

**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**<sup>1</sup>: 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

<sup>1</sup>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.

**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:

- 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.
- Outpatient<sup>1</sup> 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
- 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.

<sup>1</sup>Patients treated on an outpatient or chronic basis, includes but is not limited to those receiving clozapine via retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities and prison systems.

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

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

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

First Name:		Last Name:	
REMS Certification ID (opt):	DEA:	NPI:	
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: \_\_\_\_\_