

# Clozapine REMS

## Frequently Asked Questions

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### Table of Contents

General Section .....	2
Prescriber .....	5
Prescriber Designee .....	9
Patient Management.....	11
Pharmacy Management.....	15
Pharmacy Authorized Representative .....	18
Pharmacy Staff .....	24
Wholesaler/Distributor .....	25
Technical Support .....	26
Patient.....	28

## 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?

The Clozapine REMS is an FDA-required safety program that manages the risk of severe neutropenia, which can lead to serious infections and death, from treatment with clozapine. The Clozapine REMS is a single shared patient registry with requirements for prescribers, pharmacists, patients, and distributors.

### 3. What are the different roles of healthcare staff in the Clozapine REMS?

There are 4 different roles in the Clozapine REMS:

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

Please refer to the description of each of these roles in the appropriate sections below to determine which one best describes your duties in the Clozapine REMS.

### 4. Can a Healthcare Provider fulfill multiple roles in the Clozapine REMS?

Yes; the Clozapine REMS allows Healthcare Providers with multiple roles in the Clozapine REMS to create multiple website user accounts provided the accounts use different email addresses.

If you have any questions, call the Clozapine REMS Contact Center at 888-586-0758 for assistance.

### 5. How does a Healthcare Provider certify in more than one role in the Clozapine REMS? Can the same email address be used for multiple roles in the Clozapine REMS?

To certify in more than one role in the Clozapine REMS, you must create a Clozapine REMS Website user account for each role. For security reasons, different email addresses must be used for each account. If you have any questions, call the Clozapine REMS Contact Center at 888-586-0758 for assistance.

### 6. 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.

- For current Prescribing Information for clozapine, select the “Prescribing Information” link along the top of the Clozapine REMS Website at [www.clozapinerems.com](http://www.clozapinerems.com).

## **7. When should I submit a patient's ANC to the Clozapine REMS?**

Patient ANC information must be submitted to the Clozapine REMS using the Patient Status Form. Although the Patient Status Form is only submitted monthly, prescribers must ensure their patients are on the appropriate monitoring frequency and adhere to the corresponding blood draw intervals. Single ANCs may still be submitted via the ANC Lab Reporting Form.

Your options to submit ANCs are:

1. Submit all at once via the *Patient Status Form* monthly
2. Submit as labs are obtained via the *ANC Lab Reporting Form*

## **8. 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 clozapine directly to the Clozapine REMS Contact Center at 888-586-0758. 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>.

Suspected adverse events associated with the use of clozapine may also be submitted on the *Patient Status Form*.

To report a product complaint, or if you require medical information, you may also call the Clozapine REMS Contact Center at 888-586-0758.

## **9. How is monitoring frequency determined in the Clozapine REMS?**

Determining monitoring frequency is the responsibility of the certified prescriber.

The prescriber may modify a patient’s monitoring frequency on the monthly *Patient Status Form*.

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.

For current Prescribing Information for clozapine, select the “Prescribing Information” link along the top of the Clozapine REMS Website at [www.clozapinerems.com](http://www.clozapinerems.com).

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.

For details regarding what monitoring frequency a patient should be on, refer to the Prescribing Information.

- For current Prescribing Information for clozapine, select the “Prescribing Information” link along the top of the Clozapine REMS Website at [www.clozapinerems.com](http://www.clozapinerems.com)

## Prescriber

### 1. What is the role of a prescriber in the Clozapine REMS?

<u>Definition</u>	<u>Responsibilities</u>
<p>A prescriber is any healthcare professional who prescribes clozapine to a patient</p>	<p><u>Certification Process</u></p> <p>Step 1: Review the Prescribing Information for clozapine            Step 2: Certify* in the Clozapine REMS by:</p> <ul style="list-style-type: none"> <li>• Reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers</i></li> <li>• Successfully complete and submit the <i>Knowledge Assessment for Prescribers</i></li> <li>• Completing and submitting the <i>Prescriber Enrollment Form</i></li> </ul> <p>*Prescribers who prescribe clozapine for outpatient use and/or initiate treatment for inpatients must be certified in the Clozapine REMS. Prescribers continuing clozapine for 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. Patients in this setting are required to be enrolled in the Clozapine REMS 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.</p> <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> <li>○ Enroll every new patient in the Clozapine REMS, providing an ANC with the enrollment</li> <li>○ Counsel each patient (or their caregiver) about the risk of severe neutropenia which can lead to serious infection and death</li> <li>○ Check the ANC for each patient according to the monitoring requirements</li> <li>○ Submit ANCs monthly using the <i>Patient Status Form</i>.</li> <li>○ Provide authorization to continue treatment, if necessary, through the Clozapine REMS when the patient's ANC results meet criteria for interruption of therapy, and you decide to continue clozapine treatment. Provide a "Treatment Rationale" to authorize the continuation of clozapine therapy for general population patients with moderate or any patient with severe neutropenia if it is determined that the benefits of clozapine therapy outweigh the risks</li> <li>○ Document patients with benign ethnic neutropenia (BEN) as BEN patients, either at the time of patient enrollment or by submitting a <i>Patient Status Form</i></li> <li>○ Document a patient as hospice care by submitting a <i>Patient Status Form</i></li> </ul>

<u>Definition</u>	<u>Responsibilities</u>

**2. How can a prescriber become certified in the single shared Clozapine REMS?**

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

Prescribers who prescribe clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drugstores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems must certify in the Clozapine REMS and adhere to the Clozapine REMS requirements. Prescribers may certify online through the Clozapine REMS Website or by submitting the *Prescriber Enrollment Form* and *Knowledge Assessment for Prescribers* via fax to the Clozapine REMS Contact Center at 800-878-5927.

Prescribers who initiate clozapine treatment for inpatients must certify in the Clozapine REMS.

To complete certification on the Clozapine REMS Website:

- From the Home Page, use the “Certify Prescriber” button in the Prescriber box. You will be taken to the Prescriber Certification page, which will explain what is expected and required in the Clozapine REMS. If you have not created new login credentials for the modified Clozapine REMS, you will be directed to create them as part of your certification.
- Follow the steps outlined to complete the certification.

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

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. Patients in this setting are required to be enrolled in the Clozapine REMS 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 Website at [www.clozapinerems.com](http://www.clozapinerems.com) or call the Clozapine REMS Contact Center at 888-586-0758.

**3. 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. The new prescriber should login to the website at [www.clozapinerems.com](http://www.clozapinerems.com) and add the patient to their 'Manage Patient' list or call the Clozapine REMS Contact Center at 888-586-0758 to have the patient assigned to that covering prescriber.

**4. 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. When the eligibility of the patient to receive clozapine is checked, it does not look for an established relationship between the prescriber and patient.

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

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

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

Yes, the Clozapine REMS allows a certified prescriber to identify a prescriber designee to perform some duties or functions on behalf of the prescriber.

Prescribers may designate other healthcare providers or office staff to enroll patients and submit ANC results monthly, using the Patient Status Form, on the prescriber's behalf.

 Visit [www.clozapinerems.com](http://www.clozapinerems.com).

To enroll a prescriber designee online, log into your account and select the Manage Designees button. Select the Invite Designee button. Follow the instructions. The designee will receive an email with a link to allow them to create an account. Once created, the designee may log into their account and enroll patients and submit ANC results monthly, using the Patient Status Form, on your behalf.

To enroll a prescriber designee via fax, print out the Prescriber Designee Enrollment Form. Complete all sections. Both you and the designee must sign the form. Fax the form to 800-878-5927.

Prescriber designees can enroll patients, submit a *Patient Status Form*, 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
- Designees cannot authorize the continuation of clozapine treatment if one or more labs are missing

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

A prescriber can obtain a list of participating pharmacies by selecting the Find dropdown on the Home page of the Clozapine REMS website.

**8. Where can I find the REMS Patient ID for the *Patient Status Form*?**

The REMS Patient ID can be found on the Manage Patients screen when logged into the website, [www.clozapinerems.com](http://www.clozapinerems.com).



## Prescriber Designee

### 1. What is the role of a prescriber designee in the Clozapine REMS?

<u>Definition</u>	<u>Responsibilities</u>
A Healthcare Provider, office staff member, or pharmacist designated by a certified prescriber to act on their behalf	<p><u>Enrollment Process</u></p> <p>To enroll online, ask the prescriber to invite you to enroll via the Manage Designees feature of their dashboard.</p> <p>Or to enroll via fax, complete all required fields below and fax to 800-878-5927.</p> <p>Once you have been invited or your fax has been processed, you will receive an email providing you with a link to allow you to create website credentials.</p> <p><u>Responsibilities</u></p> <p>Prescriber designees can enroll patients, submit a <i>Patient Status Form</i>, and manage patients with the following exceptions:</p> <ul style="list-style-type: none"><li>○ Designees cannot categorize a patient as having benign ethnic neutropenia (BEN)</li><li>○ Designees cannot authorize the continuation of clozapine treatment for patients with moderate to severe neutropenia (general population) or severe neutropenia (patients with documented BEN)</li><li>○ Designees cannot categorize a patient as a hospice patient</li><li>○ Designees cannot authorize the continuation of clozapine treatment if one or more labs are missing</li></ul>

### 2. What actions can a prescriber designee perform in the Clozapine REMS?

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

- Enroll general population patients
- Counsel patients
- Submit *Patient Status Forms* on the prescriber's behalf. Note: a prescriber must sign the *Patient Status Form* in the following conditions:
  - Creating a *Treatment Rationale*
  - Indicating the patient is a BEN patient
  - Indicating the patient is a hospice patient
  - Required ANC values are missing
- View patient lists and patient ANC history

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

- 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
- Designees cannot authorize the continuation of clozapine treatment if one or more labs are missing

## Patient Management

### 1. Do patients need to be enrolled in the Clozapine REMS in order to receive clozapine?

Yes; any patient prescribed clozapine, whether in an inpatient or outpatient setting must be enrolled in the Clozapine REMS by the patient's prescriber or the prescriber designee. To enroll a patient, please visit [www.clozapinerems.com](http://www.clozapinerems.com) or fax the completed *Patient Enrollment Form* to the Clozapine REMS Contact Center at 800-878-5927.

Note: The *Patient Enrollment Form* must contain an acceptable ANC in order for the patient to receive the first prescription. Subsequent prescriptions require a monthly *Patient Status Form* to be on file.

### 2. How are patients enrolled into the Clozapine REMS?

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

Only a prescriber can enroll patients with benign ethnic neutropenia (BEN) or patients designated as being under Hospice care. The prescriber must indicate BEN and/or Hospice status as part of the enrollment process on the Clozapine REMS Website or on the *Patient Enrollment Form* to be faxed.

For assistance in enrolling your patient, please call the Clozapine REMS Contact Center at 888-586-0758.

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

### 3. Can a Healthcare Provider not certified in the Clozapine REMS submit an ANC?

No, in order to submit record of a patient's ANC, the Healthcare Provider must be certified or authorized in the Clozapine REMS. Certified Healthcare Providers can call the Clozapine REMS Contact Center at 888-586-0758 and submit an ANC over the phone or via the website, [www.clozapinerems.com](http://www.clozapinerems.com). You may be required to provide specific identifying patient information when you submit the ANC results over the phone.

An ANC can also be faxed to the Clozapine REMS Contact Center at 800-878-5927 for data entry.

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

The Clozapine REMS 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.

## 5. What is a Treatment Status?

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

There are three *Treatment Statuses* in the Clozapine REMS:

- *Enrolled*: 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 of 999/ $\mu$ L or lower (moderate to severe neutropenia) will cause *Treatment Status* to update to *Interrupted*
- For patients with documented benign ethnic neutropenia (BEN):
  - An ANC below 500/ $\mu$ L (severe neutropenia) will cause *Treatment Status* to update to *Interrupted*

A *Treatment Status* of *Interrupted* or *Discontinued* will prevent an RDA 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 (via a *Patient Status Form*) and change the patient's *Treatment Status* back to *Enrolled* hereby allowing clozapine to be dispensed.

## 6. 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 an ANC that falls below an acceptable range.

To authorize the continuation of clozapine therapy for any patient with a *Treatment Status* of *Interrupted* because of a low ANC indicating severe neutropenia, the prescriber must take action by providing a *Treatment Rationale* (via a *Patient Status Form*) to update the patient's *Treatment Status* back to *Enrolled* to allow an RDA request to be approved.

The Clozapine REMS will alert the prescriber 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. A *Treatment Rationale* indicates that in the prescriber's clinical judgment, the benefits of continuing clozapine treatment outweigh the risk of neutropenia.

Information provided in the Clozapine REMS 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.

## 7. 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 falls below the acceptable range. The *Treatment Rationale* returns the patient's *Treatment Status* in the Clozapine REMS to *Enrolled* and allows the Clozapine REMS to provide an RDA which permits the pharmacy to dispense clozapine.

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

1. Faxing a signed *Patient Status Form* to 800-878-5927 containing a completed *Treatment Rationale* section, or
2. Accessing the Clozapine REMS Website to provide a *Treatment Rationale* online. To do so, perform the following steps:
  - a. **Log in to** the Clozapine REMS Website at [www.clozapinerems.com](http://www.clozapinerems.com).
  - b. **Access** the Manage Patient screen.
  - c. **Select** ‘–“Add PSF” in the Patient Status Form column.
  - d. **Complete** the required information.

## 8. How are patient ANCs submitted to the Clozapine REMS?

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

- Prescribers and designees must submit ANC using the monthly *Patient Status Form*
- Prescribers and prescriber designees can log in to the Clozapine REMS Website at [www.clozapinerems.com](http://www.clozapinerems.com) and enter ANCs for a patient using the “Add ANC” option on the Manage Patients screen
- Inpatient pharmacy staff and pharmacy authorized representatives can submit an ANC when obtaining an RDA or by faxing a complete *ANC Lab Reporting Form* to the Clozapine REMS Contact Center at 888-586-0758
- Outpatient pharmacy staff and pharmacy authorized representatives may submit an ANC when using a *Dispense Rationale* or by faxing a complete *ANC Lab Reporting Form* to the Clozapine REMS Contact Center at 888-586-0758
- All program roles can call the Clozapine REMS Contact Center at 888-586-0758
- All program roles can fax ANCs to the Clozapine REMS Contact Center at 800-878-5927

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

No; the Clozapine REMS 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.

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

The duration and frequency of all patient ANC monitoring after discontinuation is dependent on that patient's ANC and clinical status (see Prescribing Information for more details).

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

Yes, the monitoring frequency recommendations are described in the Prescribing Information. In the Clozapine REMS, monitoring frequency is reported to the Clozapine REMS by the prescriber or designee on the monthly *Patient Status Form*.

**12. 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 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.

**13. 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?**

All patients are required to be enrolled in the Clozapine REMS 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

### 1. What are the different pharmacy certification types in the Clozapine REMS?

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

<u>Pharmacy Type</u>	<u>Definition</u>
Outpatient Pharmacy	<ul style="list-style-type: none"><li>• 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 drugstores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.</li><li>• An outpatient pharmacy is an individual location or multiple stores with an authorized representative associated to the stores. The authorized representative is responsible for ensuring certification and training in the Clozapine REMS within the individual or multiple stores.</li><li>• 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 across all stores in the chain.</li></ul>
Inpatient Pharmacy	<ul style="list-style-type: none"><li>• 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).</li><li>• Inpatient pharmacies are required to obtain a REMS Dispense Authorization to verify a patient is enrolled in the Clozapine REMS before dispensing the first dose. If the patient is found to not yet have been enrolled in the Clozapine REMS, he/she must be enrolled by a <u>certified prescriber</u> before being allowed to receive clozapine.</li></ul>

### 2. What is a *REMS Dispense Authorization (RDA)*?

A *REMS Dispense Authorization (RDA)* determines if a patient is eligible to receive clozapine and provides authorization for a pharmacy to dispense.

The RDA evaluates that:

For the first dispensing after patient enrollment, the RDA will verify that:

- the pharmacy is certified
- the patient is enrolled

- the patient's treatment is not interrupted or discontinued

For a subsequent dispensing, the RDA will verify that:

- the pharmacy is certified
- the patient is enrolled
- a *Patient Status Form* has been completed in the last 37 days
  - the prescriber has authorized the continuation of treatment if one or more labs are missing
  - the prescriber has provided a *Treatment Rationale* if the most current ANC lab value is below the acceptable range
  - the patient's treatment is not interrupted or discontinued

### 3. What is a "Dispense Rationale"?

The Clozapine REMS provides certified pharmacies with an opportunity to apply clinical judgment and continue to dispense clozapine to enrolled patients when a rejection is received because a current *Patient Status Form* is not on file. An RDA 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*:

- The patient must be enrolled in the Clozapine REMS; and,
- The pharmacist must be in possession of a current and acceptable ANC; and,
- The pharmacist must know the NPI number of the prescriber

In outpatient pharmacies, three *Dispense Rationales* may be used per patient per year. There is no limit on the number of *Dispense Rationales* that may be used by inpatient pharmacies.

It is recommended that pharmacies fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC.

### 4. 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 Website after receiving a rejection due to a missing *Patient Status Form* or by calling the Contact Center at 888-586-0758. The *Dispense Rationale* option will be available on screen upon receiving the rejection.

#### A. Upon receiving the rejection, the *Dispense Rationale* will automatically be presented:

1. **Enter** the prescriber's NPI number from the patient's prescription.
2. **Enter** the blood draw date for the ANC value.
3. **Enter** the ANC value and **click** the **Request Dispense Rationale** button.

### 5. How does a pharmacy certify in the Clozapine REMS?



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

- Complete the *Inpatient Pharmacy Enrollment Form* or the *Outpatient Pharmacy Enrollment Form*
- Review *Clozapine and the Risk of Neutropenia: A Guide for Pharmacists*
- Complete the *Knowledge Assessment for Pharmacies*

Pharmacies can also certify online through the Clozapine REMS Website at [www.clozapinerems.com](http://www.clozapinerems.com), or by submitting the completed *Inpatient Pharmacy Enrollment Form* or the *Outpatient Pharmacy Enrollment Form* via fax to the Clozapine REMS Contact Center at 800-878-5927.

For additional information, call the Clozapine REMS Contact Center at 888-586-0758.

#### **6. How often must pharmacies recertify?**

Pharmacies are required to have any new Authorized Representative (AR) enroll in the REMS Program by reviewing *Clozapine and the Risk of Neutropenia: A Guide for Pharmacists*, successfully completing the *Knowledge Assessment* and the *Outpatient Pharmacy Enrollment Form* or the *Inpatient Pharmacy Enrollment Form* and submitting both to the Clozapine REMS.

Pharmacy AR must reconfirm their role within the Clozapine REMS every two years. Failing to reconfirm the Pharmacy AR status will result in the pharmacy becoming decertified in the REMS.

Pharmacies should have internal process to track when the bi-annual AR confirmation is due

#### **7. 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 *REMS Dispense Authorization* from the Clozapine REMS until recertified.

## Pharmacy Authorized Representative

### 1. What is an authorized representative?

#### Authorized Representative for Outpatient Pharmacy

<u>Definition</u>	<u>Responsibilities</u>
<p>For outpatient pharmacies with a single location, the authorized representative may be a:</p> <ul style="list-style-type: none"> <li>• Pharmacy Manager, or</li> <li>• Staff Pharmacist</li> </ul> <p>If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement processes for all the pharmacies in your organization, the authorized representative may be a:</p> <ul style="list-style-type: none"> <li>• Director of Pharmacy Services, or</li> <li>• Corporate Executive over-seeing Pharmacy Service</li> </ul>	<p><u>Certification Process</u></p> <ul style="list-style-type: none"> <li>• An authorized representative for an outpatient pharmacy must certify in the Clozapine REMS by:               <ul style="list-style-type: none"> <li>○ Certifying their pharmacy in the Clozapine REMS by:                   <ul style="list-style-type: none"> <li>• Reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Pharmacists</i></li> <li>• Completing the <i>Outpatient Pharmacy Enrollment Form</i></li> <li>• Passing the <i>Knowledge Assessment for Pharmacies</i></li> </ul> </li> <li>○ Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS requirements using the <i>Clozapine and the Risk of Neutropenia: A Guide for Pharmacists</i></li> <li>○ Putting processes and procedures in place to verify an available, current ANC is within the acceptable range for patients enrolled but not authorized to receive clozapine</li> <li>○ Have any new Authorized Representative enroll in the Clozapine REMS by reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Pharmacists</i>, successfully completing the <i>Knowledge Assessment</i> and the <i>Outpatient Pharmacy Enrollment Form</i> and submitting both to the Clozapine REMS</li> </ul> </li> </ul>

<p>The authorized representative represents the pharmacy and is responsible for ensuring the processes and procedures within the pharmacy are in place to comply with the Clozapine REMS requirements.</p>	<p><u>Responsibilities</u></p> <ul style="list-style-type: none"><li>• Carry out the certification process and oversee implementation and compliance with the Clozapine REMS on behalf of the outpatient pharmacy</li><li>• Obtain authorization to dispense each prescription by contacting the REMS Program to verify that the patient is enrolled and authorized to receive drug</li><li>• For patients enrolled but not authorized to receive clozapine: Verify an available, current ANC is within the acceptable range through the processes and procedures established as a requirement of the REMS Program, document and submit the ANC and the prescriber's NPI to the REMS Program and obtain authorization to dispense each prescription by contacting the REMS program to verify the patient is now authorized to receive clozapine</li></ul>
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## Authorized Representative for Inpatient Pharmacy

<u>Definition</u>	<u>Responsibilities</u>
<p>For inpatient pharmacies with a single location, the authorized representative may be a:</p> <ul style="list-style-type: none"> <li>• Pharmacy Manager, or</li> <li>• Staff Pharmacist</li> </ul> <p>If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement process for all the pharmacies in your organization, the authorized representative may be a:</p> <ul style="list-style-type: none"> <li>• Director of Pharmacy Services, or</li> <li>• Corporate Executive overseeing Pharmacy Service</li> </ul> <p>The authorized representative represents the pharmacy and is responsible for ensuring the processes and procedures within the pharmacy are in place to comply with the Clozapine REMS requirements</p>	<p><u>Certification Process</u></p> <ul style="list-style-type: none"> <li>• An authorized representative for a pharmacy must certify in the Clozapine REMS by: <ul style="list-style-type: none"> <li>○ Certifying their pharmacy in the Clozapine REMS by: <ul style="list-style-type: none"> <li>• Reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Pharmacists</i></li> <li>• Completing the <i>Inpatient Pharmacy Enrollment Form</i></li> <li>• Passing the <i>Knowledge Assessment for Pharmacies</i></li> </ul> </li> <li>○ Ensuring training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS requirements using <i>Clozapine and the Risk of Neutropenia: A Guide for Pharmacists</i></li> <li>○ Putting processes and procedures in place to verify an available, current ANC is within the acceptable range for patients enrolled but not authorized to receive clozapine</li> <li>○ Have any new Authorized Representative enroll in the Clozapine REMS by reviewing <i>Clozapine and the Risk of Neutropenia: A Guide for Pharmacists</i>, successfully completing the <i>Knowledge Assessment for Pharmacies</i> and the <i>Inpatient Pharmacy Enrollment Form</i> and submitting both to the REMS Program</li> </ul> </li> </ul> <p><u>Responsibilities</u></p> <ul style="list-style-type: none"> <li>• Carry out the certification process and oversee implementation and compliance with the Clozapine REMS, on behalf of the inpatient pharmacy</li> <li>• Obtain authorization to dispense the first inpatient prescription by contacting the REMS Program to verify that the patient is enrolled and authorized to receive drug.</li> <li>• For patients enrolled but not authorized to receive clozapine: Verify an available, current ANC is within the acceptable range through the processes and procedures established as a requirement of the REMS Program, document and submit the ANC and the prescriber's NPI to the REMS Program and obtain authorization to dispense each prescription by contacting the REMS program to verify the patient is now authorized to receive clozapine.</li> </ul>

## **2. Who should act as the authorized representative in the pharmacy?**

Please refer to the FAQ on roles of healthcare staff in the Clozapine REMS in each stakeholder section of the FAQs.

## **3. 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 Contact Center for further instructions at 888-586-0758.

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

The authorized representative will need to complete the outpatient pharmacy enrollment. The authorized representative can complete enrollment through the Clozapine REMS Website or by completing the *Clozapine REMS Outpatient Pharmacy Enrollment Form* and faxing the form to the Clozapine REMS at 800-878-5927.

For additional questions, please call the Clozapine REMS Contact Center at 888-586-0758.

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

If a pharmacy is not certified in the Clozapine REMS, 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.

Pharmacies must become certified in the Clozapine REMS in order to obtain clozapine from a wholesaler.

## **6. Will pharmacies that are not certified be able to order and receive clozapine?**

If a pharmacy is not certified in the Clozapine REMS, the pharmacy will not be able to order and receive clozapine.

**7. 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 Contact Center at 888-586-0758 for assistance.

**8. Will patients still need to have blood draws?**

Yes, blood draws for ANC monitoring are required. The ANC values will be submitted monthly on the *Patient Status Form*. A current *Patient Status Form* must be on file prior to dispensing.

**9. Can clozapine be dispensed to a patient without bloodwork?**

No; patients must have ANCs submitted via the monthly *Patient Status Form* before an RDA is provided. A *Dispense Rationale* may be requested if a current *Patient Status Form* is not on file and the pharmacist is in possession of a current and acceptable ANC.

**10. 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.

Prescribing clozapine for patients receiving inpatient care does not require prescriber certification in the Clozapine REMS 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 prior to receiving the first dose of clozapine.

**11. What should a pharmacist do with a patient's ANC?**

The pharmacist should enter the patient's ANC via the Clozapine REMS Website or fax it to the Clozapine REMS Contact Center at 800-878-5927 using the *ANC Lab Reporting Form*. 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.

**12. 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. If the wholesaler needs to verify certification, they can access the Look-up on the Clozapine REMS Website or call the Clozapine REMS Contact Center at 888-586-0758 to verify the pharmacy's certification in the program.

**13. What if the authorized representative leaves the pharmacy?**

If the authorized representative leaves the pharmacy, the new authorized representative must certify in the Clozapine REMS by reviewing Clozapine and the Risk of Neutropenia: A Guide for Pharmacists, successfully completing the Knowledge Assessment for Pharmacies and the Outpatient Pharmacy Enrollment Form, or Inpatient Pharmacy Enrollment, and submitting both to the Clozapine REMS.

**14. If the patient's prescription is denied, will the Clozapine REMS system explain the reason?**

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

## Pharmacy Staff

### 1. What is the role of pharmacy staff in the Clozapine REMS?

<u>Definition</u>	<u>Responsibilities</u>
<p>Any pharmacist or pharmacy employee may assume the role of pharmacy staff member associated with a pharmacy to conduct basic program functions</p>	<p><u>Enrollment Process</u></p> <ul style="list-style-type: none"><li>• Be invited by the pharmacy authorized representative via the Manage Personnel page</li><li>• Follow the link in the email to create log in credentials</li></ul> <p><u>Responsibilities</u></p> <ul style="list-style-type: none"><li>• Outpatient pharmacy staff must:<ul style="list-style-type: none"><li>○ Obtain authorization to dispense each prescription by contacting the Clozapine REMS to verify that the patient is enrolled and authorized to receive drug</li><li>○ May submit an ANC for a patient</li></ul></li><li>• Inpatient pharmacy staff must:<ul style="list-style-type: none"><li>○ Obtain authorization to dispense the first inpatient prescription by contacting the Clozapine REMS to verify that the patient is enrolled and authorized to receive drug</li><li>○ May submit an ANC for a patient</li></ul></li></ul>



## Wholesaler/Distributor

### 1. Does a distributor have to enroll in the Clozapine REMS?

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

### 2. How can a distributor enroll in the Clozapine REMS?

To enroll in the Clozapine REMS, a distributor should call the Clozapine REMS Contact Center at 888-586-0758 to have a *Wholesaler-Distributor Enrollment Form* sent via fax or email.

A Contact Center Associate will help the distributor to complete a *Wholesaler-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 and they will comply with the program requirements.

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

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

- Downloading a current list of certified pharmacies from a secure FTP site (requires the appropriate access request be completed)
- Calling the Clozapine REMS Contact Center at 888-586-0758

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

A pharmacy is only eligible to receive clozapine if the pharmacy has certified in the Clozapine REMS. If the pharmacy is not on the current list of certified pharmacies, you must not ship clozapine to that pharmacy.

### 5. 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, distributors should reject the order per their standard procedures. At that point, the pharmacy can contact the Clozapine REMS and start the certification process.

## Technical Support

### 1. What if I need help using the Clozapine REMS Website?

Call the Clozapine REMS Contact Center for assistance at 888-586-0758.

### 2. What browser types and versions does the Clozapine REMS Website support?

We support the latest and previous releases of the Chrome browser on a rolling basis. Other HTML5 based browsers including Microsoft Edge, Firefox, and Safari may also function.

### 3. How does the Clozapine REMS Website use cookies?

Our technical cookies are used to display the correct content to assist you in complying with the Clozapine REMS 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.

### 4. What do I do if I can't view a document on the Clozapine REMS 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](#).

### 5. How do I report a problem with the Clozapine REMS Website?

If you experience an outage or need to report a problem with the Clozapine REMS Website, please call the Clozapine REMS Contact Center at 888-586-0758.

### 6. How do I obtain a username and password for the Clozapine REMS Website?

You can create a user account for the Clozapine REMS 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.

### 7. 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 Contact Center at 888-586-0758.

### 8. What do I do if I forgot my password?

If you forgot your password, you can use the "Forgot your password?" option in the Login box. Fill in the requested information and submit it online. You will be sent an email with a link to use in order to verify your account .

**9. What do I do if I forgot my username?**

If you forgot your username, please call the Clozapine REMS Contact Center at 888-586-0758.

**10. What do I do if my user account is locked?**

If your user account is locked, please wait 30 minutes for your account to unlock.

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

To change your password, select the drop-down arrow displayed next to your name in the upper right corner and select "Preferences." Next select "Change Account Information", enter the information in the fields and select "Next". To change your username, please call the Clozapine REMS Contact Center at 888-586-0758.

**12. 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 calling the Clozapine REMS Contact Center at 1-800-878-5927.

**13. 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 Website and selecting the Preferences option from the links below your account link in the upper right corner of the website. Next, select the Change my Email option.

## Patient

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

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

- 2. Where do I find a list of local pharmacies that participate in the Clozapine REMS?**

The Clozapine REMS Website has a Find feature to allow you to find pharmacies participating in the Clozapine REMS. Additionally, your Healthcare Provider can help you find a participating pharmacy. Please contact your Healthcare Provider for additional information about the Clozapine REMS.