fax (opt) Email (opt)

Search

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

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Pharmacy Name</th>
<th>Pharmacy Address</th>
<th>Pharmacy Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summer</td>
<td>Hogan</td>
<td>Joey's Apothecary</td>
<td>1 Main Street, New York, NY 10001</td>
<td>555-555-5555</td>
</tr>
</tbody>
</table>

Showing 1 of 1 entries

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

Phone/Fax User

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

Pharmacy Information

REMS Chain ID

Authorized Representative Information

First Name  Last Name  Certification ID (opt)

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

Search

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

Phone/Fax User

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

Pharmacy Information

C00121

Authorized Representative Information

Summer Hogan Certification ID (opt)

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

Search

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

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

Showing 1 of 1 entries

New User Submit

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

3.1 Create Account

Create Account

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

My Information

First Name
Last Name
Email Address
Confirm Email Address
Phone Number

Sign in

Username
Use Email Address as Username
Suggest Username
Password
Confirm Password

I'm not a robot

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

A verification email has been sent to remspogram@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: remspogram@gmail.com
Phone Number: 480-555-5555
Username: summerhogan

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

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

For additional information about the Clozapine REMS Program, please call 844-267-8076.
4. Prescriber Certification

4.1 Prescriber Intake

For additional information about the Clozapine REMS Program, please call 844-237-8678.
4.2 Prescriber Education Program

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

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

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

Prescriber intake Review

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

Prescriber Information

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

Prescriber Identifiers

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

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

Cancel    Next
4.5 Prescriber Attestation

Prescriber Attestation

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

Alternatively, you may print your online enrollment form and fax it to Clozapine REMS Program at 1-844-404-9876.

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

By signing this form, I attest that:

1. I understand that clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements to prescribe clozapine.
2. I have reviewed “Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers, reviewed the clozapine Prescribing information, and successfully completed the Clozapine REMS Knowledge Assessment for Healthcare Providers.
3. I understand the risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
4. Prior to initiating treatment, I agree to provide a Guide for Patients and Caregivers: What You Need to Know about Clozapine to each patient and/or their caregivers.
5. I understand the absolute neutrophil count (ANC) testing and monitoring requirements as described in the clozapine Prescribing information.
6. I will order ANC testing for each patient according to the clozapine Prescribing information.
7. I will submit and verify the ANC according to each patient's monitoring frequency on file with the Clozapine REMS Program and understand the ANC must be provided before clozapine can be dispensed.
8. For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw date.
9. For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw date.
10. For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of the lab draw date.
11. I agree that personnel from the Clozapine REMS Program or a designated third party acting on behalf of the Clozapine Sponsors may contact me to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program.
12. I understand that clozapine manufacturers or their agents and contractors may contact me via phone, email, or fax 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 in to the website using my credentials.

I attest to the following:

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

For additional information about the Clozapine REMS Program, please call 844-267-9678.
4.6 Prescriber Confirmation

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

Certification ID: HCP123456789

If you would like to enroll patients now, you can use Enroll Patient. If you need to manage your patients, you can use Manage Your Patients.

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

Prescriber Designee Certification

Steps for Prescriber Designee Certification

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

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

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

1. Enroll: Complete the Enrollment Form (name, address)
2. Educate: Review the REMS requirements
3. Confirm: Understanding of the requirements of the REMS

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

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

Begin Now!

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

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

General Information

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

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

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

Prescriber Designee Responsibilities

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

I understand:

- Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements.
- There is a risk of severe neutropenia associated with clozapine which can lead to serious infection and death.
- The ANC testing and monitoring requirements as described in the clozapine Prescribing Information.
- Outpatient Settings: An ANC must be submitted to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed and per the Monitoring Schedule described in the Prescribing Information:
  - For weekly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 7 days of the lab draw* date
  - For every two weeks monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 15 days of the lab draw* date
  - For monthly monitoring frequency, ANC must be submitted to the Clozapine REMS Program within 31 days of lab draw* date
  
  *Assumes the lab draw date is day 0

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

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

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

Knowledge Assessment

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

I have reviewed the requirements of the Clozapine REMS Program.

- A. Yes
- B. No

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

Knowledge Assessment Results

✅ Congratulations! You have now completed the assessment.

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

Knowledge Assessment Code: KA-1652-A6F8-0BE7

QUESTION 1

I have reviewed the requirements of the Clozapine REMS Program.

☐ A. Yes

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

Knowledge Assessment Results

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

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

QUESTION 1
I have reviewed the requirements of the Clozapine REMS Program.
X B. No

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

Designee Intake Review

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

Designee Information

- **First Name**: Jackie
- **Last Name**: Kolins
- **Email Address**: jackie@kcolins.com
- **Phone / Ext**: 123-456-7890 Ext (opt)
- **Fax**: Fax (opt)
- **Contact Preference**: Email

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

Designee Attestation

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

Alternatively, you may print your online certification form and fax it to Clozapine REMS Program at 844-404-8676.

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

I understand:

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

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

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

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

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

![Certification Confirmation]

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

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

Certification ID: HCP5027506077

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

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

6.1 Pharmacy Certification – Home Page

Pharmacy Certification

Steps for Pharmacy Certification

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

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

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

1. Enroll: Complete the Enrollment Form (name, address, NPI, DEA)
3. Assess: Successfully complete the Clozapine REMS Knowledge Assessment for Healthcare Providers
4. Implement: Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

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

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
6.2 Role Selection – New User

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

Program Role Selection

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

- **Authorized Representative of Outpatient Pharmacy** - An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual outpatient pharmacy. An authorized representative of an outpatient pharmacy cannot be affiliated with a chain pharmacy that is contracted with a pharmacy network provider.
  - Outpatient pharmacy: A pharmacy dispensing clozapine to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

- **Authorized Representative of Inpatient Pharmacy** - An authorized representative of an inpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within a pharmacy where the patient’s treatment is coordinated at a site of care and pharmacy claims are submitted as a medical benefit.
  - Inpatient pharmacy: A pharmacy within a facility dispensing clozapine to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).

- **Authorized Representative of Chain Headquarters Pharmacy** - An authorized representative of a chain headquarters pharmacy is responsible for ensuring certification and training in the Clozapine REMS Program for a corporate pharmacy contracted to participate in a pharmacy network provider. Corporate pharmacies are retail or mail outpatient pharmacy headquarters.
  - The Chain Headquarters Pharmacy certification process requires a single authorized representative to review the Education Program, complete the Clozapine REMS Knowledge Assessment for Healthcare Providers, and the Chain Headquarters Pharmacy Enrollment form.
  - Once completed, please contact your switch provider Account Manager for further instructions on submission of the Clozapine REMS Knowledge Assessment for Healthcare Providers & Enrollment Form for certification processing.
  - A contract with your switch provider is required for a Chain Headquarters Pharmacy certification to be complete.
  - Please review this important communication to Chain Pharmacies.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
6.3 Role Selection – Phone/Fax User

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

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

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

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

Authorized Representative of Independent Outpatient Pharmacy

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

An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems. As an independent outpatient pharmacy, you agree that your pharmacy is a retail, mail order or institutional outpatient pharmacy enrolling as a single pharmacy location with its own authorized representative (i.e., not a location covered by a central headquarters for enrollment or training).

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

Cancel  Confirm

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

Program Role Selection

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

- Authorized Representative of Outpatient Pharmacy - An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of pharmacy staff. The pharmacy cannot be limited to retail drug systems.
- Authorized Representative of Chain Headquarters Pharmacy - An authorized representative of a chain headquarters pharmacy is responsible for ensuring certification and training of pharmacy staff. This includes, but is not limited to, retail drug stores, ambulatory care facilities, and prison facilities. As a Chain Headquarters Pharmacy, you agree that you are acting on behalf of a group of outpatient pharmacies as a corporate headquarters enrolling in the Clozapine REMS Program for multiple pharmacy locations (e.g., chain stores or a group of pharmacies owned/operated as a single entity); and, whose enrollment and certification activities will be handled centrally by one authorized representative acting on behalf of all the locations in the "chain".

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

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

Reference ID: 4376730
6.7 Authorized Representative Intake

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

Authorized Representative Information

- First Name
- Last Name
- Credentials
- Email Address
- Phone
- Ext. (opt)
- Fax (opt)
- Contact Preference

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

You have successfully completed the required authorized representative training.

If you are ready to certify your pharmacy now, please use Certify Pharmacy. To return to your dashboard for other activities, please use the My Dashboard button at the top of the page. If you have completed your session today, simply close your browser.

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

Note:
1 – The options for type of Pharmacies are Inpatient and Outpatient. The tool-tip next to this field will include definition of inpatient and outpatient pharmacies, which are as below:
- Inpatient pharmacy: A pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition).
- Outpatient pharmacy: A pharmacy dispensing clozapine only to patients treated on an outpatient or chronic basis. This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

2 – Adjudicate claims online question – This question will be displayed only if the Pharmacy Type selected on this page is ‘Outpatient Pharmacy’.
6.10 Pharmacy Re-classification

Clozapine REMS Pharmacy Classification

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

**QUESTION 1**

Does your pharmacy management system support electronic communication with the Clozapine REMS Program using established telecommunications standards?

- Yes
- No

Next

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

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

QUESTION 1A

Is your pharmacy affiliated with a chain pharmacy that is contracted with a pharmacy network provider?

- Yes
- No

Next

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

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

**QUESTION 18**

Is your pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)?

- [ ] Yes
- [ ] No

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

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

**QUESTION 2**

Does your pharmacy dispense clozapine only to patients treated on an outpatient or chronic basis? This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

- Yes
- No

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

Please contact your chain headquarters pharmacy authorized representative for assistance. If you are the authorized representative, or if you do not know who the authorized representative is, please call the Clozapine REMS Program at 844-267-8678.

Next

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

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

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

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

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

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

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

Note: This page includes only the attestation text for the Inpatient Pharmacy from the Clozapine REMS Inpatient Pharmacy Enrollment Form.
6.14 Pharmacy Attestation – Outpatient Pharmacy

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

<table>
<thead>
<tr>
<th>Pharmacy Attestation</th>
</tr>
</thead>
<tbody>
<tr>
<td>To complete the certification for ABC Pharmacy into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement using with signature and signature date.</td>
</tr>
<tr>
<td>Alternatively, you may print your online enrollment form and fax it to Clozapine REMS Program at 1-844-404-8576.</td>
</tr>
<tr>
<td>As an authorized representative responsible for the pharmacy, I, Summer Hogan, attest to the following Clozapine REMS Program requirements:</td>
</tr>
</tbody>
</table>

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 role of severe neutropenia associated with clozapine and the importance of absolute neutrophil count (ANC) monitoring.
3. There is a different ANC monitoring algorithm for patients with documented benign neutropenia (BEN).
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program.

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. My pharmacy will establish procedures and protocols that are subject to audit to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
   a. All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained.
   b. Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program.
   c. Verify the ANC is current based on the patient's monitoring frequency (within 7 days of the ‘Predispense Authorization’ (PDA) transaction date for weekly monitoring, 15 days for every 2 weeks monitoring and 31 days for monthly monitoring).
   d. Verify the last ANC is acceptable or verify the certified prescribers authorization for continuing clozapine treatment if the ANC is low indicating moderate or severe neutropenia.
   e. Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy, institution, or prescriber who is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit.
3. Pharmacies will renew certification in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine.
4. Pharmacies will make documentation available to the clozapine manufacturer and a designated third party acting on behalf of the Clozapine Sponsors to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program.
5. Clozapine REMS Program personnel may contact my pharmacists to gather information, receive discrepancies, or to provide other information related to the Clozapine REMS Program.
6. Provide dispensing location information to the Clozapine REMS Program.
7. I will not share my credentials for the Clozapine REMS Program Website or allow others to sign in to the website using my credentials.
8. Outpatient pharmacies must obtain a PDA each time before dispensing clozapine products to a patient to ensure compliance with the required safety-use conditions.
9. Report adverse information for each clozapine prescriptio to the Clozapine REMS Program.
10. Comply with audits by the Clozapine Sponsors or a designated third party acting on behalf of the Clozapine Sponsors to ensure that all processes and procedures are in place and are being followed for the Clozapine REMS Program.

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

Signature: [Insert signature]
First and Last name (as above): [Insert name]
Signature Date: [Insert date]

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

Note: This page will be available for:

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

Certification Confirmation

Your pharmacy is now certified in the Clozapine REMS Program.

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

Certification ID: FAC7771640309

To add additional pharmacies or manage your pharmacies, please use the My Dashboard button at the top of the page.

Please download the Education Program, Knowledge Assessment for Healthcare Providers, and Knowledge Assessment Answer Guide from your Profile page. These tools should be used to train all pharmacists and relevant staff involved in dispensing clozapine. A record of the training must be maintained for future review by the Clozapine REMS Program.

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

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

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

7.1 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 --
- Zip Code
- Phone Ext (opt)
- Fax
- Training Status--

**Pharmacy Identifiers**

- NCPDP
- DEA
- NPI

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

Chain Store Confirmation

✅ The chain pharmacy store has been successfully added.

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

Add Store  My Dashboard

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

8.1 Enrollment Home Page

Pharmacy Staff Enrollment

Steps for Pharmacy Staff Enrollment

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

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

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

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

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

1. Enroll: Complete the Enrollment Form (name, address)
2. Attest: Complete and sign the Pharmacy Staff Attestation

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

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

Pharmacy Search

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

Pharmacy Information (at least one identifier is required):

Zip Code and DEA NPI NCPDP

Search

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

Pharmacy Search

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

Pharmacy Information (at least one identifier is required):

- [ ] 10001
- [ ] DEA
- [ ] NPI
- [ ] 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.

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

Showing 1 of 1 entries

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

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

Pharmacy Staff Information

First Name
Last Name
Email Address
Phone
Fax (opt)
--- Contact Preference ---

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

Pharmacy Staff Attestation

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

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

Pharmacy Staff can access the Clozapine REMS Program online at www.clozapinerems.com to complete the following:

- Enter an absolute neutrophil count (ANC) result for a patient
- Verify a patient is enrolled in the Clozapine REMS Program
- In an outpatient pharmacy:
  - Obtain a "Predispense Authorization" (PDA)\(^1\) or
  - Provide a "Dispense Rationale"
- In an inpatient pharmacy:
  - Complete an "Eligibility Check"

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

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

\(^2\)Outpatient pharmacies with a pharmacy management system that supports electronic communication with the Clozapine REMS Program using established telecommunications standards do not obtain a PDA via the Clozapine REMS Program Website.

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

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

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

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

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

Enrollment Confirmation

✅ You have now enrolled in the Clozapine REMS Program.

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

Enrollment ID: HCP123456789

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9. Knowledge Assessment for Healthcare Providers

Note: The Clozapine REMS Knowledge Assessment for Healthcare Providers pages below are for prescribers, prescriber designees, and authorized representatives.

9.1 Knowledge Assessment for Healthcare Providers Landing Page

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

Knowledge Assessment

QUESTION 1
All clozapine products are only available under the single shared Clozapine REMS Program.

A. True
B. False

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.3 Knowledge Assessment Question 2

Knowledge Assessment

**QUESTION 2**

Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

- A. True
- B. False

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.4 Knowledge Assessment Question 3

Knowledge Assessment

QUESTION 3

Severe neutropenia is defined as:

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

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.5 Knowledge Assessment Question 4

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/µL for a patient with documented benign ethnic neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/µL for a patient who is part of the general population (i.e., the patient does not have documented BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

For additional information about the Clozapine REMS Program, please call 844-267-9678.
9.6 Knowledge Assessment Question 5

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

- A. Determine if the patient has documented BEN
- B. Enroll the patient in Clozapine REMS Program
- C. Counsel the patient/caregiver about the risk of severe neutropenia
- D. Order blood work to obtain an ANC
- E. Review the ANC and submit it to the Clozapine REMS Program
- F. All of the above

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.7 Knowledge Assessment Question 6

Knowledge Assessment

QUESTION 6
In the outpatient setting, prescribers must submit the ANC to the single shared Clozapine REMS Program before the patient can be dispensed clozapine.

- A. True
- B. False

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

Knowledge Assessment

QUESTION 7

Before clozapine can be dispensed, a pharmacist in an outpatient pharmacy must:

- A. Verify the patient is enrolled in the single shared Clozapine REMS Program
- B. Verify the prescriber is certified in the single shared Clozapine REMS Program
- C. Verify the ANC is acceptable or verify the prescriber has authorized continuing treatment if the ANC is abnormal
- D. Obtain a "Prescribe Authorization" each time from the Clozapine REMS Program
- E. All of the above

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

How much clozapine can be dispensed?

A. A 30-day supply
B. A 90-day supply
C. As much as the patient wants or the insurance will pay for
D. It depends when the patient's next blood draw is according to the monitoring requirements. Dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.10 Knowledge Assessment Question 9

**Knowledge Assessment**

**QUESTION 9**

Regarding patients with documented BEN, which of the following statements are true?

- A. Patients with BEN have a different clozapine treatment algorithm and monitoring requirements
- B. Patients with BEN are healthy and do not suffer from repeated severe infections
- C. Patients with BEN are NOT at increased risk for developing clozapine-induced neutropenia
- D. Before starting clozapine, additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Hematology consultation may be necessary
- E. All of the above statements are true

Next

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

**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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.12 Knowledge Assessment Question 11

Knowledge Assessment

**QUESTION 11**

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

- A. ANC monitoring should be conducted three times weekly until ANC ≥ 1500/µL if the patient is part of the general population (i.e., if the patient does not have documented BEN)
- B. Mild neutropenia is within the normal range for a patient with documented BEN
- C. If the patient has documented BEN, ANC monitoring should be conducted weekly from initiation to 6 months, every 2 weeks from 6 to 12 months, monthly after 12 months
- D. All of the above

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.13 Knowledge Assessment Question 12

Knowledge Assessment

**QUESTION 12**

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

- A. Treatment should be continued regardless of whether the patient is part of the general population or has documented BEN
- B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt therapy and conduct ANC monitoring: daily until ANC ≥ 1000/μL; three times weekly until ANC ≥ 1500/μL; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the general population or has BEN
- D. None of the above

Next

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

Knowledge Assessment

**QUESTION 13**

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

- A. Treatment should be interrupted regardless of whether the patient is part of the general population or has BEN and a hematology consultation should be considered; resume treatment only if the prescriber determines that the benefits of clozapine therapy outweigh the risks.
- B. If the patient is part of the general population (i.e., the patient does not have documented BEN), interrupt treatment and conduct ANC monitoring: daily until ANC ≥ 1000/μL; three times weekly until ANC ≥ 1600/μL.
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber.
- D. All of the above.

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.
9.15 Knowledge Assessment Confirmation – Success

Knowledge Assessment Results

✅ Congratulations! You have now completed the assessment.

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

Knowledge Assessment Code: KA-1636-D098-1E12

QUESTION 1
All clozapine products are only available under the single shared Clozapine REMS Program.

A. True

QUESTION 2
Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

A. True

QUESTION 3
Severe neutropenia is defined as:

Next

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

Knowledge Assessment Results

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

Below is a summary of your responses. We recommend you review the Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers again before you attempt to retake the Knowledge Assessment. Once you feel your review is complete, please use the Retake Assessment button below to begin your assessment again.

QUESTION 1
All clozapine products are only available under the single shared Clozapine REMS Program.
A. True

QUESTION 2
Clozapine is associated with severe neutropenia, which can lead to serious infection and death.
X B. False

QUESTION 3
Severe neutropenia is defined as:

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

10.1 Patient Intake

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

**Patient Information**

- First Name
- Last Name
- Date of Birth (MM/DD/YYYY)
- Zip Code
- Gender
- Race
- Patient Group
- Does the patient have Benign Neonatal Neutropenia (BEN)?

Genders can be used to categorize your patients.

For additional information about the Clozapine REMS Program, please call 844-267-8878.
10.2 Patient Lab Intake

Note:
The Add Lab page allows the user to enter Patient Lab Information. Options available for Treatment Status include:
1 – Active
1 – Interrupted
1 – Discontinued
10.3 Patient Lab Intake with Treatment Rationale

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

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

ANC Calculator

WBC count (x10^9/mm^3)  Segs (%)  Bands (%)  ANC value (per µL)

WBC count (x10^9/mm^3)  Neutrophils (%)  ANC value (per µL)

NOTE:

For WBC count, data should be entered in decimal format (e.g., 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.


For additional information about the Clozapine REMS Program, please call 844-267-6678.
11. Stakeholder Profiles
Note: Stakeholder profiles are accessed via the drop-down next to the signed-in user’s name at the top of every page.

11.1 Prescriber Profile
11.2 Prescriber Designee Profile

My Profile

My Information

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

My Certification

Certification ID: HCP123456789

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

My Profile

My Information

First Name: Summer
Last Name: Hogan
Position/Title: R.Ph
Phone / Ext: 555-555-5555
Fax: 555-555-4444
Contact Preference: Email

Education Program

1. Clozapine REMS Knowledge Assessment for Healthcare Providers
2. Knowledge Assessment Answer Guide

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

My Profile

My Information

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

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

Note: The chain headquarters pharmacy authorized representative will have two options via the drop-down next to the signed-in user’s name at the top of every page; one for My Profile (authorized representative profile above) and Chain Headquarters Pharmacy Profile (below).

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
12. My Account
Note: My Account pages are accessed via the drop-down next to the signed-in user’s name at the top of every page.

12.1 Forgot Username

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

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

Username

Use Email Address as Username
Suggest Username

Change Password
Change Email Address

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

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

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

Change Password

To change your password, please complete the fields below.

Old Password
New Password
Confirm Password

Change Username
Change Email Address

Cancel Save

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

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

Change Password

- Your password has been successfully saved.

To change your password, please complete the fields below.

- Old Password
- New Password
- Confirm Password

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

Change Email Address

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

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

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

Privacy | Terms of Use | Site Map | FAQs | Contact Us
12.8 Change Email Address Confirmation

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

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

- Email Address
- Confirm Email Address

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

13.1 Manage Groups

Note:
The Manage Groups page will include a list of all groups the prescriber or designee has created for themselves. The actions the prescriber and designee can take are:

1. Add Group – will take the user to the Add Group page
2. Change Group Name – will take the user to the Edit Group page
3. Remove Group – will take the user to the Remove Group page

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

Add Group

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

Group Name

Cancel  Submit

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

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

Group Name: Group A

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

Remove Group

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

Group Name: Group A

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

![Warning Message]

Warning

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

- [ ] No
- [x] Yes

For additional information about the Clozapine REMS Program, please call 844-207-8678.
13.6 Reassign Patients

Reassign Patients

Please select the new group below and press Submit.

Group Name: -- Please Select --

Search

Cancel  Submit

For additional information about the Clozapine REMS Program, please call 844-207-6076.
14. Dashboard

14.1 Dashboard Alerts and Notifications

14.1.1 Dashboard Alerts

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

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

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

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

14.2.1 Prescriber Dashboard Patient Tab Collapsed

The table below contains all the patients you have seen in the Clozapine REMS Program. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates a National Non-Rechallenge Master File (NNRMF) patient.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>DOB</th>
<th>Enrollment</th>
<th>Group</th>
<th>Relationship</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mike</td>
<td>Brown</td>
<td>05/01/2000</td>
<td>Enrolled</td>
<td>Active</td>
<td>- Please Select --</td>
<td>Go</td>
</tr>
<tr>
<td>John</td>
<td>Smith</td>
<td>05/01/2000</td>
<td>Enrolled</td>
<td>Active</td>
<td>- Please Select --</td>
<td>Go</td>
</tr>
</tbody>
</table>

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

For definitions of terms used on this page, click [here](#).
Note:
The dashboard for the prescriber will include a list of all patients the prescriber is managing. The actions the prescriber can take are:
For patients with an enrollment status of "Incomplete", the prescriber can "Resume Patient Enrollment"
1 – Enroll Patient – will take users to the Patient Intake page and through the patient enrollment process
For patients with an enrollment status of "Enrolled", the prescriber can take the following actions:
2 – Add Lab – will take the user to the Lab Information page
2 – Change Treatment Status – will take the user to the Lab Information page
2 – Change Treatment Rationale – will take the user to the Lab Information page
2 – View Patient History – will take the user to the Patient History page
2 – View Patient Profile – will take the user to the Patient Profile page
2 – Remove from Program – will remove the patient from the program
3 – Options available for Dispense Rationale status include:
   a. Active
   b. Expired
   c. Limit Reached
   d. Not on File

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

**Definition of Terms**

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

**Enrollment Status**
- Enrolled (patients and pharmacy staff) - All enrollment requirements have been met
- Certified (for all other stakeholders) - All certification requirements have been met
- Incomplete - Requirements for enrollment or certification have not been met and must be continued

**BEN Patient** - Benign Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANCs are lower than “standard” laboratory ranges for neutrophils. Because of this condition, patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine.

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

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

Note:
The Add Lab page allows the user to enter Patient Lab Information. Options available for Treatment Status include:
1 – Active
1 – Interrupted
1 – Discontinued
14.2.5 View Patient History Lab History Tab

Patient History

<table>
<thead>
<tr>
<th>Lab History</th>
<th>Treatment Status History</th>
<th>Monitoring Frequency History</th>
<th>Dispense Rationale</th>
</tr>
</thead>
</table>

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

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

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

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

Patient History

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

<table>
<thead>
<tr>
<th>Entry Date</th>
<th>Monitoring Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/08/2017</td>
<td>Weekly</td>
</tr>
</tbody>
</table>

Showing 1 to 1 of 1 entries

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

Privacy | Terms of Use | Site Map | FAQ | Contact Us
14.2.8 View Patient History Dispense Rationale Tab

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

**Patient Profile**

**Patient Information**

- **First Name**: Chester
- **Last Name**: Smith
- **DOB**: 03/05/1983
- **Zip Code**: 85667
- **Gender**: Male
- **Race**: Caucasian
- **Group**: Group B
- **BEN Patient**: No
- **NNRMF Patient**: No

**Patient Enrollment Information**

Enrollment ID: PAT132456789

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

Note: The dashboard for the prescriber will include a list of all designees the prescriber is associated to. The actions the prescriber can take are:

1 – Add Designee – will take the user to the Add Designee page
2 – Remove Designee – will take the user to the Remove Designee page
3 – Approve Designee – will take the user to the Approve Designee page

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

Add Designee

To add a designee, please complete the fields below and press Search. All fields listed below are required unless otherwise indicated.

Designee Information

Terry White Certification ID (opt)

Phone (opt) Fax (opt) 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.

FirstName LastName Phone
Terry White 555-555-5555

Showing 1 of 1 entries

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

Remove Designee

Removing this designee will revoke their ability to perform actions on your behalf. To continue, please check the box below and press Submit.

Designee Name: Anantharaman Manickavasagam
Certification ID: HCP123456

☐ I hereby remove this designee's ability to perform actions on my behalf in the Clozapine REMS Program.

Cancel Submit

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

Designee Determination

This designee will act on my behalf in fulfilling the requirements for the Clozapine REMS Program.

Designee Name: Jane Brown
Certification ID: HCP055254

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

14.3.1 Prescriber Designee Dashboard Patient Tab Collapsed
14.3.2 Prescriber Designee Dashboard Patient Tab Expanded

Note:
The dashboard for the prescriber designee will include a list of all patients the designee’s prescriber is managing. The actions the prescriber designee can take are:

For patients with an enrollment status of "Incomplete", the prescriber designee can “Resume Patient Enrollment”.

For patients with an enrollment status of “Enrolled”, the prescriber can take the following actions:
1 – Add Lab  – will take the user to the Lab Information page
1 – Change Treatment Status  – will take the user to the Lab Information page
1 – Change Treatment Rationale  – will take the user to the Lab Information page
1 – View Patient History  – will take the user to the Patient History page
1 – View Patient Profile  – will take the user to the Patient Profile page
1 – Remove from Program  – will remove the patient from the program
2 – For definitions of terms used on this page – the definitions will pop-up when “here” is clicked (see next mockup)
14.3.3 Definitions of Terms Pop-up

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

**Enrollment Status**
- Enrolled (patients and pharmacy staff): All enrollment requirements have been met.
- Certified (for all other stakeholders): All certification requirements have been met.
- Incomplete: Requirements for enrollment or certification have not been met and must be continued.

**BEN Patient**
- Benign Ethnic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANCs are lower than “standard” laboratory ranges from neutrophils. Because of this condition, patients with documented BEN have a separate ANC monitoring algorithm when treated with clozapine.

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.3.4 Add Lab and Change Treatment Status for Prescriber Designees

Note:
The Add Lab page allows the user to enter Patient Lab Information. Options available for Treatment Status include:
1 – Active
1 – Interrupted
1 – Discontinued
14.3.5  View Patient History: Lab History Tab

![Lab History Screen](image.png)

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

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

Patient History

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

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

Patient Profile

Patient Information

First Name: Chester
Last Name: Smith
DOB: 03/05/1983
Zip Code: 85667
Gender: Male
Race: Caucasian
Group: Group B

BEN Patient: No
NNRNF Patient: No

Patient Enrollment Information

Enrollment ID: PAT132456789

For additional information about the Clozapine REMS Program, please call 844-207-8678.
14.3.10 Prescriber Designee Dashboard Prescribers Tab

Note: The dashboard for the prescriber designee will include a list of all prescribers the designee is acting on behalf of. The actions the prescriber designee can take are:
1 – Associate to Prescriber – will take the user to the Associate to Prescriber page
2 – Remove Designee Relationship – will take the user to the Remove Designee Relationship page
2 – Add Patient – user can add a patient using this option
3 – Cancel Designee Request – will take the user to the Cancel Designee Request page

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

To associate a prescriber, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

**Prescriber Information (at least one identifier is required):**
- **First Name**
- **Last Name**
- **DEA** or **NPI**
- **Phone (opt)**

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

Remove Designee Relationship

To remove your relationship with this prescriber, please check the box below and press Submit.

Prescriber Name: Summer Hogan
Relationship Status: Approved

☑️ I hereby remove my relationship with this prescriber and understand that I will no longer have the ability to perform actions on their behalf in the Clozapine REMS Program.

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

Cancel Designee Request

To cancel the approval request to act on behalf of this prescriber, please check the box below and press **Submit**.

- Prescriber Name: **Summer Hogan**
- Relationship Status: **Pending**

I hereby cancel my request to act on behalf of this prescriber in the Clozapine REMS Program.

**For additional information about the Clozapine REMS Program, please call 844-267-8678.**
14.4 Pharmacy Dashboard – Inpatient Pharmacies

14.4.1 Inpatient Pharmacy Dashboard Pharmacies Tab

Note: The dashboard for the authorized representative of inpatient pharmacy will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:

1. Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process
For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:
2 – Remove Pharmacy – will take the user to the Remove Pharmacy page
2 – View/Update Pharmacy Profile – will take the user to the Pharmacy Profile page
2 – Add Lab – will take the user to the Add Lab
2 – Eligibility Check – will take the user to the Eligibility Check page.
2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”
14.4.2 Add Lab

Note: This Add Lab page is displayed for both Inpatient, Outpatient pharmacies on- and off-switch.

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

Add Lab

To add lab information for your patient, please complete the fields below and Submit. All fields listed below are required unless otherwise indicated.

Patient Information

First Name
Last Name
Date of Birth
Zip Code

Add Patient Lab

ANC value per microlitre
Blood Draw Date

Dispensation Information (optional)

Date of Service (opt)
Manufacturer
NDC# Number
Days Supply (opt)
Quantity (opt)

At least one identifier is required
Prescriber DEA
Prescriber NPI

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

Ok

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

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

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

The below patient is eligible to receive clozapine.

Current Monitoring Frequency: Weekly

Name: Summer H
DOB

Lab Status: Lab was Saved

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

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

The below patient is eligible to receive clozapine.

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

Current Monitoring Frequency: Weekly

Name: Summer H
DOB:

Lab Status: Lab was Saved
For further assistance with this patient's eligibility, please contact the patient's prescriber.

Patient's Lab History

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

Eligibility Check Result

![Image]

The below patient is eligible to receive clozapine.

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

Current Monitoring Frequency: Weekly

Lab Status Lab was Saved

A Treatment Rationale currently exists for this patient and will expire on 06/06/2018.

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

Patient’s Lab History

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

**Note:**

1. The tool-tip next to this field will display this Monitoring Frequency text:
   - For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the *Eligibility Check* date.
   - For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the *Eligibility Check* date.
   - For monthly monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 31 days prior to the *Eligibility Check* date.
   *Assumes lab draw date is day 0

2. Patient’s Lab History – This button will take the user to the Patient’s Lab History page

---

Reference ID: 4376730
14.5 Pharmacy Dashboard – Outpatient Pharmacies

Note:
The dashboard for the authorized representative of outpatient pharmacy types will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:
1 – Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process.
For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:
2 – Remove Pharmacy – will take the user to the Remove Pharmacy page
2 – View/Update Pharmacy Profile – will take the user to the Pharmacy Profile page
2 – Add Lab – will take the user to the Add Lab
2 – Dispense Rationale – will take the user to Dispense Rationale page
2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”
14.5.1 Dispense Rationale

Note: This Dispense Rationale page is displayed for outpatient pharmacies on- & off-switch.
14.5.2 Dispense Rationale Result Screen – Success

**Dispense Rationale Result**

- The below patient is eligible to receive clozapine.

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

Current Monitoring Frequency: Weekly

Name: Summer H
DOB: 
Authorization Number: 

Lab Status: Lab was Saved
For further assistance with this patient's eligibility, please contact the patient's prescriber.

Patient's Lab History

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.5.3 Dispense Rationale Result Screen – Success (After DR is issued)

Dispense Rationale Result

- The below patient is eligible to receive clozapine.

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

- Current Monitoring Frequency: Weekly

Name: Summer H
DOB
Authorization Number

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

A Dispense Rationale currently exists for this patient and will expire on 06/06/2018.

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

Patient's Lab History

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

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

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

Current Monitoring Frequency: Weekly

Name: Summer H
DOB
Authorization Number

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

Current ANC is not on file.

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

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

Note: The dashboard for the authorized representative of the on-switch outpatient pharmacy will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are: 1 - Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process.
For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:
2 – Remove Pharmacy – will take the user to the Remove Pharmacy page
2 – View/Update Pharmacy Profile – will take the user to the Pharmacy Profile page
2 – Add Lab – will take the user to the Add Lab
2 – Predispense Authorization – will take the user to the Predispense Authorization page
2 – Dispense Rationale – will take the user to Dispense Rationale page
2 – Recertify Pharmacy – will take the user to the Pharmacy Recertification page
3 – For pharmacies with an enrollment status of “Incomplete,” the authorized representative can “Resume Pharmacy Certification”
14.6.1 Predispense Authorization

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

**Patient Information**
- First Name
- Last Name
- Date of Birth
- Zip Code

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

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

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

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

The below patient is eligible to receive clozapine.

**Lab**

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

Current Monitoring Frequency: Weekly

**Lab Status Lab was Saved**

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

**Patient's Lab History**

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

Note:
1 – The tool-tip next to this field will display this text:
   - For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the *Eligibility Check* date.
   - For every two weeks monitoring frequency, the ANC submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the *Eligibility Check* date.
   - For monthly monitoring frequency, the ANC submitted to the Clozapine REMS must be drawn* within 31 days prior to the *Eligibility Check* date.
   *Assumes lab draw date is day 0
2 – Patient’s Lab History – This button will take the user to the Patient’s Lab History page.
3 – Provide “Dispense Rationale” for this patient – This check box will take the user to the *Dispense Rationale* screen.
14.6.4 Predispose Authorization Result – Success (After DR is issued)

The below patient is eligible to receive clozapine.

Current Monitoring Frequency: Weekly

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

Pharmacy Profile

Pharmacy Information

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

Pharmacy Certification Information

Certification ID: HCP123456789

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

Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press Submit.

Pharmacy Name:  Joey's Apothecary
Certification ID:  PRS123456789

I hereby remove this pharmacy from the Clozapine REMS Program.

Cancel  Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.6.6 Recertify Pharmacy
Note: This Recertify Pharmacy page is displayed for Inpatient, Outpatient on- and off-switch Pharmacies.

14.6.6.1 Pharmacy Recertification Wizard
Note: Users will be presented with a set of questions to recertify a pharmacy

Clozapine REMS Pharmacy Classification
Please complete the following questionnaire to ensure the correct pharmacy type assignment.

QUESTION 1
Does your pharmacy management system support electronic communication with the Clozapine REMS Program using established telecommunications standards?

- Yes
- No

Next

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

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

**QUESTION 1A**

Is your pharmacy affiliated with a chain pharmacy that is contracted with a pharmacy network provider?

- Yes
- No

Next

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

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

**QUESTION 18**

Is your pharmacy within a facility dispensing clozapine **only** to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)?

- Yes
- No

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

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

**QUESTION 2**

Does your pharmacy dispense clozapine only to patients treated on an outpatient or chronic basis? This includes, but is not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

- Yes
- No

Next

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

Please contact your chain headquarters pharmacy authorized representative for assistance. If you are the authorized representative, or if you do not know who the authorized representative is, please call the Clozapine REMS Program at 844-267-8678.

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

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

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

Note:
1 – After the user attempts all the questions during pharmacy recertification, the user will be presented with the Pharmacy Intake page where the Pharmacy Type field will be disabled.
2 – If the user wishes to change the pharmacy type, then the user can click on the link and he will have to re-take the recertification wizard.
14.6.6.3 Pharmacy Reactivation: Non-Chain Pharmacy

Note: If a pharmacy does not recertify within the certification window, the pharmacy will be deactivated from the program. In order to return to the program, the pharmacy will be presented with the screen below upon logging in to their dashboard. This screen applies to Non-Chain Pharmacy only.

Based on the information provided, we have determined that your certification was deactivated. Please use the Reactivate button to start your recertification.

Reactivate

For additional information about the Clozapine REMS Program, please call 844-267-8678.
14.6.6.4 Pharmacy Reactivation: Chain Pharmacy

Note: If a pharmacy does not recertify with the certification window, the pharmacy will be deactivated from the program. In order to return to the program, the pharmacy will be presented with the screen below upon logging in to their Dashboard. This screen applies to Chain Pharmacy only.

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

Note: The dashboard for the authorized representative of inpatient and outpatient pharmacy types will include a list of all pharmacy staff that is representing the authorized representative. The actions the authorized representative can take are:
1 – Remove Pharmacy Staff – will take the user to the Remove Pharmacy Staff page

For additional information about the Clozapine REMS Program, please call 844-207-8078.
14.6.8 Remove Pharmacy Staff

Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press Submit.

Staff Member: Sally Smith
Pharmacy Name: Joey’s Apothecary
Enrollment ID: HCP123456789

I hereby remove this pharmacy staff member’s ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

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

14.7.1 Chain Pharmacy Dashboard Pharmacies Tab

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

Note: The dashboard for the authorized representative of chain headquarters pharmacy will include a list of all chain store pharmacies the authorized representative is managing. The actions the authorized representative can take are:

1 – Add Chain Store – will take the users to the Chain Pharmacy Store Intake page and through the chain store certification process

For pharmacies with an enrollment status of “Certified,” the authorized representative can take the following actions:

2 – View Pharmacy Profile – will take the user to the Pharmacy Profile page
2 – Remove Pharmacy – will take the user to the Remove Pharmacy page

3 – Certify Store button – for pharmacies with a certification status of “Incomplete,” the authorized representative can check one, numerous, or all checkboxes (located on the left side of the data grid) and press the button to certify the store once the staff is trained.
14.7.2 View Pharmacy Profile

Pharmacy Profile

**Pharmacy Information**

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

**Pharmacy Certification Information**

- **Certification ID**: HCP123456789

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

Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press Submit.

- Pharmacy Name: Joey's Apothecary
- Certification ID: PBI23456789

- I hereby remove this pharmacy from the Clozapine REMS Program.

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

Note: The dashboard for the authorized representative of chain headquarters pharmacy will include a list of all pharmacy staff that is representing the authorized representative. The actions the authorized representative can take are:

1 – Remove Pharmacy Staff – will take the user to the Remove Pharmacy Staff page

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

Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press Submit.

Staff Member: Sally Smith
Pharmacy Name: Joey's Apothecary
Enrollment ID: HCP123456789

I hereby remove this pharmacy staff member’s ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

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

14.8.1 Pharmacy Staff Dashboard Pharmacies Tab

Note: The dashboard for the pharmacy staff will include a list of all pharmacies the pharmacy staff is representing. The actions the pharmacy staff member can take are:

1 – Associate to Pharmacy – will take the user to the Associate to Pharmacy page.
2 - Add Lab- will take the user to the Add Lab page
3 - Eligibility Check – will take the user to the Eligibility Check page.
4 – Predispense Authorization – will take the user to the Predispense Authorization page.
5 – Dispense Rationale- will take the user to the Dispense Rationale page.
6 – Remove Pharmacy Relationship- will take the user to Remove Pharmacy page.
14.8.2 Associate to Pharmacy

Associate to Pharmacy

To identify the pharmacy you represent, please complete the fields below and press Search. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

10001 and DEA NPI 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.

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

Showing 1 of 1 entries

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

Eligibility Check

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

**Patient Information**

- First Name
- Last Name
- Date of Birth
- Zip Code

**Add Patient Lab (optional)**

- ANC value per microlitre (opt)
- Blood Draw Date (opt)

**Dispensation Information**

- Date of Service (opt)
- Manufacturer
- NDC# Number
- Days Supply (opt)
- Quantity (opt)

At least one identifier is required

- Prescriber DEA
- Prescriber NPI

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

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

![Eligibility Check Result](image)

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

**Predispense Authorization**

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

**Patient Information**
- **First Name**
- **Last Name**
- **Date of Birth**
- **Zip Code**

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

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

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

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

Note: This result is displayed for the *Predispose Authorization* when the result is unsuccessful.

---

**Predispose Authorization Result**

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

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

**Current Monitoring Frequency:** Weekly

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

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

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

**Patient’s Lab History**

---

For additional information about the Clozapine REMS Program, please call 844-267-8678.
15. **Dispense Rationale – Static Pages**

15.1 **Home Page**

---

**What is the Clozapine REMS Program?**

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
16. Dispense Rationale – Pharmacy Authorized Representative (Non-Switch)

16.1 Pharmacy – Authorized Representative Dashboard

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

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

The below patient is eligible to receive clozapine.

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

Current Monitoring Frequency: Weekly

Name: Summer H

DOB: 

Authorization Number: 

Lab Status: Lab was Saved

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

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

![Image of the CLOZAPINE REMS interface showing a failed predispose authorization result with a message not to dispense clozapine to the patient and providing contact information. The interface also shows a patient's lab history with current and previous values for blood draw date and ANC level (per μL). There is a note to provide dispense rationale for the patient. For additional information about the Clozapine REMS Program, please call 844-267-8678.](image-url)
16.5 Pharmacy – Authorized Representative *Predispose Authorization* Result – Successful

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

**Predisperse Authorization Result**

⚠️ The maximum number of allowable *Dispense Rationales* has been reached for this patient. 
For further assistance with this patient’s eligibility, please contact the prescriber.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
17. Dispense Rationale – Pharmacy Staff (Non-Switch)

Pharmacy Staff Dashboard

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

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

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

---

**Predispose Authorization Result**

![Image of Predispose Authorization Result](image-url)

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

**Lab**

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

**Current Monitoring Frequency:** Weekly

**Name**: Summer H

**DOB**

**Authorization Number**

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

---

Reference ID: 4376730
17.4 Pharmacy Staff *Predispense Authorization Result – Successful*

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

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

**Lab**

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

**Current Monitoring Frequency:** Weekly

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

- **Prescriber not certified.** Prescriber can certify at www.clozapinerems.com or call 844-267-8678.
- **Current ANC is not on file.**
- A *Dispense Rationale* currently exists for this patient and will expire on 06/06/2018.
- For further assistance with this patient’s eligibility, please contact the patient’s prescriber.

**Patient’s Lab History**

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

The maximum number of allowable *Dispense Rationales* has been reached for this patient. For further assistance with this patient’s eligibility, please contact the prescriber.

For additional information about the Clozapine REMS Program, please call 844-267-8678.
18. Dispense Rationale – Pharmacy Authorized Representative (Switch)
18.1 Pharmacy – Authorized Representative Dashboard

For additional information about the Clozapine REMS Program, please call 844-267-8678.
18.2 Pharmacy – Authorized Representative *Dispense Rationale*

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

- The below patient is eligible to receive clozapine.

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

- Current Monitoring Frequency: Weekly

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
18.4 Pharmacy – Authorized Representative Dispense Rationale Result Screen- Success (After DR is issued)

 berhasil
The below patient is eligible to receive clozapine.

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

Current Monitoring Frequency: Weekly

Name Summer H
DOB
Authorization Number

⚠️ Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.
⚠️ Current ANC is not on file.
A Dispense Rationale currently exists for this patient and will expire on 06/06/2018.
For further assistance with this patient's eligibility, please contact the patient's prescriber.

Patient’s Lab History

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

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

Current Monitoring Frequency: Weekly

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

Name: Summer H
DOB:
Authorization Number:

Prescriber not certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678.
Current ANC is not on file.
For further assistance with this patient's eligibility, please contact the patient's prescriber.

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

The below patient is eligible to receive clozapine.

Current Monitoring Frequency: Weekly

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

Lab Status Lab was Saved

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

For additional information about the Clozapine REMS Program, please call 844-267-3678.

Reference ID: 4376730
18.7 Pharmacy – Authorized Representative Eligibility Check Result- Unsuccessful

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

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

Current Monitoring Frequency: Weekly

The patient is not enrolled in the REMS Program. Please call the Clozapine REMS Program at 844-267-8678 for more information.

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
19. Dispense Rationale – Pharmacy Staff (Inpatient Pharmacy)

19.1 Pharmacy Staff Dashboard

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

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

The below patient is eligible to receive clozapine.

Current Monitoring Frequency: Weekly

Lab Status: Lab was Saved

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
Note: If an authorized representative or pharmacy staff using the pharmacy network (switch) receives a rejection message due to “prescriber not certified”, the following message will appear on their screen:

*REMS* Clozapine REMS – Prescriber must be certified or you can request a Dispense Rationale through www.clozapinerems.com or by calling 844-267-8678.

Once this message is received, the authorized representative or Pharmacy Staff can either call the Clozapine REMS Program contact center to obtain a Dispense Rationale or they can access the website and follow the above screens to obtain the Dispense Rationale. Once they receive confirmation of the Dispense Rationale, the authorized representative or Pharmacy Staff will need to re-run the claim to allow the authorization of the dispense.
20. Dispense Rationale – Pharmacy Staff (Switch)

20.1 Pharmacy Staff Dashboard

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

Dispense Rationale

To request a Dispense Rationale for your patient, please complete the information below and Submit. If you have no information for your patient, you can enter it here. All fields listed below are required unless otherwise indicated.

Patient Information

- First Name
- Last Name
- Date of Birth
- Zip Code

Add Patient Lab (optional)

- ANC value per microgram (opt)
- Blood Draw Date (opt)

Dispensation Information

- Date of Service (opt)
- Manufacturer
- NDC# Number
- Days Supply (opt)
- Quantity (opt)

At least one identifier is required

- Prescriber DEA
- Prescriber NPI

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
20.4 Pharmacy Staff Dispense Rationale Result - Success (After DR is issued)

Dispense Rationale Result

✅ The below patient is eligible to receive clozapine.

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

Current Monitoring Frequency: Weekly

Name: Summer H
DOB
Authorization Number

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

⚠️ Current ANC is not on file.

A Dispense Rationale currently exists for this patient and will expire on 05/06/2018.

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

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

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

Current Monitoring Frequency: Weekly

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

For additional information about the Clozapine REMS Program, please call 844-267-8678.
21. **Dispense Rationale** – Prescriber and Prescriber Designee

21.1 Prescriber and Prescriber Designee Dashboard

Note:

1. Prescriber and Prescriber Designees can also view the *Dispense Rationale* history by clicking on the drop-down menu and selecting ‘*Dispense Rationale* History’.
2. This expandable section is functionality that will be on both the Prescriber and Prescriber Designee dashboard. This section provides information about the status of the Dispense Rationale.

3. Options available for Dispense Rationale status include:
   a. Active
   b. Expired
   c. Limit Reached
   d. Not on File
21.2 Prescriber and Prescriber Designee Dispense Rationale History

For additional information about the Clozapine REMS Program, please call 844-267-8678.
Instructions
Clozapine is only available through the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. This form must be completed and returned to the Clozapine REMS Program before clozapine products may be shipped to certified pharmacy locations. This form applies to all distributors who wish to purchase any clozapine product.

In order to distribute clozapine, the distributor must designate an authorized representative.

The authorized representative for the distributor must:
• Review and agree to the responsibilities below.
• Complete and submit this one-time Clozapine REMS Distributor Enrollment Form.
• Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements.

Please complete the requested information below and submit this form to info@clozapinedistributor.com. If you have any questions, require additional information, or need copies of Clozapine REMS Program documents, please visit the Clozapine REMS Program Website at www.clozapinerems.com, or call the Clozapine REMS Program Contact Center at 844-267-8678.

Distributor Responsibilities
I am the authorized representative designated to coordinate the activities to comply with the Clozapine REMS Program distribution requirements. I understand:
• Distributors must enroll in the Clozapine REMS Program to distribute clozapine
• Distributors will have access to a secure daily pharmacy certification file from the Clozapine REMS Program

On behalf of the distributor, I agree to establish procedures that are subject to audit to help ensure compliance with the following program requirements:
• Train relevant staff involved in distributing clozapine on the distribution requirements of the Clozapine REMS Program
• Provide clozapine only to certified pharmacies and enrolled distributors in the Clozapine REMS Program
• Provide complete, unblinded and unblocked data to individual sponsors, including information on shipments to pharmacies
• Cooperate with periodic audits, REMS Assessments, or noncompliance investigations to ensure that clozapine products are distributed in accordance with the Clozapine REMS Program requirements

Distributor Information (All Fields Required)

Name:
Address:  
City:  State:  Zip Code:  
Phone:  Fax:  
DEA:

Authorized Representative Information (All Fields Required)

First Name:  Last Name:
Phone:  Fax:
Email:
Contact Preference (please select one):  Email  Fax

Authorized Representative Signature:  Date (MM/DD/YYYY):
Dear Clozapine Prescriber:

On October 12, 2015, the single shared Clozapine REMS Program replaced all individual clozapine registries. Our records indicate you have not certified in the Clozapine REMS Program. As a reminder, one of the key requirements of the Clozapine REMS Program is that any Healthcare Provider who prescribes or dispenses clozapine must certify in the program.

Since you have not certified, your account with the Clozapine REMS Program has been deactivated and interruption of patient therapy is imminent.

If you wish to treat patients using clozapine products, you must certify online through the Clozapine REMS Program Website at www.clozapinerems.com; by completing the Clozapine REMS Prescriber Enrollment Form, training, and the Clozapine REMS Knowledge Assessment for Healthcare Providers and faxing the completed documents to 844-404-8876; or, by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If you have any questions, or if you believe that you have received this letter in error, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Regards,

The Clozapine REMS Program

Please review Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers available at www.clozapinerems.com for more detailed information about the Clozapine REMS Program requirements and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit www.clozapinerems.com to review the complete Prescribing Information.
Dear Pharmacy Manager:

On October 12, 2015, the single shared Clozapine REMS Program replaced all individual clozapine registries. Our records indicate your pharmacy dispenses clozapine and is not yet certified in the Clozapine REMS Program.

Because you are not yet certified, on <Deactivation Date> your account with the Clozapine REMS Program will be deactivated and you will no longer be able to receive and dispense clozapine.

You must certify in the Clozapine REMS Program to avoid interruption in your ability to receive and dispense clozapine products, and to avoid potential interruption in a patient’s clozapine therapy.

Pharmacies can certify online through the Clozapine REMS Program Website at www.clozapinerems.com; by completing the appropriate Clozapine REMS Enrollment Form, training, and Clozapine REMS Knowledge Assessment for Healthcare Providers, and faxing the completed documents to 844-404-8876; or, by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If you have any questions, or believe that you have received this letter in error, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Regards,

The Clozapine REMS Program

Please review Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers available at www.clozapinerems.com for more detailed information about the Clozapine REMS Program requirements and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit www.clozapinerems.com to review the complete Prescribing Information.

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

This letter is intended to inform outpatient pharmacies who must obtain a “Predispose Authorization” (PDA) via the Clozapine REMS Program Website or who obtain a PDA by calling the Clozapine REMS Program Contact Center of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program occurring in the February, 2019 REMS Modification. If your pharmacy is part of a pharmacy chain, contact your chain’s authorized representative to complete enrollment and certification. If you need assistance, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Changes to the Clozapine REMS Program in February, 2019 may affect your ability to dispense clozapine.

1. **Only pharmacies certified in the Clozapine REMS Program will be able to receive and dispense clozapine.**
   - All pharmacies that dispense clozapine must be certified in the Clozapine REMS Program to purchase or receive clozapine from a wholesaler or distributor.
   - If your pharmacy dispenses clozapine and is not yet certified in the Clozapine REMS Program, certify online at www.clozapinerems.com or download the Clozapine REMS Outpatient Pharmacy Enrollment Form and fax the completed form to 844-404-8876.

2. **Pharmacy Classification and program requirements may have changed.**
   Pharmacies previously certified in the Clozapine REMS Program may be reclassified using the following definitions:
   - **Inpatient pharmacy:** a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions or injuries (usually for a short-term illness or condition)
   - **Outpatient pharmacy:** a facility that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems

   This pharmacy reclassification, if necessary, will occur at your next scheduled pharmacy recertification. Requirements of pharmacy types differ so if you were an inpatient pharmacy now reclassified as an outpatient pharmacy, please review additional information on outpatient pharmacy requirements available in the Clozapine REMS PDA Fact Sheet attached to this letter; in the Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers, in the Clozapine REMS Frequently Asked Questions (FAQ’s) available at www.clozapinerems.com; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

   You may call the Clozapine REMS Program Contact Center at 844-267-8678 if you are unsure whether your pharmacy type is inpatient or outpatient (based on the definitions above) or if your pharmacy provides both inpatient and outpatient pharmacy services to patients being treated with clozapine.

3. **Prescribing clozapine for patients in an outpatient setting** requires certification in the Clozapine REMS Program.
   If the prescriber is not certified in the Clozapine REMS Program, an outpatient pharmacy will not receive authorization to dispense clozapine.

4. **Certified pharmacies may apply clinical judgment and continue to dispense clozapine to enrolled patients if the prescriber is not certified in the Clozapine REMS Program by utilizing a new function, the "Dispense Rationale."

   The use of a Dispense Rationale is limited. Refer to the Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers or the Clozapine REMS FAQ’s available at www.clozapinerems.com; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

---

1An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.
What is a Dispense Rationale?

- The Clozapine REMS Program will alert the pharmacy when the prescriber is not certified in the Clozapine REMS Program via a reject message of the PDA request. The pharmacy may then exercise clinical judgement to provide a Dispense Rationale to authorize the dispense if:
  - The patient is enrolled in the Clozapine REMS Program; and,
  - Has an acceptable absolute neutrophil count (ANC) value on file; or,
  - If the last ANC on file indicates moderate or severe neutropenia, has a “Treatment Rationale” on file.
- Dispense Rationales are valid for 72 hours (3 calendar days) and limited to no more than three (3) occurrences for an individual patient within a rolling six (6) month period.

How can I provide a Dispense Rationale?

- Certified pharmacies can provide a Dispense Rationale:
  - Via the Clozapine REMS Program Website at www.clozapinerems.com, or
  - By calling the Clozapine REMS Program Contact Center at 844-267-8678, or
  - By following the step-by-step instructions provided in the enclosed Clozapine REMS Predispense Authorization Fact Sheet.

Patient dispensing

- A PDA will be issued if the patient meets the following program Elements to Assure Safe Use:
  - The patient must be enrolled in the Clozapine REMS Program; and,
  - An acceptable ANC value is on file; or,
  - Has a Treatment Rationale on file if the last ANC submitted to the Clozapine REMS Program indicates moderate or severe neutropenia.
- Pharmacies should dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.
- All PDA responses will provide the dispensing pharmacy with the most recent ANC value and the associated blood draw date, and patient’s monitoring frequency (MF) on file with the Clozapine REMS Program.

Pharmacies are encouraged to submit the ANC to the Clozapine REMS Program when:

- The pharmacist is made aware of a more current ANC than the most recent lab value reported in the PDA response.
- The most recent ANC indicates moderate or severe neutropenia. The prescriber must provide a Treatment Rationale to the Clozapine REMS Program to allow the pharmacy to receive a PDA and dispense clozapine to the patient. The pharmacy may contact the prescriber to remind them of the need for a Treatment Rationale.
- Pharmacies may submit ANCs to the Clozapine REMS Program at www.clozapinerems.com, by calling the Clozapine REMS Program Contact Center at 844-267-8678; or, faxing a completed Clozapine REMS ANC Lab Reporting Form (available from the website) to the Clozapine REMS Program.
- If the ANC result on file with the Clozapine REMS Program is not current according to the patient’s MF (within 7 days of the PDA transaction date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring), a PDA will still be issued, but the pharmacist will receive a warning message regarding the need to ensure the ANC is current.

The pharmacy’s authorized representative must ensure that all pharmacy staff are aware of these modifications to the Clozapine REMS Program effective February 2019.

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

Sincerely,

The Clozapine REMS Program

Enclosures: Clozapine REMS Predispense Authorization Fact Sheet

How to Start Clozapine and Monitor Patients Fact Sheet

The products covered under the Clozapine REMS Program are: Clozaril® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension

Fazaclo® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products
Dear Pharmacy Manager:

This letter is intended to inform outpatient pharmacies who must obtain a “Predispose Authorization” (PDA) electronically via their pharmacy management system (i.e., “the switch”) of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program that will occur in the February 2019 REMS Modification.

Changes to the Clozapine REMS Program in February 2019 may affect your ability to dispense clozapine.

1. Only pharmacies certified in the Clozapine REMS Program will be able to receive and dispense clozapine.
   - Only pharmacies certified in the Clozapine REMS Program will be able to purchase or receive clozapine from a wholesaler or distributor.
   - If your pharmacy dispenses clozapine and is not yet certified in the Clozapine REMS Program, certify online at www.clozapinerems.com or download the Clozapine REMS Outpatient Pharmacy Enrollment Form and fax the completed form to 844-404-8876.
   - If your pharmacy is part of a pharmacy chain, contact your chain’s authorized representative to complete enrollment and certification. If you need assistance, call the Clozapine REMS Program Contact Center at 844-267-8678.

2. Prescribing clozapine for patients in an outpatient setting requires certification in the Clozapine REMS Program.
   If the prescriber is not certified in the Clozapine REMS Program, the outpatient pharmacy will not receive authorization to dispense clozapine.

3. Certified pharmacies may apply clinical judgment and continue to dispense clozapine to enrolled patients if the prescriber is not certified in the Clozapine REMS Program by utilizing a new function, the "Dispense Rationale."
   The use of a Dispense Rationale is limited. Refer to information provided below, the Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers or Clozapine REMS Frequently Asked Questions (FAQ’s) available at www.clozapinerems.com; or, call the Clozapine REMS Program Contact Center at 844-267-8678.

What is a Dispense Rationale?
   - The Clozapine REMS Program will alert the pharmacy when the prescriber is not certified in the Clozapine REMS Program via a reject message of the PDA request. The pharmacy may then exercise clinical judgement to provide a Dispense Rationale to authorize the dispense if:
     - The patient is enrolled in the Clozapine REMS Program; and
     - Has an acceptable absolute neutrophil count (ANC) value on file; or
     - The last ANC on file indicates moderate or severe neutropenia, and has a “Treatment Rationale” on file.
   - Dispense Rationales are valid for 72 hours (3 calendar days) and are limited to no more than three (3) occurrences for an individual patient within a rolling six (6) month period.

---

2 An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

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

02/2019
How can I provide a Dispense Rationale?

- Certified pharmacies can provide a Dispense Rationale:
  - Via the Clozapine REMS Program Website at www.clozapinerems.com, or
  - By calling the Clozapine REMS Program Contact Center at 844-267-8678, or
  - By following the step-by-step web instructions provided in the enclosed Clozapine REMS Predispense Authorization Fact Sheet.

Patient dispensing

- A PDA will be issued if the patient meets the following program Elements to Assure Safe Use:
  - The patient must be enrolled in the Clozapine REMS Program; and,
  - An acceptable ANC value is on file;
  - A Treatment Rationale is on file if the last ANC submitted to the Clozapine REMS Program indicates moderate to severe neutropenia.
- Pharmacies should dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber.
- All PDA responses will provide the dispensing pharmacy with the most recent ANC value, the associated blood draw date, and patient’s monitoring frequency (MF) on file with the Clozapine REMS Program.

Pharmacies are encouraged to submit the ANC to the Clozapine REMS Program when:

- The pharmacist is made aware of a more current ANC than the most recent lab value reported in the PDA response.
- The most recent ANC indicates moderate or severe neutropenia. The prescriber must provide a Treatment Rationale to the Clozapine REMS Program to allow the pharmacy to receive a PDA and dispense clozapine to the patient. The pharmacy may contact the prescriber to remind them of the need for a Treatment Rationale.
- Pharmacies may submit ANCs to the Clozapine REMS Program at www.clozapinerems.com, by calling the Clozapine REMS Program Contact Center at 844-267-8678 or faxing a completed Clozapine REMS ANC Lab Reporting Form (available from the website) to the Clozapine REMS Program.
- If the last ANC result on file with the Clozapine REMS Program is not current according to the patient’s MF (within 7 days of the PDA transaction date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring), a PDA will still be issued, but the pharmacist will receive a warning message regarding the need to ensure that the ANC is current.

The pharmacy’s authorized representative must ensure that all pharmacy staff are aware of these modifications to the Clozapine REMS Program effective February 2019.

For additional information related to the Clozapine REMS Program or use of the REMS Pharmacy Network, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Sincerely,

The Clozapine REMS Program

Enclosures: Clozapine REMS Predispense Authorization Fact Sheet
How to Start Clozapine and Monitor Patients Fact Sheet
Dear Inpatient Pharmacy Personnel:

This letter is intended to inform inpatient pharmacies of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program that will occur in the 02/2019 REMS Modification.

**Changes to the Clozapine REMS Program in 02/2019 may affect your ability to dispense clozapine.**

1. **Only pharmacies certified in the Clozapine REMS Program will be able to receive and dispense clozapine.**
   - Only pharmacies certified in the Clozapine REMS Program will be able to purchase or receive clozapine from a wholesaler or distributor.
   - If your pharmacy dispenses clozapine and is not yet certified in the Clozapine REMS Program, certify online at www.clozapinerems.com or download the Clozapine REMS Inpatient Pharmacy Enrollment Form and fax the completed form to 844-404-8876.

2. **Pharmacy classification and program requirements may have changed.**
   Inpatient pharmacies previously certified in the Clozapine REMS Program may be reclassified using the following definitions:
   - **Inpatient pharmacy**: a pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions, or injuries (usually for a short-term illness or condition).
   - **Outpatient pharmacy**: a pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

   This pharmacy reclassification, if necessary, will occur during the next scheduled pharmacy recertification. If an inpatient pharmacy is reclassified as an outpatient pharmacy, the requirements for dispensing clozapine are different. Please review the Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers available on the Clozapine REMS Program Website at www.clozapinerems.com for more information.

   You may call the Clozapine REMS Program Contact Center at 844-267-8678 if you are unsure whether your pharmacy type is inpatient or outpatient (based on the definitions above) or if your pharmacy provides both inpatient and outpatient pharmacy services to patients being treated with clozapine.

3. **Certification is not required to prescribe clozapine for patients receiving inpatient care if the patient is enrolled in the Clozapine REMS Program.**
   Prescribers who continue clozapine for patients during inpatient medical care and other related services for surgery, acute medical conditions, or injuries (usually for a short-term illness or condition) will not be required to become certified in the Clozapine REMS Program if the patient is already enrolled in the Clozapine REMS Program.
   - A patient being initiated on clozapine while in an inpatient setting who is not enrolled in the Clozapine REMS Program must be enrolled by a certified prescriber.

4. **Dispense a temporary supply of clozapine to an enrolled patient upon discharge from a healthcare facility that is not more than:**
   - A 7-day supply, or
   - An amount sufficient to supply the patient until their next blood draw date per the monitoring frequency (MF) on file with the Clozapine REMS Program; or
   - The amount authorized by the prescriber.
The “Eligibility Check” (EC) process for inpatient pharmacies is also changing as outlined below:

**The Eligibility Check for Inpatient Pharmacies will evaluate:**

- **Patient Enrollment Status:** The patient **must** be enrolled in the Clozapine REMS Program to receive clozapine.
  - If the patient is enrolled, you will receive an authorization to dispense clozapine.
  - If the patient is not enrolled, a certified prescriber must enroll the patient before the patient becomes eligible to receive clozapine.

- **Absolute Neutrophil Count (ANC):** Inpatient pharmacies can determine if the patient ANC is on file with the Clozapine REMS Program, if it’s current, and if it’s within the normal range. Abnormalities or an absence of this information will not prevent dispensing of clozapine.
  - All EC responses will provide inpatient pharmacies with the patient’s most recent ANC value and the associated blood draw date, and his/her MF on file with the Clozapine REMS Program.
  - The pharmacy may access the inpatient medical record system to verify:
    - The ANC is current based on the patient’s MF (i.e., within 7 days of the EC date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring)
    - ANC is within the acceptable range described in the Prescribing Information or the certified prescriber has authorized clozapine treatment if the patient’s ANC falls below the acceptable range when the prescriber determines the benefits exceed the risks of developing severe neutropenia.
  - If the patient’s ANC is low and there is no “Treatment Rationale” on file, the inpatient pharmacy will receive a warning message. Inpatient prescribers should use clinical judgment to determine if benefits of receiving clozapine outweigh its risks if a patient has an ANC indicating moderate or severe neutropenia.
  - If the patient has an ANC that is more current than the ANC draw date on file with the Clozapine REMS Program as received in the EC response, the pharmacy is encouraged to submit the ANC to the Clozapine REMS Program utilizing the step-by-step instructions provided in the enclosed Clozapine REMS Eligibility Check Fact Sheet.

The pharmacy’s authorized representative must ensure that all pharmacy staff are aware of these modifications to the Clozapine REMS Program effective 02/2019.

For additional information related to the Clozapine REMS Program, visit the Clozapine REMS Program Website at [www.clozapinerems.com](http://www.clozapinerems.com) or call the Clozapine REMS Program Contact Center at 844-267-8678.

Sincerely,

The Clozapine REMS Program

Enclosures: **Clozapine REMS Eligibility Check Fact Sheet**  
**How to Start Clozapine and Monitor Patients Fact Sheet**
Dear Prescriber and/or Prescriber Designee:

This letter is intended to notify prescribers and prescriber designees of changes to the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program that will occur in the 02/2019 REMS Modification.

**Changes to the Clozapine REMS Program in 02/2019 may affect your ability to prescribe clozapine.**

1. **Only prescribers certified in the Clozapine REMS Program will be able to prescribe clozapine to patients for outpatient use.**

   If you need to prescribe clozapine but are not yet certified in the Clozapine REMS Program, go immediately to www.clozapinerems.com to certify online. You may also download the Clozapine REMS Prescriber Enrollment Form and Clozapine REMS Knowledge Assessment for Healthcare Providers, and fax the completed forms to 844-404-8876. Once a prescriber is certified, his/her designees must enroll online at www.clozapinerems.com.

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

   Prescribers in an inpatient setting should use clinical judgment to determine if the benefits of receiving clozapine outweigh its risks if a patient has an absolute neutrophil count (ANC) indicating moderate or severe neutropenia. For more information on patient access to clozapine in the inpatient setting, please review the Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers available on the Clozapine REMS Program Website at www.clozapinerems.com.

3. **Pharmacies that dispense clozapine must be certified in the Clozapine REMS Program.**

   A list of certified pharmacies is available on the Clozapine REMS Program Website at www.clozapinerems.com.

   **Prescribers, once certified, must:**
   - Enroll all patients in the Clozapine REMS Program prior to their first dose of clozapine.
   - Order ANC lab work according to the monitoring frequency (MF) described in the Prescribing Information.
   - Submit ANC according to the patient’s MF on file with the Clozapine REMS Program:
     - For weekly MF, ANC must be submitted within 7 days of the lab draw* date
     - For every two weeks MF, ANC must be submitted within 15 days of the lab draw* date
     - For monthly MF, ANC must be submitted within 31 days of the lab draw* date
   
   *Assumes the lab draw date is day 0.

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

02/2019
Patient ANCs may be submitted by:
- By logging in to the Clozapine REMS Program Website at www.clozapinerems.com,
- By calling the Clozapine REMS Program Contact Center at 844-267-8678; or
- By using the Clozapine REMS ANC Lab Reporting Form (available at www.clozapinerems.com) and faxing it to 844-404-8876. Labs submitted via the Clozapine REMS Program Website are available immediately; however, allow up to 48 hours to process ANC labs submitted by fax.

Provide a “Treatment Rationale” to authorize dispensing via an outpatient pharmacy for patients who have an ANC indicating moderate or severe neutropenia. Treatment Rationales may be provided online or on the Clozapine REMS ANC Lab Reporting Form (available at www.clozapinerems.com) and faxed to 844-404-8876.

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

Sincerely,

The Clozapine REMS Program

Enclosure: How to Start Clozapine and Monitor Patients Fact Sheet
Dear <Prescriber FirstName LastName>:

On October 12, 2015, the single shared Clozapine Risk Evaluation Mitigation Strategy (REMS) Program replaced all individual clozapine registries. Our records indicate you prescribe clozapine to patients and that you currently have <Enrolled Patient Count> enrolled patients affiliated and under your care within the Clozapine REMS Program. Our records also indicate that you have not yet certified in the Clozapine REMS Program.

You must certify in the Clozapine REMS Program to avoid interruption in your ability to continue prescribing clozapine products, and to avoid potential delays to your patient’s clozapine therapy. As a reminder, one of the key requirements of the Clozapine REMS Program is that any Healthcare Provider who prescribes clozapine must certify in the program.

**If you have not completed certification by <Certification Deadline>, your account with the Clozapine REMS Program will be deactivated.**

If you wish to continue to treat patients using clozapine products, you must certify online through the Clozapine REMS Program Website at [www.clozapinerems.com](http://www.clozapinerems.com); or by completing the *Clozapine REMS Prescriber Enrollment Form*, training, and the *Clozapine REMS Knowledge Assessment for Healthcare Providers* and faxing the completed documents to 844-404-8876; or, by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If you have any questions, or if you believe that you have received this letter in error, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Regards,

The Clozapine REMS Program

---

Please review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* available at [www.clozapinerems.com](http://www.clozapinerems.com) for more detailed information about the Clozapine REMS Program requirements and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit [www.clozapinerems.com](http://www.clozapinerems.com) to review the complete Prescribing Information.
Dear <Prescriber FirstName LastName>:

On October 12, 2015, the single shared Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program replaced all individual clozapine registries. Your prescriber information was migrated from an existing registry to the Clozapine REMS Program. Our records indicate that you may not be currently prescribing clozapine and do not currently have enrolled patients affiliated under your care within the Clozapine REMS Program. Our records also indicate that you have not certified in the Clozapine REMS Program.

On <Deactivation Date>, your account with the Clozapine REMS Program will be deactivated.

If you prescribe clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems, you must certify in the Clozapine REMS Program to avoid interruption in your ability to prescribe clozapine products, and to avoid potential delays to a patient’s clozapine therapy. As a reminder, one of the key requirements of the Clozapine REMS Program is that any Healthcare Provider who prescribes clozapine for outpatient use must certify in the program.

If you wish to treat patients using clozapine products, you must certify online through the Clozapine REMS Program Website at www.clozapinerems.com; by completing the Clozapine REMS Prescriber Enrollment Form, training, and Clozapine REMS Knowledge Assessment for Healthcare Providers; and faxing the completed documents to 844-404-8876; or, by calling the Clozapine REMS Program Contact Center at 844-267-8678.

If you have any questions, or believe that you have received this letter in error, please call the Clozapine REMS Program Contact Center at 844-267-8678.

Regards,

The Clozapine REMS Program

Please review Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers available at www.clozapinerems.com for more detailed information about the Clozapine REMS Program requirements and additional information about changes related to clozapine treatment and monitoring. This letter does not contain the complete safety profile for clozapine. Visit www.clozapinerems.com to review the complete Prescribing Information.

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

The Clozapine REMS Program is pleased to announce a program modification slated to become effective February 2019. A summary of changes is provided below:

- A pharmacy cannot dispense clozapine to patients if the pharmacy is not certified in the Clozapine REMS Program.
- Reclassification of certain inpatient and outpatient pharmacies may be needed at recertification with related updates to enrollment forms.
- Patients in inpatient settings no longer require a program-certified prescriber unless the patient has never been enrolled into the Clozapine REMS Program.
- A “Treatment Rationale” is required prior to dispensing in outpatient settings if the patient’s absolute neutrophil count (ANC) indicates moderate or severe neutropenia.
- In an outpatient setting, a “Dispense Rationale” may be provided to allow dispensing of clozapine for a limited time when a prescriber is not certified.

Please assist the Clozapine REMS Program in notifying pharmacies of these important program modifications by distributing this letter to your membership. You may direct them to contact the Clozapine REMS Program with any questions or for additional information.

Sincerely,

The Clozapine REMS Program

Enclosures:

- Dear Inpatient Pharmacy Letter
- Dear Outpatient Pharmacy Using Switch Letter
- Dear Outpatient Pharmacy Using Web PDA Letter
- Clozapine REMS PDA Fact Sheet
- Clozapine REMS Eligibility Check Fact Sheet
- How to Start Clozapine and Monitor Patients Fact Sheet

The products covered under the Clozapine REMS Program are: Clozaril® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension • Fazaclor® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products
Dear <Professional Society>:

The Clozapine REMS Program is pleased to announce a program modification slated to become effective 02/2019. A summary of the changes is provided below:

- If patients in inpatient settings are already enrolled in the Clozapine REMS Program, they no longer require a program-certified prescriber to prescribe clozapine for inpatient use.
- In order to be considered current, patient’s absolute neutrophil count (ANC) values must be on file and within 7 days of the lab draw date for weekly monitoring, 15 days for every two weeks monitoring, and 31 days for monthly monitoring.
- A “Treatment Rationale” is required prior to dispensing in outpatient settings if the patient’s ANC level indicates moderate or severe neutropenia.
- Only a certified prescriber can provide a valid *Treatment Rationale* to continue clozapine treatment in a patient whose ANC indicates moderate or severe neutropenia.

Please assist the Clozapine REMS Program in notifying prescribers of these important program modifications by distributing this letter to your membership. You may direct them to contact the Clozapine REMS Program with any questions or for additional information.

Sincerely,

The Clozapine REMS Program

Enclosures:

- *Dear Prescriber Letter*
- *How to Start Clozapine and Monitor Patients Fact Sheet*