

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

What are the important changes for pharmacies?	
Obtaining Authorization to Dispense for Outpatient Pharmacies	
Previous Requirement	New Requirement
Obtain a Predispense Authorization (PDA) each time from the Clozapine REMS by accessing the Clozapine REMS website, Clozapine REMS Contact Center, or enabling the SWITCH (pharmacy management system) to support communication with the Clozapine REMS.	Obtain a REMS Dispense Authorization (RDA) to dispense each prescription ONLY by accessing the Clozapine REMS website or the Clozapine REMS Contact Center to verify that the patient is enrolled and authorized to receive the drug. RDA's may no longer be obtained via the SWITCH (the pharmacy management system).
A REMS Dispense Authorization (RDA) Verifies...	
<p>The patient is enrolled by a <u>certified prescriber or prescriber designee</u>.</p> <p>A Patient Status Form has been completed by a certified <u>prescriber or prescriber designee</u> in the last 37 days.</p> <p>For the first dispensing after patient enrollment, the RDA will verify that:</p> <ul style="list-style-type: none"> the patient is enrolled the patient's treatment is not interrupted or discontinued <p>For a subsequent dispensing, the RDA will verify that:</p> <ul style="list-style-type: none"> 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 <p>If a Patient Status Form is not received, the pharmacist may use a Dispense Rationale to dispense (see Dispense Rationale below).</p>	

Dispense Rationale	
Previous Requirement	New Requirement
<p>To avoid disruption in patient care, and to allow certified outpatient pharmacies an opportunity to apply clinical judgment to continue to dispense clozapine to enrolled patients, certified outpatient pharmacies will be allowed to provide a “Dispense Rationale” when a patient’s prescriber is not certified in the Clozapine REMS.</p>	<p>To avoid disruption in patient care, and to allow certified outpatient and inpatient pharmacies an opportunity to apply clinical judgment to continue to dispense clozapine to enrolled patients, certified pharmacies will be allowed to provide a “Dispense Rationale” when a <i>Patient Status Form is not received</i> from the patient’s prescriber within 37 days of the patient’s enrollment or previous <i>Patient Status Form</i>.</p> <p>The Dispense Rationale will be automatically presented to the pharmacist when the RDA is rejected for this reason.</p> <p>To provide a Dispense Rationale, the pharmacist must be in possession of:</p> <ul style="list-style-type: none"> - A current ANC (within 30 days of the attempted fill) within an acceptable range for the patient - The prescriber’s NPI number <p style="color: red;">Three Dispense Rationales may be used per patient per year by outpatient pharmacies.</p> <p>There is no limit to the number of Dispense Rationales used by inpatient pharmacies.</p>
Information about the New Patient Status Form	
<p>This form must be completed monthly by a certified prescriber or their designee for each patient continuing treatment with clozapine.</p> <p>This form may also be used to:</p> <ul style="list-style-type: none"> • Interrupt, Discontinue, or Resume Treatment • Designate the patient as a Benign Ethnic Neutropenia (BEN) patient • Create a Treatment Rationale when the patient’s ANC level is < 1000/μL for a general population patient or < 500/μL for a BEN patient • Designate the patient as a Hospice patient <p>A <i>Patient Status Form</i> must be received within 37 calendar days after the date of the <i>Patient Enrollment Form</i> or the last <i>Patient Status Form</i>.</p> <p>The certified prescriber or their designee must provide the ANCs according to the patient’s current monitoring frequency. If an ANC is missing, the prescriber is required to provide authorization to continue therapy.</p>	

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Information about the New Patient Status Form (continued)

The *Patient Status Form* may also be used to create a Treatment Rationale to indicate that the benefits of continuing clozapine treatment outweigh the risk of neutropenia when the patient has moderate neutropenia (ANC 500-999/ μ L for the general population) or severe neutropenia (ANC < 500/ μ L for general population and patients with BEN).

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 Submit ANC Lab button. Enter information to find the patient and then select the Continue button. Enter the ANC Lab information and select the Save button.
- 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.

Certification Requirements

Previous Requirement	New Requirement
	A pharmacy may now designate up to two authorized representatives .
Pharmacies must re-certify every two years.	Pharmacies are no longer required to renew certification every two years. Now, every two years the pharmacy must confirm that the designated authorized representative is the same . If different, the pharmacy must re-certify with the new authorized representative.

Staff Training

Previous Requirement	New Requirement
Pharmacy staff must complete the Knowledge Assessment .	Pharmacy <u>staff</u> are no longer required to complete the Knowledge Assessment . However, the <u>authorized representative</u> must still complete the Knowledge Assessment .