

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:

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

Outpatient Pharmacy Authorized Representative Responsibilities (continued)

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?

<input type="checkbox"/> Yes	By selecting “ Yes ”, you are confirming that your pharmacy management system CAN support electronic communication with the Clozapine REMS Program using established telecommunications standards. Clozapine will be dispensed only after obtaining electronic authorization for all clozapine prescriptions, including cash claims, through your pharmacy management system. After submitting this form, you will receive instructions through the contact preference indicated in the authorized representative information section 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.
<input type="checkbox"/> No	By selecting “ No ”, you are confirming that your pharmacy management system CANNOT support electronic communication with the Clozapine REMS Program and you will access the Clozapine REMS Program Website at www.clozapinerems.com 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.

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: <input type="checkbox"/> RPh <input type="checkbox"/> PharmD <input type="checkbox"/> BCPS <input type="checkbox"/> Other		
Phone:	Fax:	Email:
Contact Preference (please select one): <input type="checkbox"/> Email <input type="checkbox"/> Fax		
Authorized Representative Signature:		Date: