

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

Outpatient pharmacies must obtain a PDA each time before dispensing clozapine. PDAs may be obtained through the pharmacy management system (via the switch network), via the Clozapine REMS Program Website at www.clozapinerems.com, or by calling the Clozapine REMS Program Contact Center at 844-267-8678.

CLOZAPINE REMS PROGRAM ELEMENT EVALUATED BY THE PREDISPENDE AUTHORIZATION	POSSIBLE OUTCOMES	ELIGIBILITY TO RECEIVE CLOZAPINE	ACTION BY PHARMACY
		All PDA responses will provide the dispensing pharmacy with the most recent absolute neutrophil count (ANC) value, the associated blood draw date, and the patient's monitoring frequency ¹	Pharmacies are encouraged to submit the patient's ANCs through the Clozapine REMS Program Website, by phone, or by fax according to the patient's monitoring frequency ¹
Patient enrollment in the Clozapine REMS Program	Patient is enrolled	PDA Successful	No action necessary. Dispense.
	Patient is not enrolled	PDA Unsuccessful	Contact a <u>certified</u> prescriber (or his designee) to enroll new patient. Do not dispense.
Prescriber Certification	Prescriber is certified	PDA Successful	No action necessary. Dispense.
	Prescriber is not certified	PDA Unsuccessful	Contact prescriber to inform them they must be certified. Pharmacy can provide a “Dispense Rationale” and reattempt PDA. ²
Pharmacy Certification	Pharmacy is certified	PDA Successful	No action necessary. Dispense.
	Pharmacy is not certified	PDA Unsuccessful	Contact Pharmacy Manager to inform them the pharmacy must be certified to order, purchase, and dispense clozapine. Do not dispense.
Patient ANC is on file	ANC on file	PDA Successful	No action necessary. Dispense.
	No ANC on file	PDA Unsuccessful: A warning message will be displayed, reattempt PDA ² after ANC is obtained	If the pharmacist is in possession of an ANC, they are encouraged to submit the ANC to the Clozapine REMS Program; if not, contact the patient's certified prescriber. Reattempt PDA ² after ANC is obtained.
Last ANC value on file is acceptable	ANC is acceptable	PDA Successful	No action necessary. Dispense.
	ANC indicates moderate or severe neutropenia; and a “Treatment Rationale” <u>is</u> on file	PDA Successful	No action necessary. Dispense.
	ANC on file for patient indicates moderate or severe neutropenia; and a <i>Treatment Rationale is not</i> on file	PDA Unsuccessful: A warning message will be displayed	Do not dispense , unless one of these two possible follow-up actions are successful: <ul style="list-style-type: none"> If the pharmacist is in possession of an ANC that is more current and acceptable, the pharmacist is encouraged to submit the ANC to the Clozapine REMS Program and reattempt PDA.² Contact the prescriber to provide a <i>Treatment Rationale</i> or current acceptable ANC, reattempt the PDA.²
ANC is current according to the patient's monitoring frequency: ¹	ANC is current	PDA Successful	No action necessary. Dispense.
	ANC is not current	PDA Successful: a warning message will be displayed	Dispense clozapine; and: <ul style="list-style-type: none"> Submit current ANC results to the Clozapine REMS Program according to the patient's monitoring frequency.¹ Contact Prescriber to inform them that the ANC is not current according to the patient's monitoring frequency.¹

¹Monitoring frequency:

- For weekly monitoring frequency, the ANC submitted to the Clozapine REMS Program must have been drawn* within 7 days prior to the PDA date.
- For every two weeks monitoring frequency, the last ANC result submitted to the Clozapine REMS Program must be drawn* within 15 days prior to the PDA date.
- For monthly monitoring frequency, the last reported ANC result submitted to the Clozapine REMS must be drawn* within 31 days prior to the PDA date.

*Assumes lab draw date is day 0

²Wait approximately 2 minutes to reprocess the claim transaction through the pharmacy switch system.

HOW DO I REQUEST A PREDISPENSE AUTHORIZATION?

Pharmacies using a pharmacy management system (via the switch network):

1. **Process all clozapine claims, including cash claims,** through the pharmacy management system.
2. Responses:
 - a. A **success** message will appear; **displaying the PDA and recent ANC information, or**
 - b. A **warning** message will inform you of next steps to take. Refer to page 1 of this *Fact Sheet* for further guidance.

Pharmacies that do not use an electronic pharmacy management system (without switch network access):

Option 1: Use the Clozapine REMS Program Website to:

1. **Log in** to your account at www.clozapinerems.com
2. **Access the dashboard**
3. **Select 'Predispense Authorization' from the drop-down menu and click the GO button**
4. **Enter the patient information on the 'Predispense Authorization' screen and click Submit**
5. The '*Predispense Authorization Result*' screen will appear with a success or warning message. Refer to page 1 of this *Fact Sheet* for further guidance.

Option 2: Call the Clozapine REMS Program Contact Center at 844-267-8678.

HOW CAN I PROVIDE A DISPENSE RATIONALE?

When a PDA is denied with the warning message: "Prescriber not certified in the Clozapine REMS Program" for an enrolled patient, a certified authorized representative or enrolled pharmacy staff in a certified pharmacy may exercise clinical judgment and continue to dispense clozapine by providing a *Dispense Rationale* electronically via one of two processes below:

Option 1: Pharmacies using the Clozapine REMS Program Website to request a PDA should:

1. **Continue from Step 2b above at the PDA Result reject message screen.**
2. **Click the 'Provide a Dispense Rationale for this patient' check box** at the bottom of the 'PDA Result' screen and **click the Submit** button.
3. If the *Dispense Rationale* was provided successfully, a success screen will appear.

Option 2: Pharmacies using the pharmacy network system (i.e., "switch") to request a PDA should:

1. **Log in** to the Clozapine REMS Program Website at www.clozapinerems.com.
2. **Access** the dashboard.
3. **Select 'Dispense Rationale' from the drop-down menu and click the Go button. Enter the patient information on the Dispense Rationale screen and click Submit.**
4. The '*Dispense Rationale Result*' screen will appear with a reject message similar to the switch reject message.
5. **Click on the 'Provide a Dispense Rationale for this patient' check box at the bottom** of the '*Dispense Rationale Result*' screen and **click Submit.**
6. If the *Dispense Rationale* is provided successfully, a **success screen** will appear.
7. **Wait approximately 2 minutes to reprocess the claim transaction** through the pharmacy switch system.

Option 3: Call in to the Clozapine REMS Program Contact Center at 844-267-8678

HOW DO I SUBMIT ANC VALUES?

Pharmacies are encouraged to submit the patient's ANC according to the patient's monitoring frequency by utilizing one of the following methods:

Option 1: Submit via the Clozapine REMS Program Website by:

1. **Logging in** at www.clozapinerems.com
2. **Accessing** the dashboard
3. **Selecting 'Add Lab' from the drop-down menu and click the GO button**
4. **Entering the patient information and ANC results** on the 'Add Lab' screen and **click Submit**
5. User will be returned to the dashboard when completed.

Option 2: Fax to the Clozapine REMS Program by:

1. **Logging in to your account** at www.clozapinerems.com
2. **Choosing** the *Resources* tab
3. **Clicking** on *Program Materials*
4. **Selecting 'Clozapine REMS ANC Lab Reporting Form' from the list**
5. **Printing and completing** the form
6. **Faxing the completed form to 844-404-8876.**

NOTE: ANC values will be available immediately when submitted via the Clozapine REMS Program Website, but are delayed up to 48 hours for processing of the paper form.

Option 3: Call in to the Clozapine REMS Program Contact Center at 844-267-8678