

Instructions

Assess the patient by obtaining complete blood counts, including the absolute neutrophil count (ANC), as described in the Prescribing Information. Record the ANC data on this form.

You can complete this form online at www.clozapinerems.com or fax it to the Clozapine REMS Contact Center at 1-800-878-5927.

This form must be completed monthly for each patient continuing treatment with clozapine. Please submit page 1 and any pages that apply to your patient's monitoring frequency.

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

This form can be used by both a prescriber and prescriber designee. The following activities require the signature of a certified prescriber:

- 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

By submitting this form, you are authorizing this patient to continue treatment on clozapine, unless Interrupt Treatment or Discontinue Treatment is selected.

Prescriber Information (* Indicates a Required Field)

First Name*:		Last Name*:		Individual NPI #*:
Phone*:	Email Address*:		Fax:	

Prescriber Designee Information (* Indicates a Required Field if form is completed by a Prescriber Designee)

First Name*:		Last Name*:		
Phone*:	Email Address*:		Fax*:	

Patient Information (* Indicates a Required Field)

First Name*:		Last Name*:		REMS Patient ID:
Date of Birth*:	MM / DD / YYYY	Zip Code:	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other	

Patient Status (* Indicates a Required Field)

1. Are you monitoring the patient as recommended in the Prescribing Information?*	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
2. What is the patient's current monitoring frequency?*	<input type="checkbox"/> 3 times a week	<input type="checkbox"/> Every 2 weeks	
	<input type="checkbox"/> Weekly	<input type="checkbox"/> Monthly	
3. Change the patient's monitoring frequency to*:	<input type="checkbox"/> 3 times a week	<input type="checkbox"/> Every 2 weeks	<input type="checkbox"/> No Change to the Monitoring Frequency
	<input type="checkbox"/> Weekly	<input type="checkbox"/> Monthly	
4. Did the patient experience any adverse event(s) due to clozapine-induced neutropenia (e.g. infection)?*	<input type="checkbox"/> No		
	<input type="checkbox"/> Yes → If yes, please provide a phone number where you may be reached by the Clozapine REMS Contact Center for additional information related to this event: (____) ____-____.		

Hospice Care patient designation. This section must be completed by the prescriber. The prescriber must sign below.

For hospice patients (i.e., terminally ill patients with an estimated life expectancy of six months or less), the **prescriber** may reduce the frequency of submitting a Patient Status Form to once every 6 months after a discussion with the patient and his/her caregiver. To change the frequency of submitting a Patient Status Form to once every 6 months for a hospice patient, **the prescriber must sign below.**

By signing below, I attest that the above is a hospice care patient.

Prescriber Signature:	Date (MM/DD/YYYY):
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Benign Ethnic Neutropenia (BEN) patient designation. This section must be completed by the prescriber. The prescriber must sign below.

A BEN patient designation provides a separate ANC monitoring algorithm for the patient. The BEN designation is a permanent status.

By signing below, I attest that the above is a patient with documented benign ethnic neutropenia.

Prescriber Signature:	Date (MM/DD/YYYY):
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Continue to the next pages to provide ANC Lab Data

Reporting ANC Lab Data

Instructions for entering ANC lab data on the following pages:

1. Locate the section below that aligns with the patient's current monitoring frequency
2. Enter the blood draw date and the ANC range in the appropriate patient population (general or BEN) column or enter the ANC value.
3. If a lab is missing, select the reason for missing the lab. **Note: If one or more labs are missing, the prescriber is required to authorize the continuation of therapy by providing a signature and date.**
4. **Report of an ANC lab value indicating moderate (general population) or severe neutropenia (general or BEN population) requires treatment to be interrupted or discontinued or the creation of a Treatment Rationale by the prescriber unless a more recent ANC lab value is provided that is $\geq 1000/\mu\text{L}$ for a general population patient or $\geq 500/\mu\text{L}$ for a BEN population patient.**

Weekly Monitoring Frequency (Enter data for the last four weekly blood draws for this patient)

Blood Draw Date:	General Patient Population	BEN Patient Population	or	ANC (per μL):
MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors (e.g., weather, transportation issues)	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²		
Blood Draw Date:	General Patient Population	BEN Patient Population	or	ANC (per μL):
MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²		
Blood Draw Date:	General Patient Population	BEN Patient Population	or	ANC (per μL):
MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²		
Blood Draw Date:	General Patient Population	BEN Patient Population	or	ANC (per μL):
MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²		

¹ Prescriber signature is required to authorize the continuation of therapy if one or more labs are missing.

² Interrupt / Discontinue treatment or create a Treatment Rationale.

Prescriber Signature:

Date (MM/DD/YYYY):

Patient Treatment Status

Complete this section to interrupt, discontinue, or resume treatment for this patient. No selection indicates the patient may continue treatment.

- Interrupt Treatment
 Discontinue Treatment
 Resume Treatment

Treatment Rationale (If Required) (Prescriber Signature required below)

Complete this section to continue treatment if the patient has moderate neutropenia (ANC 500-999/ μL for the general population) or severe neutropenia (ANC $<500/\mu\text{L}$ for general population and patients with benign ethnic neutropenia). check and sign below:

- Benefits of continuing clozapine treatment outweigh the risk of neutropenia.
 Until (MM/DD/YYYY) _____ (not to exceed 6 months)

Prescriber Signature:

Date (MM/DD/YYYY):

Continue to the next page for additional monitoring frequencies

Every 2 Weeks Monitoring Frequency (Enter data for the last two every two weeks blood draws for this patient)

Blood Draw Date: MM / DD / YYYY	General Patient Population	BEN Patient Population	or	ANC (per μ L):
Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors (e.g., weather, transportation issues)	<input type="checkbox"/> Normal Range ($\geq 1500/\mu$ L) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μ L) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μ L) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu$ L) ²	<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu$ L) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μ L) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu$ L) ²		
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	<input type="checkbox"/> Normal Range ($\geq 1500/\mu$ L) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μ L) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μ L) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu$ L) ²	<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu$ L) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μ L) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu$ L) ²	or	ANC (per μ L):

¹ Prescriber signature is required to authorize the continuation of therapy if one or more labs are missing.
² Interrupt / Discontinue treatment or create a Treatment Rationale.

Prescriber Signature:

Date (MM/DD/YYYY):

Patient Treatment Status

Complete this section to interrupt, discontinue, or resume treatment for this patient. No selection indicates the patient may continue treatment.

Interrupt Treatment Discontinue Treatment Resume Treatment

Treatment Rationale (If Required) (Prescriber Signature required below)

Complete this section to continue treatment if 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 benign ethnic neutropenia). check and sign below:

Benefits of continuing clozapine treatment outweigh the risk of neutropenia.
 Until (MM/DD/YYYY) _____ (not to exceed 6 months)

Prescriber Signature:

Date (MM/DD/YYYY):

Monthly Monitoring Frequency (Enter data for the last monthly blood draw for this patient)

Blood Draw Date: MM / DD / YYYY	General Patient Population	BEN Patient Population	or	ANC (per μ L):
Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors (e.g., weather, transportation issues)	<input type="checkbox"/> Normal Range ($\geq 1500/\mu$ L) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μ L) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μ L) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu$ L) ²	<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu$ L) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μ L) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu$ L) ²		

¹ Prescriber signature is required to authorize the continuation of therapy if one or more labs are missing.
² Interrupt / Discontinue treatment or create a Treatment Rationale.

Prescriber Signature:

Date (MM/DD/YYYY):

Patient Treatment Status

Complete this section to interrupt, discontinue, or resume treatment for this patient. No selection indicates the patient may continue treatment.

Interrupt Treatment Discontinue Treatment Resume Treatment

Treatment Rationale (If Required) (Prescriber Signature required below)

Complete this section to continue treatment if 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 benign ethnic neutropenia). check and sign below:

Benefits of continuing clozapine treatment outweigh the risk of neutropenia.
 Until (MM/DD/YYYY) _____ (not to exceed 6 months)

Prescriber Signature:

Date (MM/DD/YYYY):

Continue to the next page for additional monitoring frequencies

3 Times Weekly Monitoring Frequency (Enter all ANC lab data collected in the last four weeks). This section may also be used to record ANCs for patients requiring daily monitoring.				
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors (e.g., weather, transportation issues)	General Patient Population		BEN Patient Population	
	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²		<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population		BEN Patient Population	
	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²		<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population		BEN Patient Population	
	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²		<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population		BEN Patient Population	
	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²		<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population		BEN Patient Population	
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	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²		<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population		BEN Patient Population	
	<input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²		<input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	

Continued on next page

Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population <input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	BEN Patient Population <input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	or ANC (per μL):
	Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population <input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population <input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	BEN Patient Population <input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	or ANC (per μL):
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population <input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	BEN Patient Population <input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	
Blood Draw Date: MM / DD / YYYY Reason for missing lab¹: <input type="checkbox"/> Patient Refused <input type="checkbox"/> Clinician discretion <input type="checkbox"/> Extrinsic factors	General Patient Population <input type="checkbox"/> Normal Range ($\geq 1500/\mu\text{L}$) <input type="checkbox"/> Mild Neutropenia (1000 to 1499/ μL) <input type="checkbox"/> Moderate Neutropenia (500 to 999/ μL) ² <input type="checkbox"/> Severe Neutropenia ($< 500/\mu\text{L}$) ²	BEN Patient Population <input type="checkbox"/> Normal BEN Range ($\geq 1000/\mu\text{L}$) <input type="checkbox"/> BEN Neutropenia (500 to 999/ μL) <input type="checkbox"/> BEN Severe Neutropenia ($< 500/\mu\text{L}$) ²	or ANC (per μL):

¹ Prescriber signature is required to authorize the continuation of therapy if one or more labs are missing.

² Interrupt / Discontinue treatment or create a Treatment Rationale.

Prescriber Signature:

Date (MM/DD/YYYY):

Patient Treatment Status

Complete this section to interrupt, discontinue, or resume treatment for this patient. No selection indicates the patient may continue treatment.

Interrupt Treatment Discontinue Treatment Resume Treatment

Treatment Rationale (If Required) (Prescriber Signature required below)

Complete this section to continue treatment if the patient has moderate neutropenia (ANC 500-999/ μL for the general population) or severe neutropenia (ANC $<500/\mu\text{L}$ for general population and patients with benign ethnic neutropenia). check and sign below:

Benefits of continuing clozapine treatment outweigh the risk of neutropenia.

Until (MM/DD/YYYY) _____ (not to exceed 6 months)

Prescriber Signature:

Date (MM/DD/YYYY):