

Dear Inpatient Pharmacy Authorized Representative:

In late 2015, the Clozapine REMS Program, in consultation with the FDA, extended the deadline for implementing the outpatient Pre-Dispense Authorization (PDA). The goal was to minimize treatment disruption for patients while allowing more time for pharmacies and prescribers to complete certification. At that time, the Clozapine REMS Program indicated additional communication would be provided when additional information is available.

The audience for this letter is authorized representatives of inpatient pharmacies. Inpatient pharmacies must verify that a patient is eligible to receive clozapine before the initial dispense in an inpatient setting. Inpatient pharmacies can accomplish this by performing an eligibility check via the Clozapine REMS Program website or by calling the Clozapine REMS Program Contact Center at 844-267-8678.

Although inpatient pharmacies do not perform Pre-Dispense Authorizations (PDAs), this letter is intended to describe the changes that will happen to the inpatient pharmacy eligibility check process with the initial outpatient Pre-Dispense Authorization (PDA) launch in May 2016. The inpatient pharmacy eligibility check will continue to evaluate some of the program elements that the Clozapine REMS Program has defined, and provide a determination back to the inpatient pharmacy on whether or not the patient is eligible to receive clozapine. Changes to the eligibility check are described in detail in the chart below.

As part of a 2-phase implementation, the initial outpatient PDA launch will provide warning messages if a prescriber and/or a pharmacy is not certified – but it will not prevent a dispense from being authorized. Similarly, if the most recent Absolute Neutrophil Count (ANC) is not current based on the patient's Monitoring Frequency (MF), this will not prevent a dispense from being authorized.



Note: When the full outpatient PDA launch occurs later in the year, if prescribers and/or pharmacies are not certified in the Clozapine REMS Program, or a patient's ANC is not current, this will impact the pharmacy's ability to dispense clozapine, negatively affecting patient care.

Inpatient pharmacy authorized representatives need to:




1. Read this letter and understand the upcoming changes in the eligibility check that will occur with the initial outpatient PDA launch and how it will affect your inpatient pharmacy dispensing locations
2. Ensure that all inpatient pharmacy dispensing locations within your organization are prepared to address these updates and use the eligibility check to support decisions to dispense clozapine

Plan for changes to the eligibility check and initial outpatient PDA launch




The initial launch of changes to the Web-based eligibility check is targeted for May 2016. Inpatient pharmacies must use the Web-based eligibility check to evaluate the following program elements before dispensing clozapine to a patient for the first time in the inpatient setting.

Clozapine REMS Program Elements	Eligibility Check
<p><u>Patient is registered</u></p> <ul style="list-style-type: none"> • Patient registration in the REMS will be evaluated • If the patient is not registered in the REMS or not found in the REMS, a dispense will not be authorized and the claim will be rejected • The patient may be registered by the prescriber at www.clozapinerems.com or by phone at 844-267-8678 • The patient may be registered by the pharmacy via phone at 844-267-8678 during the transition period <p>Note: Once the <u>full</u> PDA launch is implemented <u>later in the year</u>, patients must be registered by a prescriber or prescriber designee</p> <ul style="list-style-type: none"> • Once the patient is registered and a current ANC is on file with the REMS, the claim may be re-submitted for dispense authorization • Sample reject message (actual message may vary): <i>“*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient.”</i> 	<p><u>Patient Registered</u></p> <div style="text-align: center;">  </div> <p><u>Patient not Registered</u></p> <div style="text-align: center;">  </div>

The products covered under the Clozapine REMS Program are: Clozaril® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension • Fazaclor® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products

Clozapine REMS Program Elements	Eligibility Check
<p><u>Patient Absolute Neutrophil Count (ANC) on file</u></p> <ul style="list-style-type: none"> • If a patient does not have an ANC on file with the REMS, a dispense will not be authorized and the claim will be rejected • Patient ANCs may be submitted to the program at www.clozapinerems.com or by phone at 844-267-8678 • The ANC reporting form (available at www.clozapinerems.com) can also be used for submitting a patient ANC, however it will take up to 48 hours to process this form • Once the patient ANC is submitted, the claim may be re-submitted for dispense authorization • Sample reject message (actual message may vary): <i>"Patient not eligible for dispense. ANC results not on file. Contact prescriber."</i> 	<p><u>No ANC on File</u></p>  <p>Dispense Not Authorized</p>
<p><u>Patient has a low ANC</u></p> <ul style="list-style-type: none"> • If the last ANC on file for a patient is low, indicating moderate or severe neutropenia, the patient will not be eligible for dispense • The pharmacy is requested to notify the prescriber of the low ANC • If upon consult with the prescriber, the prescriber chooses to continue the patient on clozapine therapy, a Treatment Rationale must be provided to the REMS from the prescriber before the dispense can be authorized • A prescriber may submit a Treatment Rationale at www.clozapinerems.com or by phone at 844-267-8678 • The ANC reporting form can also be used for submitting a Treatment Rationale, however it will take up to 48 hours to process this form • Once the Treatment Rationale is submitted, the claim may be re-submitted for dispense authorization • Sample reject message (actual message may vary): <i>"*REMS* - ANC results out of acceptable range"</i> • Patient's last 2 ANCs (with blood draw date), and patient's Monitoring Frequency (MF) will be displayed on screen (sample message; actual message may vary): <ul style="list-style-type: none"> • ANC: 400 01/12/16 • ANC: 730 12/18/15 • Monitoring Frequency: Weekly 	<p><u>Low ANC</u></p>  <p>Dispense Not Authorized</p> <p><u>Low ANC & Treatment Rationale On File</u></p>  <p>Authorized</p>

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Clozapine REMS Program Elements	Eligibility Check
<p><u>Patient ANC is current</u></p> <ul style="list-style-type: none"> All Web-based eligibility check responses will provide the dispensing inpatient pharmacy with the following information: <ul style="list-style-type: none"> The 2 most recent ANC values and the associated blood draw dates Patient Monitoring Frequency (MF) As long as the patient is registered, has an ANC on file, and the ANC is not low, a dispense will be authorized If the last ANC draw date is not current based on the patient's Monitoring Frequency (MF), this will not prevent a dispense from being authorized <p>Note: Once the <u>full</u> outpatient PDA launch is implemented <i>later in the year</i>, patient ANCs must be current for a dispense to be authorized</p> While not required, it is recommended for patient safety that pharmacies contact the prescriber to acquire the most recent patient ANC information and/or use clinical judgment before proceeding with dispense If the pharmacy has or acquires an ANC that is more current than the last ANC draw date received back in the claim response, the pharmacy should submit the ANC to the Clozapine REMS Program Patient ANCs may be submitted to the program at www.clozapinerems.com or by phone at 844-267-8678 The ANC reporting form (available at www.clozapinerems.com) can also be used for submitting a patient ANC, however it will take up to 48 hours to process this form Sample eligibility message (actual message may vary): <i>"Patient is eligible to receive clozapine. Please evaluate latest ANC is current"</i> Patient's 2 most recent ANCs (with blood draw date), and patient's Monitoring Frequency (MF) will be displayed on screen (sample message; actual message may vary): <ul style="list-style-type: none"> ANC: 5100 01/12/16 ANC: 5300 12/18/15 Monitoring Frequency: Monthly 	<p><u>ANC is Current</u></p> 
<p><u>Prescribers are certified</u></p> <ul style="list-style-type: none"> Prescriber certification status will be evaluated; however, it will <u>not</u> prevent a patient from being eligible to receive clozapine If a prescriber is not certified in the system, a warning message will be displayed that the prescriber is not yet certified The warning message will contain content directing prescribers how to contact the Clozapine REMS Program to certify While not required, pharmacies may decide to contact prescribers regarding the need to certify soon Sample warning message (actual message may vary): <i>"*REMS* Rx authorized. Prescriber not currently certified. Prescriber can certify at www.clozapinerems.com or call 844-267-8678"</i> 	<p><u>Prescriber Certified</u></p>  <p><u>Prescriber not Certified</u></p>  <p>Authorized w/Warning</p>

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Clozapine REMS Program Elements

Eligibility Check

Pharmacies are certified

- Pharmacy certification status will be evaluated; however, it will not prevent a dispense from being authorized
- If a pharmacy is not certified in the system, a warning message will be displayed that the pharmacy is not yet certified
- The warning message will contain content that directs pharmacies to contact the Clozapine REMS Program to certify. If a pharmacy dispense location receives this message, they must work with their authorized representative to complete training and necessary steps for enrollment
- Sample warning message (actual message may vary): *“REMS* Rx authorized, however pharmacy not enrolled. Chain Pharmacies contact HQ Auth Rep. Others contact your organization’s Help Desk or enroll at www.clozapinerems.com or call 844-267-8678”*

Pharmacy Certified



Pharmacy not Certified



Authorized w/Warning

Once the changes to the eligibility check have been launched, data will continue to be evaluated. Should data demonstrate the need to modify the above criteria, pharmacies will be contacted accordingly.

For additional information related to the Clozapine REMS Program or the REMS Pharmacy Network, please contact the Clozapine REMS Program Contact Center at 844-267-8678.

Sincerely,

The Clozapine REMS Program

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