

## Dear Pharmacy Authorized Representative:

In late 2015, the Clozapine REMS Program, in consultation with the FDA, extended the deadline for implementing the 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 outpatient pharmacies that will adjudicate claims via a Web-based PDA or obtain a PDA by calling the Clozapine REMS Contact Center at 844-267-8678. This letter is intended to describe the changes that will happen with the initial Pre-Dispense Authorization (PDA) launch in May 2016. The initial PDA launch evaluates some of the program elements that the Clozapine REMS Program has defined, and provides an authorization to dispense accordingly.

As part of a 2-phase implementation, the initial 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 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.*

### Pharmacy authorized representatives that adjudicate claims via a Web-based PDA need to:




1. Read this letter and understand the upcoming initial PDA launch and how it will affect your outpatient pharmacy dispensing locations
2. Ensure that all outpatient pharmacy dispensing locations within your organization are prepared to use the Web-based PDA to support decisions to dispense clozapine

## Initial PDA Launch Plan




The Clozapine REMS Program is targeting the initial PDA launch for May 2016. The initial PDA launch will evaluate the following program elements before authorizing the dispense of clozapine.

Clozapine REMS Program Elements	PDA
<p><b><u>Patient is registered</u></b></p> <ul style="list-style-type: none"><li>• Patient registration in the REMS will be evaluated</li><li>• 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</li><li>• The patient may be registered by the prescriber at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or by phone at 844-267-8678</li><li>• The patient may be registered by the pharmacy via phone at 844-267-8678 during the transition period</li></ul> <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"><li>• Once the patient is registered and a current ANC is on file with the REMS, the claim may be re-submitted for dispense authorization</li><li>• Sample reject message (actual message may vary): <i>“*REMS* - Patient not enrolled. Call 844-267-8678 for additional information and to enroll patient.”</i></li></ul>	<p><b><u>Patient Registered</u></b></p>  <p><b><u>Patient not Registered</u></b></p> 



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	PDA
<p><b><u>Patient Absolute Neutrophil Count (ANC) on file</u></b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Patient ANCs may be submitted to the program at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or by phone at 844-267-8678</li> <li>• The ANC reporting form (available at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a>) can also be used for submitting a patient ANC, however it will take up to 48 hours to process this form</li> <li>• Once the patient ANC is submitted, the claim may be re-submitted for dispense authorization</li> <li>• Sample reject message (actual message may vary): <i>“REMS* - ANC results not on file. Contact prescriber”</i></li> </ul>	<p><b><u>No ANC on File</u></b></p>  <p>Dispense Not Authorized</p>
<p><b><u>Patient has low ANC</u></b></p> <ul style="list-style-type: none"> <li>• If the last ANC on file for a patient is a low ANC indicating moderate or severe neutropenia, a dispense will not be authorized</li> <li>• The pharmacy is requested to notify the prescriber of the low ANC</li> <li>• 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</li> <li>• A prescriber may submit a Treatment Rationale at <a href="http://www.clozapinerems.com">www.clozapinerems.com</a> or by phone at 844-267-8678</li> <li>• 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</li> <li>• Once the Treatment Rationale is submitted, the claim may be re-submitted for dispense authorization</li> <li>• Sample reject message (actual message may vary): <i>“REMS* - ANC results out of acceptable range”</i></li> <li>• 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"> <li>• ANC: 400 01/12/16</li> <li>• ANC: 730 12/18/15</li> <li>• Monitoring Frequency: Weekly</li> </ul> </li> </ul>	<p><b><u>Low ANC</u></b></p>  <p>Dispense Not Authorized</p> <p><b><u>Low ANC &amp; Treatment Rationale On File</u></b></p>  <p>Authorized</p>

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

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<p><b><u>Pharmacies are certified</u></b></p> <ul style="list-style-type: none"><li>• Pharmacy certification status will be evaluated; however, it will <u>not</u> prevent a dispense from being authorized</li><li>• If a pharmacy is not certified in the system, a warning message will be displayed that the pharmacy is not yet certified</li><li>• 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</li><li>• Sample warning message (actual message may vary): <i>“*REMS* Rx auth’d, but pharmacy not enrolled. Chain pharmacies contact HQ Auth Rep. Others call your Help Desk or enroll at www.clozapinerems.com or call 844-267-8678”</i></li></ul>	<p><b><u>Pharmacy Certified</u></b></p>  <p><b><u>Pharmacy not Certified</u></b></p>  <p>Authorized w/Warning</p>

After the initial PDA launch has occurred, 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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