

A “REMS Dispense Authorization” (RDA) determines if a patient is eligible to receive clozapine and provides an authorization for a pharmacy to dispense. An outpatient pharmacy dispenses clozapine only to patients treated on an outpatient or chronic basis, including but not limited to, retail drugstores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities, and prison systems.

Outpatient pharmacies must obtain an RDA each time before dispensing clozapine. RDAs may be obtained via the Clozapine REMS Website at www.clozapinerems.com, or by calling the Clozapine REMS Contact Center at 888-586-0758.

RDA Requirements	Possible Outcomes	Action by Pharmacy
Patient enrollment in the Clozapine REMS	Patient is enrolled	No action necessary.
	Patient is not enrolled	Do not dispense. Contact a <u>certified</u> prescriber (or their designee) to enroll new patient.
Pharmacy Certification	Pharmacy is certified	No action necessary.
	Pharmacy is not certified	Do not dispense. Contact Pharmacy Manager to inform them the pharmacy must be certified to order, purchase, and dispense clozapine.
Monthly Patient Status Form	Monthly <i>Patient Status Form</i> on file	No action necessary.
	No Monthly <i>Patient Status Form</i> on file	Contact the patient's certified prescriber. Reattempt RDA after Patient Status Form is entered. If you are in possession of a current ANC within an acceptable range for the patient, you may enter a <i>Dispense Rationale</i> to dispense clozapine to the patient.
The patient's treatment is interrupted or discontinued	Patient is continuing	No action necessary.
	Patient treatment is interrupted or discontinued	Do not dispense. The prescriber must submit a new Patient Status Form to the Clozapine REMS to restart the patient on clozapine treatment. Contact the prescriber to provide a <i>Patient Status Form</i> . Talk with the patient and ask them to also contact their prescriber.

How Do I Request a REMS Dispense Authorization?

Option 1: Use the Clozapine REMS Website to:

1. **Log in** to your account at www.clozapinerems.com
2. **Select the button 'Obtain a Patient RDA'**
3. **Enter the patient information, prescriber information, NDC, days' supply, and quantity dispensed on the screen and click Submit**
4. The screen will present a successful REMS Dispense Authorization or unsuccessful message(s). Refer to the table above for further guidance.

Option 2: Call the Clozapine REMS Contact Center at 888-586-0758.

How Do I Request a Dispense Rationale?

A Dispense Rationale may be used to dispense clozapine to a patient when the dispense authorization is rejected because a current Patient Status Form is not on file for the patient. The Dispense Rationale is automatically presented when the dispense authorization is rejected for this condition.

If you are in possession of an ANC that is current (within the last 30 days) and within acceptable range, enter the prescriber's NPI number, the blood draw date, and the ANC value and select the 'Request Dispense Rationale' button.

If the ANC is not current or within acceptable range, contact the patient's certified prescriber to enter the Patient Status Form or to obtain a current ANC lab within acceptable range. Reattempt RDA after Patient Status Form is entered, or a current ANC lab within acceptable range is obtained.

A Dispense Rationale may also be used when obtaining the RDA over the phone.

Three Dispense Rationales may be used per patient per year.

How Do I Submit ANC Labs?

Option 1: Use the Clozapine REMS Website to:

1. **Log in** to your account at www.clozapinerems.com
2. **Select the button 'Submit ANC Lab'**
3. **Find the patient information and enter the ANC value and Blood Draw Date**

Option 2: Document the ANC results on an *ANC Lab Reporting Form* and fax the completed form to 800-878-5927.

Option 3: Call the Clozapine REMS Contact Center at 888-586-0758.