

General Information

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

- Designees cannot categorize a patient as diagnosed with BEN
- Designees cannot authorize the continuation of clozapine treatment for patients with moderate to severe (General Population) or severe neutropenia (Patients with 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, that clozapine is available only through the Clozapine REMS Program, and that you understand:

- Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements
- There is a risk of severe neutropenia associated with clozapine
- The ANC testing and monitoring requirements as described in the clozapine Prescribing Information
- **For Outpatients:** An ANC must be reported to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed
- **For Inpatients:** An ANC must be reported to the Clozapine REMS Program for each patient within 7 days from the date of the blood draw
- To continue treatment with clozapine, the certified prescriber must provide a valid treatment rationale before clozapine can be dispensed to a patient, if the patient has moderate or severe neutropenia
- Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program
- Personnel from the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
- I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials