

Starting November 15, 2021, requirements to the Clozapine REMS will change.

What are the important changes for prescribers and their designees?	
During Treatment	
Previous Requirement	New Requirement
<p>Using the <i>ANC Lab Reporting Form</i>, submit ANC according to the patient's monitoring frequency on file with the Clozapine REMS as described in the Monitoring Schedule of the Prescribing Information.</p> <ul style="list-style-type: none"> 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. 	<p>Monthly, using the <i>new Patient Status Form</i>, document the patient's ANC results, the monitoring frequency, and appropriateness for continuing treatment and submit to the Clozapine REMS. The prescriber must authorize the continuation of therapy if one or more ANC is missing for the month.</p> <p>Individual ANCs may still be submitted when obtained by completing and submitting an <i>ANC Lab Reporting Form</i>.</p>
After Treatment Discontinuation	
Previous Requirement	New Requirement
	<p>Assess the patient's ANC according to the monitoring frequency in the Prescribing Information. Document and submit the ANC results to the Clozapine REMS using the <i>Patient Status Form</i>.</p>

More Information about the New Patient Status Form

This form must be completed monthly for each patient continuing treatment with clozapine.

This form may also be used to:

- Interrupt, Discontinue, or Resume Treatment
- Designate the patient as a Benign Ethnic Neutropenia patient
- Create a Treatment Rationale when the patient's ANC level is < 1000/ μ L for a general population patient or < 500/ μ L for a BEN patient
- Designate the patient as a Hospice patient

The *Patient Status Form* may be completed by a certified prescriber or their designee. However, the following actions require the signature of a certified prescriber on the *Patient Status Form*:

- Designating a patient as a Hospice Care patient
- Designating a patient as a Benign Ethnic Neutropenia patient
- Authorizing the continuation of therapy if one or more required labs are missing
- Creating a Treatment Rationale for a patient

A *Patient Status Form* must be received within 37 calendar days after the date of the *Patient Enrollment Form* or the last *Patient Status Form*.

If the *Patient Status Form* is not received within 37 calendar days, the patient is not authorized to receive clozapine until a completed form is received. If the *Patient Status Form* is missing, the pharmacist, if in possession of a current ANC within the acceptable range, may use a Dispense Rationale to dispense clozapine to the patient. A Dispense Rationale may be used up to three times per patient per year for outpatient dispensing.

The following questions are required to be answered on the *Patient Status Form*:

Are you monitoring the patient as recommended in the Prescribing Information?
Yes/No

What is the patient's current monitoring frequency? 3 times weekly, Weekly, Every 2 weeks, Monthly

Did the patient experience any adverse event(s) due to clozapine-induced neutropenia (e.g., infection)? Yes/No

The Patient Status Form may be submitted online or via a fax.

- To submit online, log into your account at www.clozapinerems.com and select the Manage Patient button. Select the Create or Add buttons for the appropriate patient.
- To submit via fax, complete the form and fax to 800-878-5927.

How to Submit ANCs using the ANC Lab Reporting Form

ANCs may still be submitted via the *ANC Lab Reporting Form* online or via fax.

- To submit online, log into your account at www.clozapinerems.com and select the Manage Patient button. Select the Create or Add buttons in the Patient Status Form (PSF) column for the appropriate patient.
- To submit via fax, complete the ANC Lab Reporting Form and fax to 800-878-5927.

The Patient Status Form must still be submitted monthly.