New Service Request (NSR) #20100703

National Clozapine Coordination Project

Requirements Specification Document



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Revision History

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# Introduction

The National Clozapine Coordinating Center (NCCC) has the responsibility for enterprise-wide tracking of clozapine prescriptions, the collection and reporting of data required by the Food and Drug Administration (FDA)-mandated Clozapine Risk Evaluation Management System (REMS), monitoring of compliance with FDA requirements (Lab test: Absolute Neutrophil Count [ANC] at specific intervals), and authorizing approval of patients to be placed on clozapine therapy. REMS is also a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File. The NCCC is responsible for much of the work that is not automated, leading to delays in prescriptions being approved and posing potential risks or errors when manual review is required. More specifically, the Veterans Health Information Systems and Technology Architecture (VistA) Outpatient Pharmacy application currently performs clozapine safety checks, but the same safety checks are not performed in the Inpatient Medications application, requiring pharmacists to check an inpatient’s lab test results using Outpatient Pharmacy before finishing the order in Inpatient Medications.

## Purpose

The purpose of this Requirements Specification Document (RSD) is to delineate specific functional requirements for Increments 1 and 2 as assessed by the National Clozapine Coordination (NCC) Department of Veterans Affairs (VA) team to develop new functionality and enhancements needed for processing, tracking, and reporting clozapine usage within the VA.

The audience for this document is the NCC project development team, stakeholders, business owners, architects, Software Quality Assurance (SQA), and managerial authorities for this effort.

### Clozapine Treatment and Risk of Neutropenia

Clozapine is prescribed for patients suffering with Serious Mental Illness. Mental health staff members are prescribing clozapine at an increasing rate to meet the requirements of the Uniform Services for Mental Health (USMH) Handbook (1160.01), however, continued reliance on manual tracking methods are proving to be inadequate.

Clozapine treatment poses a high risk of neutropenia which is an abnormally low count of neutrophils. Neutrophils are a type of white blood cell (WBC) that helps to fight infections, particularly those caused by bacteria and fungi. The absolute neutrophil count (ANC) blood test is used to monitor the effect of the clozapine medication on the neutrophil count. The WBC count is usually used to calculate the ANC; however, ANC is a more relevant indicator of drug-induced neutropenia than WBC count. The FDA has determined that the ANC is the laboratory blood test of choice for monitoring patients on clozapine. Enhancements for monitoring patients in the Inpatient and Outpatient Pharmacy systems will use the following current FDA guidelines. The FDA ANC value ranges are listed in the table below:

Table 1: FDA ANC Values and Monitoring

|  |  |  |
| --- | --- | --- |
| **ANC Level** | **ANC Monitoring** | **Frequency of ANC lab tests** |
| Normal range | ANC ≥ 1500 | Weekly for patients 1 – 6 months on therapy  Bi-weekly for patients 6 – 12 months on therapy  Monthly for patients >12 months on therapy |
| Mild neutropenia | 1000 – 1499 | 3x weekly until ANC stabilizes to 1500 or greater |
| Moderate neutropenia | 500 – 999 | Daily until ANC stabilizes to 1000 or greater, then 3x weekly until ANC stabilizes to 1500 or greater |
| Severe neutropenia | < 500 | Daily until ANC stabilizes to 1000 or greater then 3x weekly until ANC stabilizes to 1500 or greater |

### NCC Background

The NCC has responsibility for enterprise-wide tracking of clozapine prescriptions. This includes collection and reporting of data required by the FDA Clozapine REMS. NCCC monitors the compliance of lab result testing and authorizing approval of patients to be placed on clozapine therapy. Much of the work NCCC is responsible for is not automated, leading to delays in prescription approval and posing potential risks or errors when manual review is required. The goal is to integrate safety checks for the clozapine inpatient to provide a seamless start to finish ordering process to meet the following objectives:

* Reduction in the amount of time currently required to manually retrieve missing information and correcting erroneous information before transmission to the FDA.
* Eliminating the necessity for Inpatient pharmacists to initially run the safety checks in Outpatient pharmacy, and then switch over to the Inpatient Medications to complete the order.
* Improving data accuracy and timeliness for FDA reporting requirements with storing the patient information in a local XTMP file for a nightly transfer of data based on patient and provider location.

## Scope

The scope of the NCC Project is to provide enhancements and new functionality that will provide and improve an automated process for the Inpatient Medications to track and manage the clozapine inpatient and to enhance Outpatient Pharmacy where needed. Functionality includes:

* Update Mental Health Clozapine Application Programming Interface (CLAPI) with new values of normal, mild, moderate, and sever neutropenia based on ANC as defined by the FDA REMS program
* Add special clozapine processing and reporting to Inpatient Medications including all patient safety check features currently provided by Outpatient Pharmacy.
* Ensure measures are taken, per FDA and VA business rules, to lockout or require an override when mild, moderate, or severe neutropenia is detected by the software.
* Provide storage of order’s clozapine data for a later data transfer of new and updated clozapine ordering information and patient demographics to the national clozapine data files.
* Add new local override functionality to both Inpatient and Outpatient Pharmacy to facilitate recording and dispensing of clozapine for unregistered patients when NCCC is closed and an authorization number cannot be acquired in a timely manner.
* Add new local override functionality to both Inpatient and Outpatient Pharmacy to facilitate recording and dispensing of clozapine without a recent ANC result under special conditions such as in anticipation of a natural disaster (storms, hurricanes, etc.)
* Provide capability for NCCC to be automatically notified when the pharmacy programming changes a clozapine patient’s status to “Discontinue.”

Any Computerized Patient Record System (CPRS) code change is out of scope for this project; however, changes to Mental Health CLAPI will impact ordering clozapine in CPRS and updating the Order Entry Results Reporting (OERR) message content is within scope.

## References

Enhancements to Support the National Clozapine Coordinating Center New Service Request (NSR) 20100703, Requirements Elaboration Document (RED), dated August 2011

Enhancements to Support the National Clozapine Coordinating Center Work Effort Unique Identifying # 20100703, Business Requirements Document (BRD) #20100703, dated November 2010

Veterans Health Administration (VHA) Handbook 1160.02, Clozapine Patient Management Protocol (CPMP), December 23, 2008

Federal Identity, Credential, and Access Management (FICAM) Roadmap,Dated December 2, 2011

VHA Handbook 1004, Informed Consent for Clinical Treatments and Procedures, Dated August 14, 2009

Computerized Patient Record System (CPRS) User Guide, Dated April 2011

FDA Regulatory Changes for Clozapine Outpatient Pharmacy Release Notes PSO\*7\*222, September 2006

Memorandum of Understanding between the Office of the Assistants Secretary of Defense (Health Affairs), the VHA, and the Indian Health Service, and the US FDA, Approved and Accepted by FDA on 8/5/2010

Section 508 Standards, published December 21, 2000

Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers, published September 2015

One-VA Technical Reference Model v16.3

# Overall Description

## Accessibility Specifications

The NCC functionality complies with Section 508 of the Rehabilitation Act of 1973. Section 508 of the Rehabilitation Act of 1973 and the Rehabilitation Act Amendments of 1998 mandate that all software developed by federal agencies allow access to and use of information and data by individuals with disabilities. Section 508 enhancements to NCCC ensure accessibility for users with various disabilities without impacting software usability for the primary audience of users.

Any NCC enhancements to the CPRS graphical user interface (GUI) are out of scope for this project.

## Business Rules Specification

The business rules supported by this project focus on new or enhanced software and business process improvements that will further enforce the highest level of safety when administering clozapine treatment for both inpatients and outpatients within the VA. These rules are mandated both by FDA and VA and include checking that a patient’s ANC and associated WBC count results are within acceptable levels. The FDA mandates reporting the lab test values in addition to patient and Provider data.

The following business rules support Design Constraint Specifications:

* A second Approving Member of the clozapine team who holds the PSOLOCKCLOZ key must authorize all overrides.
* Patients that are not actively registered at NCCC may have a temporary local authorization number assigned in an emergency during non-duty NCCC hours, weekends or holidays.
* An ANC and Matching WBC is defined as being from the same draw and both have the same date and time
* Although FDA REMS only requires an ANC for lab safety checks, VA requires a valid ANC to be accompanied by a matching WBC.
* New FDA-mandated ANC lab range values and monitoring guidelines as outlined in the Clozapine REMS (Section 1 Introduction), are to be included in order check logic in CPRS, Inpatient Medications and Outpatient Pharmacy.

## Design Constraints Specification

The scope of this project is restricted to modifications to Mental Health, Inpatient Medications, and Outpatient Pharmacy and OERR The schedule does not allow coordination with the CPRS project team so new override functionality cannot create an order with the new override in CPRS; however, a pharmacist will enter an order and use the new override functionality in Inpatient Medications and Outpatient Pharmacy if they have a written order from an authorized clozapine prescriber.

## Disaster Recovery Specifications

The functions performed by the NCC are mission-critical to both VA inpatients and outpatients being treated with clozapine. Therefore, disaster recovery is an important aspect of the system’s design. The back-up and data recovery process provides the business community with disaster recovery procedures when the clozapine software is brought off-line for planned maintenance or unplanned technical issues.

The clozapine software inherits the Disaster Recovery (DR) procedures of the VA hosting environment supporting the application, with additional DR specifications defined at a later date. Also note that the recovery strategies for all system software solutions that support clozapine software include the sequence of activities, as well as detailed procedures for the technical recovery of operations until all interfaced systems can be reconstituted.

The VA Handbook 6500.8 outlines the guidance for Information System Contingency Planning (ISCP) process, and the Information Systems (IS) Contingency Planning Assessment (ISCPA). The ISCPA will be used in the development of the Disaster Recovery Plan (DRP), Business Continuity Plans (BCPs), and to help shape the development of future Information System (IS) designs and engineering.

Although current applications supporting clozapine processing functions have an existing information system disaster recovery plan in place, the enhancements specified in this RSD would require the performance of a Business Impact Analysis (BIA) to identify Critical Business Processes, clozapine processing consumer Service requirements, and the Maximum Tolerable Downtime (MTD) for clozapine processing services. The completed BIA results should be used to determine if current DRP is appropriate for NCC and in alignment with VA Handbook 6500.8 guidelines.

Relevant nonfunctional requirements from the Requirements Elaboration Document (RED) are traced to and expanded upon in Epic 1 Mission Critical Systems located in Appendix A.

## Documentation and Training Specifications

Requirements for training and documentation, including user documentation, help systems, help about notices, installation guide, security guide, implementation guide, and any other forms of documentation are in process.

## Functional Specifications

Functional requirements for the NCC Project are delineated in the following tables and are associated with User Stories defined in Rational Requirements Composer (RRC).

### STORY 1 – Add Clozapine Processing to Inpatient Medications

|  |
| --- |
| As a Pharmacist, I want to ensure that clozapine processing functionality (that currently exists in Outpatient Pharmacy, i.e. safety checks, overrides, data reporting) is added to Inpatient Medications, so that I am warned or prevented from prescribing clozapine when the safety checks fail.  As a pharmacist, I want to ensure that the existing NCCC Authorized National Override or Mild Neutropenia Local Overrides are available when conditions (such as below normal ANC lab values or no lab results) would prevent clozapine processing in Inpatient Medications in order to ensure patient treatment is not interrupted. |
| *There are two paths for processing Inpatient Medications: either through a CPRS-originated order from the Provider (Pending order) or a Written order from the Provider.* |

Table 2: Requirements for Processing Pending Order in IP Pharmacy

| **RRC#** | **Pending Clozapine order Originated in CPRS** |
| --- | --- |
| 685324 | When an order originates in CPRS, the IP pharmacist shall use of any of the following menu options when processing a Pending order:   * Inpatient Order Entry [PSJ OE] * Non-Verified/Pending Orders [PSJU VBW] * Order Entry [PSJU NE] |
| 685325 | During processing of a Pending clozapine order in the IP pharmacy, the system shall verify that the provider is authorized to prescribe clozapine and has the following authorization in File 200:   * YSCL Authorized Key * Provider contains a valid DEA and VA numbers or valid VA and institution DEA numbers * Provider is Authorized to Prescribe Medications |
| 685333 | During processing of a Pending clozapine order in the IP pharmacy when the Provider is authorized, the system shall determine if the inpatient is actively registered at NCCC and has a clozapine Authorization number in File 55. |
| 685335 | Whenever a clozapine order is managed in the IP pharmacy for a Pending order, the system shall use the new FDA ANC lab results to determine how to proceed with monitoring and dispensing clozapine:   * ANC (with matching WBC) ≥ 1500 (Normal) * ANC (with matching WBC) 1000 – 1499 (Mild Neutropenia) * ANC (with matching WBC) 500 – 999 (Moderate Neutropenia) * ANC (with matching WBC) <500 (Severe Neutropenia) |
| 703720 | When a pharmacist processes a Pending order in IP pharmacy menu and both the ANC and WBC are present, the system shall verify that the ANC and WBC match, i.e., were drawn from the same draw, at the same date and time. |

Table 3: Requirements for Processing Written Order in IP Pharmacy

| **RRC#** | **Written Clozapine order from the Provider** |
| --- | --- |
| 709341 | With a Written order in IP pharmacy, an IP pharmacist shall use either of the following menu options when processing a Written order:   * Inpatient Order Entry [PSJ OE] * Order Entry [PSJU NE] |
| 685346 | After a new Written order for clozapine and dosage is entered in the IP VistA pharmacy, the system shall prompt the IP pharmacist to enter the name of the Provider who wrote the order at the Provider prompt to verify the following authorization in File 200:   * YSCL Authorized Key * Provider contains a valid DEA# or VA DEA# and Institution# * Provider is “Authorized to Prescribe Medications” |
| 685348 | For a Written order in IP pharmacy, in the event the Provider is not authorized to prescribe clozapine, the system shall display one of the applicable following messages to the IP pharmacist:  Provider must have a DEA# or VA# to write prescriptions for this drug.  Provider must hold YSCL AUTHORIZED key to write prescriptions for clozapine. |
| 709342 | For a Written order in IP pharmacy, in the event the provider was selected by mistake or another Provider name needs to be entered, the system shall allow the IP Pharmacist to select another Provider without having to start the order process over again. |
| 685349 | For a Written order in IP pharmacy, if the Provider is authorized, the system shall determine if the patient is actively registered at NCCC and has a clozapine Authorization number in File 55. |
| 685350 | For a Written order, if the patient is not actively registered at NCCC, the system shall trigger the Emergency Registration Override flow, whereby a temporary local authorization number can be assigned. (See Emergency Registration Override requirements) |
| 685347 | For a Written order in IP pharmacy, the system shall use the new FDA ANC lab results to determine how to proceed with monitoring and dispensing clozapine:   * ANC (with matching WBC) ≥ 1500 (Normal) * ANC (with matching WBC) 1000 – 1499 (Mild Neutropenia) * ANC (with matching WBC) 500 – 999 (Moderate Neutropenia) * ANC (with matching WBC) <500 (Severe Neutropenia) |
| 703721 | When the clozapine order originated in Vista backdoor IP pharmacy menu and both the ANC and WBC are present, the system shall verify that the ANC and WBC match, i.e., were drawn from the same draw, at the same date and time. |

Table 4: Requirements for 28 day and 56 Day Triggers

| **RRC#** | **28 Day and 56 Day Triggers to Discontinue** |
| --- | --- |
| 691809 | In the event a newly authorized clozapine Inpatient has not filled the clozapine order within 28 days after being marked ‘Active’, the system shall automatically change the status from ‘Active’ to ‘Discontinued.’ |
| 691810 | In the event a currently ‘Active’ clozapine Inpatient has not filled a clozapine order for 56 days or longer, the system shall automatically change the status from ‘Active’ to ‘Discontinued.’ |

Table 5: Requirements for Edit Options in IP Pharmacy

| **RRC#** | **Inpatient Pharmacy Edit Option** |
| --- | --- |
| 718397 | For Inpatient orders where a patient is on a management dose of clozapine, the system shall automatically default the Stop date (similar to current OP pharmacy) that correlates with the dispense schedule of:   * Weekly (stop date is 7 days) * Bi-weekly (stop date is 14 days), * Monthly (stop date is 28 days) |
| 720253 | When the Inpatient pharmacist is processing a clozapine order, the system shall allow the pre-populated Stop date fields that are presented in parens (  ) to be edited by the pharmacist to change the date to less than the maximum default date, such as:   * 4 days default for an emergency supply can be edited to less than the default 4 days * 7 days default for a patient on weekly dispense frequency can be edited to less than the default 7 days * 14 days default for a patient on bi-weekly dispense frequency can be edited to less than the default 14 days * 28 days default for a patient on monthly dispense frequency can be edited to less than the default 28 days |
| 720269 | For Inpatient orders, whenever an editable field is selected to be modified – delineated by an asterisk (\*) – the system shall discontinue the current clozapine order and create a new order which repeats the order and safety checks. Editable fields include:  \*(1) Orderable item  \*(2) Dosage ordered  \*(3) Start  \*(4) Med Route  \*(5) Stop  \*(8) Schedule  \*10) Provider |

#### Renewal Orders - BLOCKED

The ability to Renew orders is blocked for CPRS Providers and both Outpatient and Inpatient VistA Backdoor Pharmacy. The following requirement provides for an error response in the event a pharmacist attempts to Renew (RN) a clozapine order in VistA Backdoor Pharmacy.

Table 6: Error Requirement for Blocked Renewal Option in OP and IP

| **RRC#** | **Outpatient Pharmacy and Inpatient Medications Renewal Error Message** |
| --- | --- |
| 728053 | When a pharmacist attempts to use the Renew (RN) menu option in either Outpatient Pharmacy or Inpatient Medications, the system shall display the following error message and the functionality is not supported:  Clozapine orders cannot be renewed |

#### Copy Orders (CO)

The Copy Order menu option is accessible as a hidden VistA menu when the ‘?’ is used. An active, expired or discontinued order can be selected and the CO entry used to pre-populate order information by copying it into the new order. Since this is a new order, safety and order checks must be run.

Table 7: Requirement for Copy Order Option in IP Medications

| **RRC#** | **Outpatient Pharmacy and Inpatient Medication Copy Order** |
| --- | --- |
| 728054 | For an Inpatient order, the system shall support a Copy Order (CO) whereby an active, discontinued or expired order can be copied to pre-populate fields to create a new order, which then runs all safety and order checks. |

#### Total Daily Dose

The Total Daily Dose functionality in Outpatient Pharmacy prompts the pharmacist to manually calculate and enter the Total Daily Dose (mg/day) when a clozapine order is created. This same functionality will reside in the Inpatient Medications pharmacy. The data transaction will be stored in an XTMP file and will be sent in the nightly batch file to the National data files to populate the Total Daily Dose field.

Table 8: Requirement for Manual Entry of Total Daily Dose in IP Medications

| **RRC#** | **Inpatient Pharmacy Total Daily Dose** |
| --- | --- |
| 728055 | When an order is added to Inpatient Medications, the system shall require the pharmacist to manually enter the active Clozapine dose (mg/day) across all outpatient and inpatient prescriptions/orders. |

### STORY 2 – Update ANC Lab Range Values for Outpatient Pharmacy and Inpatient Medications

|  |
| --- |
| As a pharmacist, I want to ensure that new FDA ANC lab range values signifying normal, mild, moderate and severe Neutropenia are updated in the Outpatient and Inpatient Medication systems, so that appropriate actions, warning messages, hard stops and overrides can be used. |
| *FDA has mandated new lab range values and monitoring guidelines listed in Section 1.1.1 above. All treatment and monitoring for clozapine patients in OP or IP Pharmacy will use these new guidelines when the ANC is normal or abnormal indicating mild neutropenia or moderate to severe neutropenia. \*Both Moderate and Severe neutropenia are treated the same – both have an ANC less than 1000.* |

Table 9: Requirements for Updated Lab Range Values in OP and IP

| **RRC#** | **FDA - Updated Lab Range Values in OP and IP Pharmacy** |
| --- | --- |
| 685335 | Whenever a clozapine OP prescription/ IP order is managed in the OP or IP pharmacy, the system shall use the new FDA ANC lab results to determine how to proceed with monitoring and dispensing clozapine:   * ANC (with matching WBC) ≥ 1500 (Normal) * ANC (with matching WBC) 1000 – 1499 (Mild Neutropenia) * ANC (with matching WBC) 500 – 999 (Moderate Neutropenia) * ANC (with matching WBC) <500 (Severe Neutropenia) |

### STORY 2.1 – Update Normal ANC Results (ANC ≥1500)

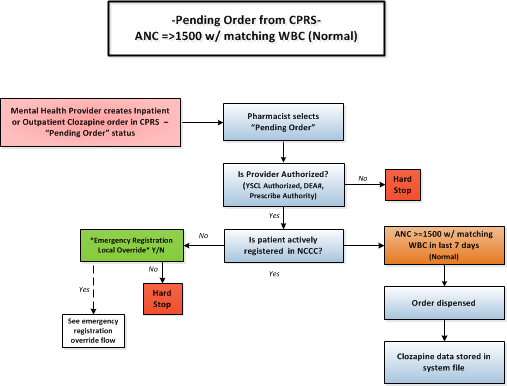
|  |
| --- |
| As a pharmacist, I want to ensure that when a clozapine patient’s lab results have an ANC blood test result ≥1500 (normal) and a matching WBC within the last 7 days, I can dispense the clozapine to the patient without the need for an override. |
| *When ANC results are normal, the OP or IP pharmacist will activate/verify the OP prescription / IP order and dispense the clozapine. The pharmacist does not need to have the PSOLOCKCLOZ key in this situation.* |

Table 10: Requirements for Normal ANC – Pharmacy

| **RRC#** | **Normal ANC Values – Pending Order** |
| --- | --- |
| 685345 | When the OP or IP pharmacist receives a Pending or Written clozapine order and the ANC is greater than or equal to 1500 with a matching WBC in the last 7 days (Normal), the system shall prompt the pharmacist to activate/verify the clozapine prescription/order. |
| 689680 | Following dispense of clozapine by the pharmacist, the system shall store the data in a local XTMP variable file. |

Figure 1 illustrates the data flow for a CPRS-originated pending order when the ANC is Normal (≥1500) received by the IP or OP pharmacist.

Figure 1: Pharmacy Pending Order for Normal ANC Results (Normal ANC ≥1500)



### STORY 2.2 – Update Mild Neutropenia Values (ANC 1000-1499) in Pharmacy

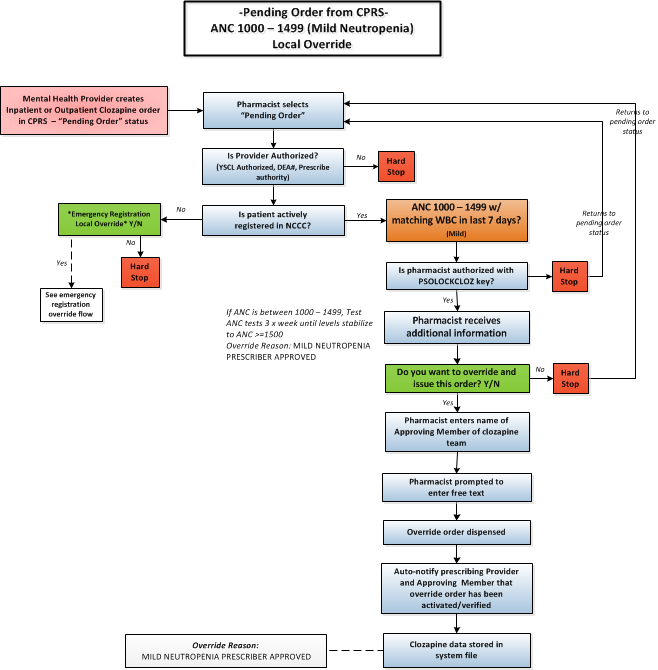
|  |
| --- |
| As a pharmacist, I want to ensure that when a patient’s lab results have an ANC between 1000 and 1499 (Mild neutropenia) and a matching WBC within the last 7 days, the software prevents the dispensing of clozapine unless I choose to use the Mild Neutropenia Local Override. If I choose to use the Mild Neutropenia Local Override, I am instructed to test blood levels 3x week until ANC stabilizes ≥1500. |
| *A pending order for Mild neutropenia is received in the pharmacy. Two users with PSOLOCKCLOZ key authority are required to sign the order. This flow is applicable for a Pending order from CPRS or an entry from VistA Backdoor Pharmacy Written order.* |

Table 11: Requirements for Mild Neutropenia – Pharmacy

| **RRC#** | **Mild Neutropenia - Local override** |
| --- | --- |
| 685287 | When the OP or IP pharmacist proceeds with a Pending or Written Clozapine order for Mild neutropenia, the system shall display a message to the pharmacist which includes the following elements:  Now doing clozapine Order checks. Please wait...  <\*\*\*Last XX WBC and NEUTROPHILS ABSOLUTE (ANC) results\*\*\*  *<Displays date/time, Results for WBC and ANC>*  *<Displays up to the last four results in the last 30 days>* |
| 685296 | If the pharmacist is not authorized with PSOLOCKCLOZ key to override, the system shall display the following message and issue a hard stop, whereby the order is returned to Pending order status, or in the event of a Written order, the system issues a hard stop and the order is deleted and not processed:  You Are Not Authorized to Override! See Clozapine Manager with PSOLOCKCLOZ key. No prescription entered! |
| 685303 | If the pharmacist is authorized with PSOLOCKCLOZ key to override below normal ANC results for Mild neutropenia, the system shall prompt the authorized pharmacist with the following message:  Override reason: MILD NEUTROPENIA PRESCRIBER APPROVED  Test ANC labs 3x weekly until levels stabilize to greater than or equal to 1500  Do you want to override and issue this order? Y/N |
| 685305 | If the pharmacist selects NO and does not want to continue with the Local Override for Mild neutropenia, the system shall issue a hard stop and the order is returned to Pending order status, or in the event of a Written order, the system issues a hard stop and the order is deleted and not processed. |
| 685306 | If the pharmacist selects YES and wants to continue with the Local Override for Mild neutropenia, the system shall prompt the pharmacist to enter the name of an Approving Member of the clozapine team from a list of active authorized users with PSOLOCKCLOZ key. The list is displayed by entering ?? or a partial name search. |
| 685307 | With Mild Neutropenia, once the active Approving Member with the PSOLOCKCLOZ key is selected, the system shall pre-populate the following into the Remarks field:  REASON FOR OVERRIDE: MILD NEUTROPENIA PRESCRIBER APPROVED ***plus***  *<the pharmacist may add additional free text up to a total of 200 characters>* |
| 685308 | When the Local Override for Mild neutropenia is completed with two users possessing the PSOLOCKCLOZ key, the system shall prompt the pharmacist to dispense the clozapine OP prescription or IP order. |
| 689696 | The system shall send an auto-notification via VistA Alerts to both the prescribing Provider and the active Approving Member of the clozapine team with PSOLOCKCLOZ key that an prescription/order has been activated/verified. |
| 685310 | Following dispense of the Local Override order for Mild neutropenia, the system shall store the data in a local XTMP variable file. |

Figure 2 illustrates the data flow for a CPRS-originated pending order when the ANC is abnormal (1000-1499 Mild neutropenia) that is received by the IP or OP pharmacist.

Figure 2: Pharmacy Pending Order for Mild Neutropenia (ANC 1000-1499– Local Override)



### STORY 2.3 – Update Moderate to Severe Neutropenia Values (ANC <1000) in Pharmacy

|  |
| --- |
| As a pharmacist, I want to ensure that when a clozapine patient’s lab results have an ANC <1000 (Moderate to Severe neutropenia) and a matching WBC within the last 7 days, the software prevents the dispense of clozapine unless an NCCC Authorized National Override is recorded in the local VistA system. |
| *When a National Override is in effect and originated in CPRS, the pharmacist will receive a ‘pending’ order and must complete the order prior to midnight of the day it was approved by NCCC.* |

Table 12: Requirements for Moderate to Severe Neutropenia – No National Override

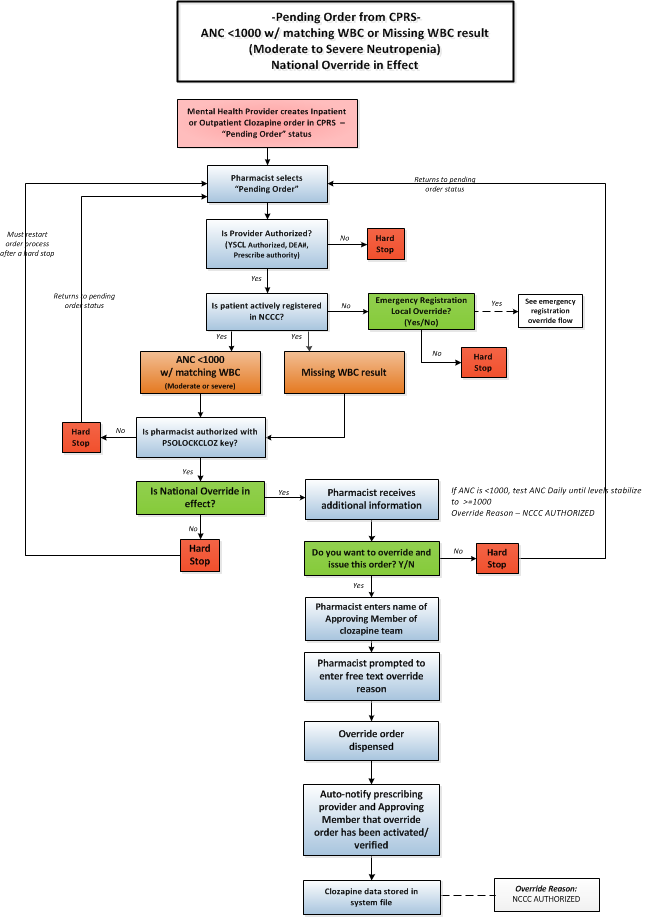
| **RRC#** | **Moderate to Severe Neutropenia - No National Override** |
| --- | --- |
| 709350 | In the event an authorized pharmacist proceeds with a Pending or Written clozapine prescription/order for Moderate to Severe neutropenia and a National Override is not is effect (e.g., expired at midnight or labs have changed since Pending order was received), the system shall display the following message to the pharmacist and issue a hard stop:  Now doing clozapine Order checks. Please wait...  National Override expired at midnight on Month Day, Year  <*Displays up to the last 4 results within the last 30 days, if available*>  Permission to dispense clozapine has been denied. If the results of the latest Lab Test drawn in the past 7 days show ANC below 1000/mm3 and you wish to dispense outside the FDA and VA protocol ANC limits, document your request to Request for Override of Pharmacy Lockout (from VHA Handbook 1160.02) Director of the VA National Clozapine Coordinating Center (Phone: 214-857-0068 Fax: 214-857-0339) for a one-time override permission.  A CBC/Differential including ANC Must Be Ordered and Monitored on a Daily basis until the ANC above 1000/mm3 with no signs of infection. If ANC is between 1000-1499, therapy can be continued but physician must order lab test three times weekly.  Also make sure that the LAB test, ANC is set up correctly in the Mental Health package using the CLOZAPINE MULTI TEST LINK option. |

Table 13: Requirements for Moderate to Severe Neutropenia – National Override in Effect

| **RRC#** | | **Moderate to Severe Neutropenia - National Override in Effect** |
| --- | --- | --- |
| 689691 | | When a National Override is in effect, the system shall require the OP or IP pharmacist to complete the order prior to its expiration at midnight of the same day it was approved by NCCC, or the approval expires. |
| 689689 | If the pharmacist is **not** authorized with the PSOLOCKCLOZ key when a National Override is in effect for Moderate to Severe neutropenia, the system shall display the following message and issue a hard stop, whereby the prescription/order is returned to Pending status, or in the event of a Written order, the system issues a hard stop and the prescription/order is deleted and not processed:  You Are Not Authorized to Override! See Clozapine Manager with PSOLOCKCLOZ key. No prescription entered**!** | |
| 689688 | | When the authorized pharmacist proceeds with the Pending or Written clozapine order for Moderate to Severe neutropenia and a National Override is in effect, the system shall display the following message to the pharmacist:  Now doing clozapine Order checks. Please wait...  Permission to dispense clozapine has been authorized by NCCC  Test ANC labs Daily until levels stabilize to ANC greater than or equal to 1000  Override reason: NCCC AUTHORIZED |
| 689690 | | If the pharmacist is authorized with PSOLOCKCLOZ key to override low ANC results for Moderate to Severe neutropenia, the system shall prompt the authorized pharmacist with the following message:  Do you want to override and issue this order? Y/N |
| 689692 | | If the pharmacist selects NO and does not want to continue with the National Override for Moderate to Severe neutropenia, the system shall issue a hard stop and the order is returned to Pending order status, or in the event of a Written order, the system issues a hard stop and the order is deleted and not processed. |
| 689693 | | If the pharmacist selects YES and wants to continue with the National Override for Moderate to Severe neutropenia, the system shall prompt the pharmacist to enter the name of an Approving Member of the clozapine team from a list of active authorized users with PSOLOCKCLOZ key. The list is displayed by entering ?? or a partial name search. |
| 689694 | | With a National Override in effect for Moderate to Severe neutropenia, the system shall pre-populate the following into the Remarks field:  REASON FOR OVERRIDE: NCCC AUTHORIZED ***plus***  *<the pharmacist may add additional free text up to a total of 200 characters>* |
| 689695 | | When the National Override for Moderate to Severe neutropenia is completed with an Approving Member possessing the PSOLOCKCLOZ key, the system shall prompt the pharmacist to dispense the clozapine prescription/order. |
| 689696 | | The system shall send an auto-notification via VistA Alerts to both the prescribing Provider and the active Approving Member of the clozapine team with PSOLOCKCLOZ key that an prescription/order has been activated/verified. |
| 704044 | | Following dispense of the National Override order for Moderate to Severe neutropenia, the system shall store the data in a local XTMP variable file. |

Figure 3 illustrates the data flow for a CPRS-originated pending order when the ANC is abnormal (<1000 (Moderate to Severe neutropenia) that is received by the IP or OP pharmacist.

Figure 3: Pharmacy Pending Order for Moderate to Severe Neutropenia (ANC <1000)



### STORY 2.4 – Update No Matching WBC in Pharmacy

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| --- |
| As a pharmacist, I want to ensure that if a clozapine patient’s lab results have an ANC result but No Matching WBC, the software prevents the dispensing of clozapine with an explanatory error message unless an NCCC Authorized National Override is in effect. |
| *When there is an ANC result, it is expected that a Matching WBC must be present from the same draw date and time. In the event the Matching WBC is not available, a National Override authorization must be in effect in order to dispense clozapine.* |

Table 14: Requirements for No Matching WBC – No National Override

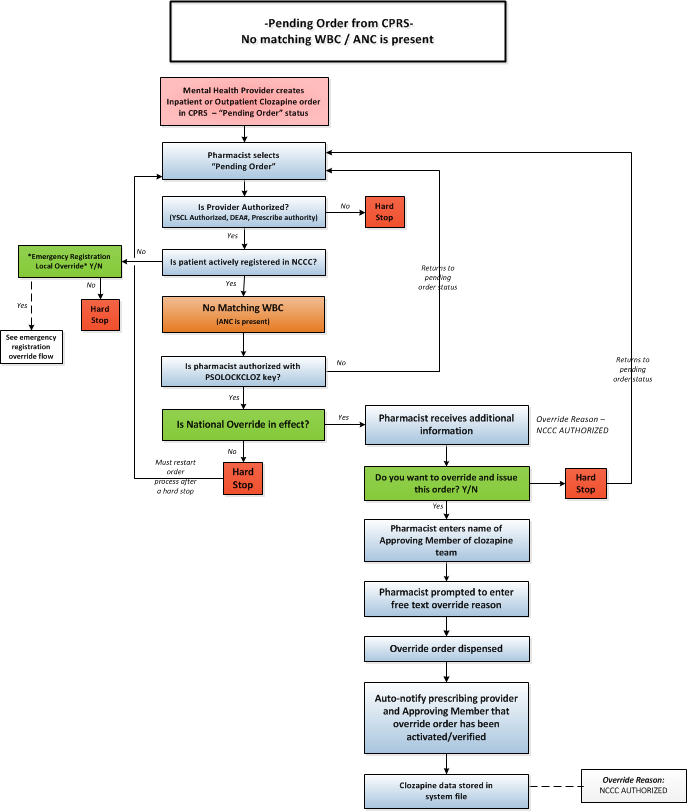
| **RRC#** | **No Matching WBC - No National Override** |
| --- | --- |
| 709446 | In the event an authorized pharmacist proceeds with a Pending or Written clozapine prescription/order for ANC Result with No Matching WBC and a National Override is not in effect (e.g., expired at midnight or labs have changed since Pending order was received), the system shall display the following message to the pharmacist and issue a hard stop:  Now doing clozapine Order checks. Please wait...  <*Displays up to the last 4 results within the last 30 days, if available*>  Permission to dispense clozapine has been denied. The result of the latest Lab Test drawn in the past 7 days shows ANC results but No Matching WBC. If you wish to dispense outside the FDA and VA protocol ANC limits, document your request to Request for Override of Pharmacy Lockout (from VHA Handbook 1160.02) Director of the VA National Clozapine Coordinating Center (Phone: 214-857-0068 Fax: 214-857-0339) for a one-time override permission. |

Table 15: Requirements for No Matching WBC – National Override in Effect

| **RRC#** | **No Matching WBC – National Override in Effect** |
| --- | --- |
| 709385 | When a National Override is in effect, the system shall require the OP or IP pharmacist to complete the order prior to its expiration at midnight of the same day it was approved by NCCC, or the approval expires. |
| 690231 | If the pharmacist is **not** authorized with the PSOLOCKCLOZ key when a National Override is in effect for an ANC with No Matching WBC, the system shall display the following message and issue a hard stop, whereby the prescription/order is returned to Pending status, or in the event of a Written order, the system issues a hard stop and the prescription/order is deleted and not processed:  You Are Not Authorized to Override! See Clozapine Manager with PSOLOCKCLOZ key. No prescription entered**!** |
| 690232 | If the pharmacist is authorized with the PSOLOCKCLOZ key, the system shall prompt the authorized pharmacist with the following message:  Now doing clozapine Order checks. Please wait...  Permission to dispense clozapine has been authorized by NCCC  Override Reason: NCCC Authorized  Do you want to override and issue this order? Y/N |
| 690220 | If the pharmacist selects NO and does not want to continue with the National Override for No Matching WBC, the system shall issue a hard stop and the prescription/order returned to Pending status, or in the event of a Written order, the systems issues a hard stop and the prescription/order is deleted and not processed. |
| 690221 | If the pharmacist selects YES and wants to continue with the National Override for ANC with No Matching WBC, the system shall prompt the pharmacist to enter the name of an Approving Member of the clozapine team from a list of active authorized users with PSOLOCKCLOZ key. The list is displayed by entering ?? or a partial name search. |
| 690222 | With a National Override in effect for ANC with No Matching WBC, the system shall pre-populate the following into the Remarks field:  REASON FOR OVERRIDE: NCCC AUTHORIZED ***plus***  *<the pharmacist may add additional free text up to a total of 200 characters>* |
| 690223 | When the National Override for ANC with No Matching WBC is completed with an Approving Member possessing the PSOLOCKCLOZ key, the system shall prompt the pharmacist to dispense the clozapine prescription/order. |
| 690224 | The system shall send an auto-notification via VistA Alerts to both the prescribing Provider and the active Approving Member of the clozapine team with PSOLOCKCLOZ key that the National Override order has been activated/verified. |
| 690225 | Following dispense of the National Override order when there is an ANC and No Matching WBC, the system shall store the data in a local XTMP variable file. |

Figure 4 illustrates the data flow for a CPRS-originated pending order for No Matching WBC that is received by the IP or OP pharmacist.

Figure 4: Pharmacy Pending Order for No Matching WBC



### STORY 3 – Update ANC Lab Range Values in CPRS

|  |
| --- |
| As a clozapine Provider, I want to ensure that new FDA ANC lab range values signifying normal, mild, moderate and severe Neutropenia and associated warning/error messages are updated in the CPRS system, so that appropriate actions, warning messages, hard stops and overrides can be used. |
| *FDA has mandated new lab range values and monitoring guidelines listed in Section 1.1.1 above. All treatment and monitoring for clozapine patients with orders originated in CPRS will use these new guidelines when the ANC is normal or abnormal indicating mild neutropenia or moderate to severe neutropenia.* |

Table 16: Requirement to Update ANC Lab Values – CPRS

| **RRC#** | **FDA** – **Update Lab Range Values in CPRS** |
| --- | --- |
| 685321 | Whenever a clozapine order is managed in CPRS, the system shall use the new FDA ANC lab results to determine how to proceed with monitoring and dispensing clozapine:   * ANC (with matching WBC) ≥ 1500 (Normal) * ANC (with matching WBC) 1000 – 1499 (Mild Neutropenia) * ANC (with matching WBC) 500 – 999 (Moderate Neutropenia) * ANC (with matching WBC) <500 (Severe Neutropenia) |
| 701303 | During the CPRS IP pharmacy order process where both the ANC and WBC are present, the system shall verify that the ANC and WBC match, i.e., were drawn from the same draw, at the same date and time. |

### STORY 3.1 – Update Normal ANC Values in CPRS

|  |
| --- |
| As a clozapine Provider, I want to ensure that when a clozapine patient’s lab results have an ANC blood test result ≥1500 (Normal) and a matching WBC in the last 7 days, I can prescribe clozapine to the patient using CPRS without the need for an override and accurate clozapine alert messages appear in the CPRS. |
| *The new requirement for CPRS is that it must be based on the new FDA range for Normal ANC result (≥1500)* |

Table 17: Requirement for Normal ANC Value - CPRS

| **RRC#** | **Normal ANC Values** |
| --- | --- |
| 685343 | In CPRS, when ANC results are greater than or equal to 1500 with a Matching WBC in the last 7 days (Normal), the system shall prompt the authorized Provider to sign the order whereby a Pending clozapine order is created in the OP or IP Pharmacy. |

### STORY 3.2 – Update Mild Neutropenia Values (ANC 1000-1499) in CPRS

|  |
| --- |
| As a clozapine Provider, I want to ensure that when a patient’s lab results have an ANC between 1000 and 1499 (Mild neutropenia) and a Matching WBC in the last 7 days, CPRS prevents the dispensing of clozapine unless I choose to use the Mild Neutropenia Local Override. If I choose to use the Mild Neutropenia Local Override, I am warned to test blood levels 3x week until ANC stabilizes greater than or equal to 1500. |
| *The new requirement for CPRS is that it must be based on the new FDA range for Mild Neutropenia when the ANC result is between 1000-1499 and include instructions to test ANC 3x weekly until it stabilizes to greater than or equal to 1500.* |

Table 18: Requirements for Mild Neutropenia - CPRS

| **RRC#** | **Mild Neutropenia** – **Local override** |
| --- | --- |
| 685279 | In CPRS, when the ANC is between 1000 and 1499 with a Matching WBC in the last 7 days (Mild neutropenia), the system shall display a warning message to the Provider that updates the instructions to test ANC 3x weekly until it stabilizes to greater than or equal to 1500.  Message:  Mild Neutropenia – please repeat CBC/Diff including WBC and ANC tests immediately and 3X weekly until ANC stabilizes to greater than or equal to 1500 – Most recent results – WBC X.X (Date Time) ANC X.X (Date Time)  cid:image001.png@01D19AE3.5AA288B0 |

### STORY 3.3 – Update Moderate to Severe Neutropenia Values (ANC <1000) in CPRS

|  |
| --- |
| As a clozapine Provider, I want to ensure that when a clozapine patient’s lab results have an ANC  <1000 (Moderate to Severe neutropenia) and a Matching WBC in the last 7 days, CPRS prevents the dispense of clozapine unless an NCCC Authorized National Override is recorded in the local VistA system. I want accurate warning/error messages with the new FDA values to appear in CPRS. |
| *The new requirement for CPRS is that it must be based on the new FDA range for Moderate to Severe Neutropenia when the ANC result is <1000 and include instructions to test ANC Daily until it stabilizes to greater than or equal to 1000. The only new requirement is to use new FDA guidelines with information for testing.* |

Table 19: Requirement for Moderate to Severe Neutropenia - CPRS

| **RRC#** | **Moderate to Severe Neutropenia** – **National override in effect** |
| --- | --- |
| 689687 | Once a National Override is in effect when the ANC is less than 1000 with a Matching WBC in the last 7 days (Moderate to Severe neutropenia), the system shall display a warning message to the Provider that updates the instructions to test ANC Daily until levels stabilize to greater than or equal to 1000. This is the first of two messages that displays the instructions.  Message:  Moderate/Severe Neutropenia - please repeat CBC/Diff including WBC and ANC tests immediately Daily until ANC stabilizes to greater than or equal to 1000. – Most recent results – WBC X.X (Date Time) ANC X.X (Date Time)  cid:image004.png@01D19BD5.C5B248F0 |
| 685326 | Once the Provider presses Accept Order on the first Order Checking window, a second message window shall display with additional information (may require scrolling), including a repeat of the message to perform ANC tests Daily. The Provider will then be required to press Accept Order on this window to complete the order process for a Pending order.  Message:  Moderate/Severe Neutropenia - please repeat CBC/Diff including WBC and ANC tests immediately Daily until ANC stabilizes to greater than or equal to 1000. Most recent results – WBC X.X (Date Time) ANC X.X (Date Time)  cid:image005.png@01D19BD5.C5B248F0 |

### STORY 3.4 – Update CPRS Warning/Error Messages for No ANC Results Found in Last 7 days

|  |
| --- |
| As a clozapine Provider, I want to ensure that when a clozapine patient has no ANC lab results (with or without a WBC) in the last 7 days, CPRS prevents the dispense of clozapine unless an NCCC Authorized National Override is recorded in the local VistA system (\*or I choose to use the Special Conditions Local Override\*). Message to the Provider states:  A Special Conditions Local Override can be approved for (1) weather-related conditions, (2) mail order delays of clozapine, or (3) inpatient going on leave. With Provider’s documentation of approval, you may dispense a one-time supply not to exceed 4 days.  \*It is preferred that the new Special Conditions Local Override be added to No ANC Results Found in Last 7 days, but that new functionality is separate and more difficult than updating the warning/error message.\* |
| *The new requirement for CPRS is that the message box that displays to the Provider when there are No ANC results in the last 7 days, is updated to alert the Provider that they can get a National Override and dispense at the patient’s normal frequency or send a Written order to the Pharmacy for a Special Conditions Local Override.* |

Table 20: Requirement for No ANC in Last 7 Days – No National Override OUTPATIENT

| **RRC#** | **No ANC in Last 7 Days – No National Override OUTPATIENT** |
| --- | --- |
| 689829 | In CPRS when there are No ANC results in the last 7 days and a National Override is not in effect, the system shall display the following message to the Provider to either request a National Override or an Outpatient Special Conditions Local Override.  Message:  \*\*\* Permission to dispense clozapine has been denied based on the available lab tests related to the clozapine treatment program. \*\*\*  For a National Override to dispense at the patient’s normal frequency, contact the NCCC.  A local emergency override for Outpatient can be approved for:  (1) weather-related conditions, (2) mail order delays of clozapine, or (3) inpatient going on leave.  For an Outpatient Special Conditions Local Override, a written prescription from the provider with documentation to the pharmacist is required to dispense a one-time emergency 4-day supply.  cid:image002.png@01D1D11B.28F67E20 |

Table 21: Requirement for No ANC in Last 7 Days – No National Override INPATIENT

| **RRC#** | **No ANC in Last 7 Days – No National Override INPATIENT** |
| --- | --- |
| 734557 | In CPRS when there are No ANC results in the last 7 days and a National Override is not in effect, the system shall display the following message to the Provider to either request a National Override or an Inpatient Special Conditions Local Override.  Message:  \*\*\* Permission to dispense clozapine has been denied based on the available lab tests related to the clozapine treatment program. \*\*\*  For a National Override to dispense at the patient’s normal frequency, contact the NCCC.  A local emergency override for an Inpatient can be approved for:  IP Order Override with Outside Lab Results.  For a Special Conditions Local Override, a written order from the provider with documentation to the pharmacist is required to dispense a one-time 4-day supply.  The provider must record the ANC from another facility including date/time in both the Provider Progress Note and Comment field in CPRS. |

Table 22: Requirement for No ANC in Last 7 Days – National Override in Effect

| **RRC#** | **No ANC in Last 7 Days – National Override in Effect** |
| --- | --- |
| 685334 | If there is No ANC result in the last 7 days and a National Override is in effect, the system shall display the following Order Checking message to the Provider in CPRS:  Message:  Clozapine orders require a CBC/Diff within past 7 days. Please order CBC/Diff with WBC and ANC immediately. Most recent results – WBC x.x (Date/Time) ANC x.x (Date/Time)  cid:image002.png@01D19AEE.4CC18560 |

### STORY 3.5 – Update CPRS Warning/Error Messages for No Matching WBC Found

|  |
| --- |
| As a clozapine Provider, I want to ensure that when a clozapine patient’s lab results have an ANC result but no matching WBC in the last 7 days, CPRS prevents the dispensing of clozapine unless an NCCC Authorized National Override is recorded in the local VistA system. I want accurate warning/error messages referencing the lack of a Matching WBC result to appear in CPRS. |
| *The new requirement for CPRS is that the message box that displays to the Provider when there is No Matching WBC result when an ANC is present in the last 7 days, alerts the Provider to request a National Override.* |

Table 23: Requirement for No Matching WBC (ANC is Present) - CPRS

| **RRC#** | **No Matching WBC in Last 7 Days - No National Override** |
| --- | --- |
| 690219 | In CPRS when there is an ANC and No Matching WBC in the last 7 days and a National Override is not in effect, the system shall display the following message to the Provider and issue a hard stop:  Message:  \*\*\* Permission to dispense clozapine has been denied based on the available lab tests related to the clozapine treatment program.\*\*\*  The latest lab test results drawn in the past 7 days have ANC results but no matching WBC. Redo the lab tests or contact the NCCC for a National Override to dispense clozapine with no matching WBC results.  WBC: xx  ANC: xx  Date/time of last tests: mm/dd/yyyy  cid:image002.png@01D19AFF.3F2C4960 |

Table 24: Requirement for No Matching WBC – National Override in Effect

| **RRC#** | **No Matching WBC in Last 7 Days - National Override in Effect** |
| --- | --- |
| 689791 | If there is an ANC result and No Matching WBC in the last 7 days and a National Override is in effect, the system shall display the following Order Checking message to the Provider in CPRS:  Message:  Clozapine orders require a CBC/Diff within past 7 days. Please order CBC/Diff with WBC and ANC immediately. Most recent results – WBC x.x (Date/Time) ANC x.x (Date/Time)  cid:image001.png@01D19AED.55E4F510 |

### STORY 4 – Add Special Conditions Local Override to Outpatient Pharmacy and Inpatient Medications

|  |
| --- |
| As a Pharmacist, I want to have the option to use a Special Conditions Local Override to dispense a 4-day supply of clozapine when a registered clozapine patient has no ANC results in the last 7 days. If the Special Conditions Local Override is used, I want the reason for override code reported in the patient’s clozapine data transmitted at time of dispense. As with existing overrides, the software will not allow an override unless I possess the PSOLOCKCLOZ key and provide the name of a second authorized member of the clozapine team who also possesses the PSOLOCKCLOZ key. |
| *There is no Pending order from CPRS when a Provider wants to dispense for Special Conditions Local Override. The Provider is instructed to provide a Written order to be processed through the VistA Backdoor Pharmacy when Special Conditions exist. The Written order from the Provider must include an approved reason for the override and is limited to a one-time order not to exceed 4 days. An Outpatient Special Condition override can be used for: (1) Weather Related Condition, (2) Mail Order Delay or (3) Inpatient Going On Leave; an Inpatient Special Condition override can be used for an IP Order Override with Outside Lab Results. The Pharmacist will record the outside ANC results in Pharmacy comments. This scenario assumes that the Provider is authorized to prescribe and the patient is actively registered.* |

Table 25: Requirements for No ANC – National Override in Effect

| **RRC#** | **No Matching WBC in Last 7 Days – National Override in Effect** |
| --- | --- |
| 709385 | When a National Override is in effect, the system shall require the OP or IP pharmacist to complete the order prior to its expiration at midnight of the same day it was approved by NCCC, or the approval expires. |
| 710611 | If the pharmacist is not authorized with the PSOLOCKCLOZ key when a National Override is in effect for No ANC results, the system shall display the following message and issue a hard stop, whereby the prescription/order is returned to Pending status, or in the event of a Written order, the system issues a hard stop and the prescription/order is deleted and not processed:  You Are Not Authorized to Override! See Clozapine Manager with PSOLOCKCLOZ key. No prescription entered! |
| 712711 | When the authorized pharmacist proceeds with the Pending or Written clozapine order for No ANC and a National Override is in effect, the system shall display the following message to the pharmacist:  Now doing Clozapine Order checks. Please wait. . .  Permission to dispense clozapine has been authorized by NCCC  Override reason: NCCC AUTHORIZED |
| 712713 | If the pharmacist is authorized with PSOLOCKCLOZ key to override No ANC results, the system shall prompt the authorized pharmacist with the following message:  Do you want to override and issue this order? Y/N |
| 712715 | If the pharmacist selects NO and does not want to continue with the National Override for No ANC results, the system shall issue a hard stop and the order is returned to Pending order status, or in the event of a Written order, the system issues a hard stop and the order is deleted and not processed. |
| 712716 | If the pharmacist selects YES and wants to continue with the National Override for No ANC results, the system shall prompt the pharmacist to enter the name of an Approving Member of the clozapine team from a list of active authorized users with PSOLOCKCLOZ key. The list is displayed by entering ?? or a partial name search. |
| 712718 | With a National Override in effect for No ANC results, the system shall pre-populate the following into the Remarks field:  REASON FOR OVERRIDE: NCCC AUTHORIZED ***plus***  *<the pharmacist may add additional free text up to a total of 200 characters>* |
| 712719 | When the National Override for No ANC results is completed with an Approving Member possessing the PSOLOCKCLOZ key, the system shall prompt the pharmacist to dispense the clozapine prescription/order. |
| 690224 | The system shall send an auto-notification via VistA Alerts to both the prescribing Provider and the active Approving Member of the clozapine team with PSOLOCKCLOZ key that an prescription/order has been activated/verified. |
| 712720 | Following dispense of the National Override order for No ANC results, the system shall store the data in a local XTMP variable file. |

Table 26: Requirements for Outpatient Special Conditions Pharmacy Message – No National Override

| **RRC#** | **Outpatient Special Conditions – Pharmacy Message** |
| --- | --- |
| 689817 | In the event an authorized pharmacist proceeds with a written clozapine prescription for No ANC Results in the last 7 days and a National Override is not in effect (e.g., expired at midnight or labs have changed after prescription was received), the system shall display the following message to the pharmacist and issue a hard stop:  Now doing clozapine Order checks. Please wait...  <*Displays up to the last 4 results within the last 30 days, if available*>  \*\*\* Permission to dispense clozapine has been denied based on the available lab tests related to the clozapine treatment program. \*\*\*  For a National Override to dispense at the patient’s normal frequency, please contact the VA National Clozapine Coordinating Center to request an Override of Pharmacy Lockout (from VHA Handbook 1160.02) (Phone: 214-857-0068 Fax: 214-857-0339).  A Special Conditions Local Override for Outpatients can be approved for (1) weather-related conditions, (2) mail order delays of clozapine, or (3) inpatient going on leave. With Provider’s documentation of approval, you may dispense a one-time supply not to exceed 4 days. |

Table 27: Requirements for Inpatient Special Conditions Pharmacy Message – No National Override

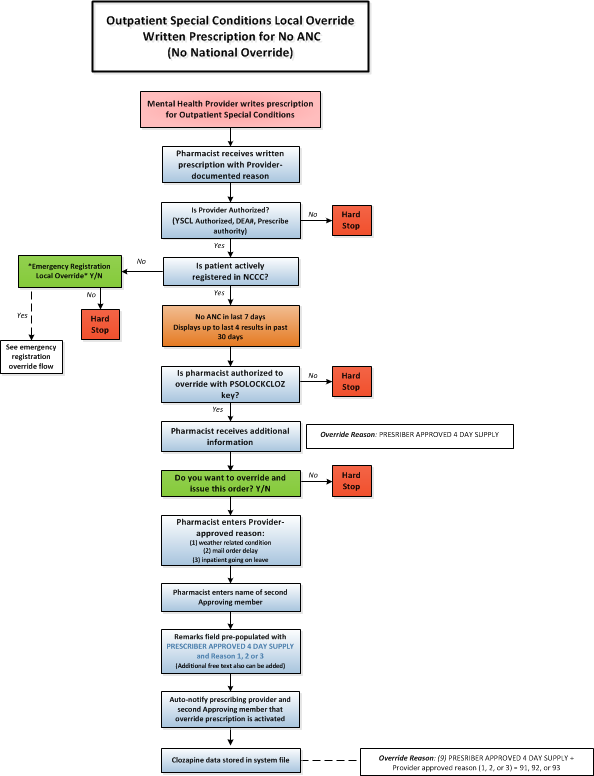
| **RRC#** | **Inpatient Special Conditions – Pharmacy Message** |
| --- | --- |
| 733228 | In the event an authorized pharmacist proceeds with a written clozapine order for No ANC Results in the last 7 days and a National Override is not in effect (e.g., expired at midnight or labs have changed after order was received), the system shall display the following message to the pharmacist and issue a hard stop:  Now doing clozapine Order checks. Please wait...  *<Displays up to the last 4 results within the last 30 days, if available>*  \*\*\* Permission to dispense clozapine has been denied based on the available lab tests related to the clozapine treatment program. \*\*\*  For a National Override to dispense at the patient’s normal frequency, please contact the VA National Clozapine Coordinating Center to request an Override of Pharmacy Lockout (from VHA Handbook 1160.02) (Phone: 214-857-0068 Fax: 214-857-0339).  A Special Conditions Local Override for Inpatients can be approved for an IP Override Order with Outside Lab Results. With Provider’s documentation of approval, you may dispense a one-time IP supply not to exceed 4 days. The ANC from another facility must be recorded in the Progress note/comments in pharmacy. |

Table 28: Requirements for OP and IP Special Conditions Flow

| **RRC#** | **OP and IP Special Conditions Requirements** |
| --- | --- |
| 689819 | If the pharmacist is **not** authorized with the PSOLOCKCLOZ key, the system shall display the following message and issue a hard stop, whereby the order is deleted and not processed:  You Are Not Authorized to Override! See Clozapine Manager with PSOLOCKCLOZ key. No prescription entered**!** |
| 712721 | If the pharmacist is authorized with the PSOLOCKCLOZ key, the system shall prompt the authorized pharmacist with the following message:  Override Reason: PRESCRIBER APPROVED 4 DAY SUPPLY  Do you want to override and issue this order? Y/N |
| 689820 | If the pharmacist selects NO and does not want to issue the Special Conditions Local Override, the system shall issue a hard stop and the order is deleted and not processed. |
| 704045 | For an Outpatient Special Conditions Local Override, if the pharmacist selects YES and wants to issue the override, the system shall prompt the pharmacist:  Select one of the following:  (1) Weather Related Condition  (2) Mail Order Delay  (3) Inpatient Going On Leave  Prescriber’s reason for Special Conditions Local Override: <<< *prompt* |
| 734567 | For an Inpatient Special Conditions Local Override, if the pharmacist selects YES and wants to issue the override, the system shall default and display the following Provider reason to the pharmacist:  IP Order Override with Outside Lab Results |
| 689821 | When the Prescriber’s reason is entered, the system shall prompt the pharmacist with the following message to enter an Approving Member of the clozapine team from a list of active authorized users with the PSOLOCKCLOZ key. The list is displayed by entering ?? or a partial name search:  Approving member of Clozapine team? |
| 689822 | With an Outpatient Special Conditions Local Override when there are no ANC results in the last 7 days, the system shall pre-populate the following into the Remarks field:  REASON FOR OVERRIDE: PRESCRIBER APPROVED 4 DAY SUPPLY ***plus***   1. Prescriber’s reason description: (1) Weather Related Conditions (2) Mail Order Delay, or (3) Inpatient Going On Leave) ***plus***   *<the pharmacist may add additional free text up to a total of 200 characters>* |
| 733227 | With an Inpatient Special Conditions Local Override when there are no ANC results in the last 7 days, the system shall pre-populate the following into the Remarks field:  REASON FOR OVERRIDE: PRESCRIBER APPROVED 4 DAY SUPPLY ***plus***   1. Prescriber’s reason description: IP Order Override with Outside Lab Results ***plus***   *<the pharmacist may add additional free text up to a total of 200 characters to include ANC result and date/time>* |
| 689823 | When the Special Conditions Local Override is complete with an Approving Member that has the PSOLOCKCLOZ key, the system shall prompt the pharmacist to dispense a one-time supply not to exceed 4 days. |
| 689824 | The system shall send an auto-notification via VistA Alerts to both the prescribing Provider and the active Approving Member of the clozapine team with PSOLOCKCLOZ key that the Special Conditions Local Override order has been activated/ verified. |
| 689825 | Following dispense of the Outpatient Special Conditions Local Override prescription for clozapine, the system shall store the data in a local XTMP variable file and in VistA File #52.52 including:  REASON: FOR OVERRIDE: PRESCRIBER APPROVED 4 DAY SUPPLY ***plus***  COMMENTS: <Prescriber’s reason description for 1, 2, or 3> ***plus***  Any additional free text comments up to a total of 200 characters |
| 733226 | Following dispense of the Inpatient Special Conditions Local Override order for clozapine, the system shall store the data in a local XTMP variable file and in VistA File #53.8  including:  REASON FOR OVERRIDE: PRESCRIBER APPROVED 4 DAY SUPPLY ***plus***  COMMENTS: IP Order Override with Outside Lab Results ***plus***  Any additional free text comments up to a total of 200 characters to include outside ANC result and date/time |

As an example, Figure 5 illustrates the data flow for a Written prescription to Outpatient Pharmacy when there are No ANC results and a Special Conditions Local Override is completed. A Special Conditions Local Override is also available for Inpatient.

Figure 5: Outpatient Pharmacy Special Conditions Local Override – Written Order



### STORY 6 – Add Emergency Registration Local Override to Outpatient Pharmacy and Inpatient Medications

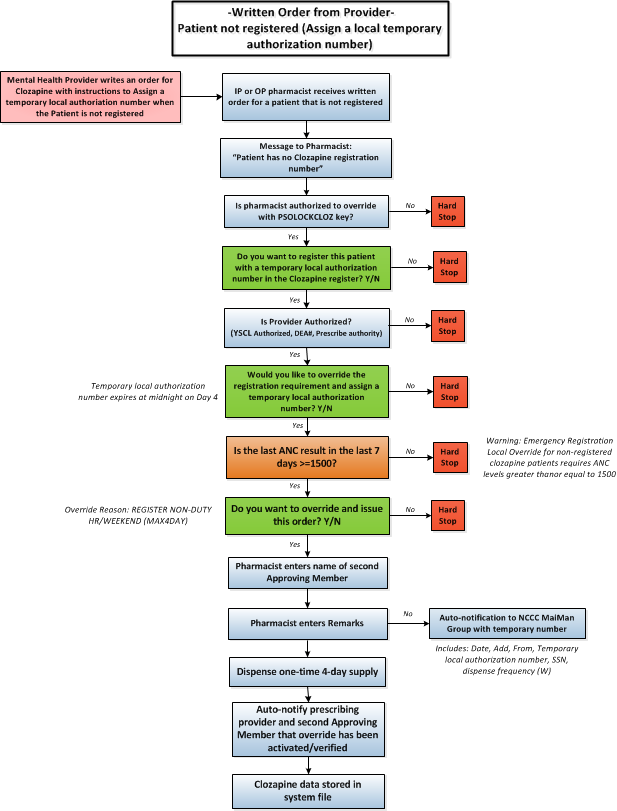
|  |
| --- |
| As a pharmacist, I want to have the option to use an Emergency Registration Local Override to order a 4 day supply when a patient is not a locally registered clozapine patient but does have an ANC ≥1500. (No other overrides are allowed in conjunction with this override.) If the Emergency Registration Local Override is used, I want the reason for override code reported in the patient’s clozapine data transmitted at time of dispense. As with existing overrides, the software will not allow an override unless I possess the PSOCLOZLOCK key and provide the name of a second authorized user who also possesses the PSOCLOZLOCK key. |
| *The Pharmacist receives a Written order when an override is required if the patient is not actively registered and has either a Discontinued status or has never been registered at the local facility. The functionality to electronically communicate this from CPRS is not currently available. The pharmacist flow allows a temporary local authorization number to be assigned to the patient in emergency situations during non-duty hours at NCCC, holidays or weekends.* |

Table 29: Requirements for Emergency Registration Local Override – VistA Pharmacy

| **RRC#** | **Emergency Registration Local Override – Written Order to Pharmacy** |
| --- | --- |
| 701411 | After a new order for clozapine and dosage is entered in the VistA pharmacy from a Written order and if the patient is not actively registered at NCCC (the patient has never been registered at this facility or is registered but is now on discontinued status), the system shall display the following message:  \*\*\* This patient has no clozapine registration number \*\*\* |
| 701413 | If the pharmacist is authorized with the PSOLOCKCLOZ key, the system shall display the following message:  Do you want to register this patient with a temporary local authorization number in the Clozapine register? Y/N |
| 701416 | If the pharmacist is not authorized with the PSOLOCKCLOZ key, the system shall display the following message and the order is deleted and not processed:  You Are Not Authorized to Override! See Clozapine Manager with PSOLOCKCLOZ key. No prescription entered! |
| 701417 | If the pharmacist selects NO and does not want to register this patient, the system shall issue a hard stop and the order is deleted and not processed. |
| 701419 | If the pharmacist selects YES and wants to register this patient with a temporary local authorization number, the system shall prompt the pharmacist to enter the name of the  Provider responsible |
| 701420 | If the Provider is not authorized to prescribe clozapine, the system shall display the following message:  Provider must have a DEA# or VA# to write prescription for clozapine  OR  Provider must hold YSCL AUTHORIZED key to write prescriptions for clozapine.  The message will continue to display until an authorized Provider is selected or the pharmacist uses the ‘^’ to stop the order. |
| 701421 | If the Provider is authorized to prescribe clozapine, the system shall display the following message to the pharmacist (which includes a temporary local authorization number, e.g., “Z442001” and is sequentially assigned from File #603.01):  Would you like to override the registration requirement and assign a temporary local authorization number for <LASTNAME,FIRSTNAME> <last 4 digits of SSN> <Z442001>? Y/N |
| 701422 | If the pharmacist selects NO and does not want to issue the new temporary local authorization number, the system shall issue a hard stop and the order is deleted and not processed. |
| 701424 | When the pharmacist selects YES to issue the new temporary local authorization number to the patient and the ANC result within the last 7 days is greater than or equal to 1500 and has a matching WBC, the system shall display the following information to the pharmacist:  Now doing Clozapine Order checks. Please wait...  \*\*\* Most recent NEUTROPHILS ABSOLUTE (ANC) results \*\*\*       performed on are: MonthXX,XXXX       WBC: XXXX       ANC: XXXX |
| 701425 | When the pharmacist has selected YES to issue the new temporary local authorization number to the patient, but the ANC result in the last 7 days is less than 1500 or there is no ANC result in the last 7 days or the ANC does not have a matching WBC, the system shall display the following message and issue a hard stop, whereby the order is deleted and not processed:  Emergency Registration Local Override for non-registered clozapine patients requires ANC levels great than or equal to 1500. |
| 701426 | When the temporary local authorization number is assigned, the system shall prompt the pharmacist with the following message:  Override Reason: REGISTER NON-DUTY HR/WEEKEND (MAX 4DAY)  Do you want to override and issue this order? Y/N |
| 701427 | If the pharmacist selects NO and does not want to override and issue the order, the system shall issue a hard stop and the order is deleted and not processed. |
| 701428 | If the pharmacist selects YES to override, the system shall prompt the pharmacist with the following message to enter an Approving Member of the clozapine team from a list of active authorized users with the PSOLOCKCLOZ key. The list is displayed by entering ?? or a partial name search:  Approving member of clozapine team? |
| 701429 | When the second Approving Member name is entered, the system shall pre-populate the following into the Remarks field:  REASON FOR OVERRIDE: REGISTER NON-DUTY HR/WEEKEND (MAX 4DAY) ***plus***  *<the pharmacist may add additional free text up to a total of 200 characters>* |
| 701430 | Once the override order is complete, the system shall dispense a 4-day supply of clozapine that ends midnight of the 4th day and sends a real-time MailMan message to the NCCC MailMan Group to include the following patient information:   * Date: current date and time * Add: * From: * Temporary local Authorization number (Z442001) * Station# * Social Security Number of the patient * Dispense frequency (W) |
| 701431 | The system shall send an auto-notification via VistA Alerts to both the prescribing Provider and the active Approving Member of the clozapine team with PSOLOCKCLOZ key that the Emergency Registration Local Override order has been activated/ verified. |
| 701432 | Following dispense of clozapine for an Emergency Registration Local Override, the system shall store the data in a local XTMP variable file. |
| 701434 | At the end of the 4-day dispense window, the system shall mark the temporary authorization number to expire at midnight of the 4th day so that it cannot be reused. |
| 701436 | In the event that the pharmacist chooses to create a temporary local authorization number, but later does not finish the process (either because of choosing not to or a lack of lab results greater than or equal to 1500 in the last 7 days), the system shall support the pharmacist to restart a clozapine order for the same patient (with the already-created temporary local authorization number), and will retain the number with the patient name until it expires at midnight of the 4th day. |
| 709373 | In the event the system uses all the temporary numbers (Z001-999), the system shall then revert to using the next letter down in the alphabet (upper case Y) and assign 001-999 sequentially. This will continue until all letters in the alphabet are used (X, W, U, T, etc.). |

Figure 6 illustrates the data flow for a Written order processed in the IP or OP Pharmacy when an Emergency Registration Override is completed.

Figure 6: Pharmacy Emergency Registration Override – Written Order



### STORY 7 – Update CPRS Warning/Error Message for Unregistered Patient

|  |
| --- |
| As a clozapine Provider, I want to ensure that when a clozapine patient is not actively registered, CPRS prevents the ordering of clozapine. I want the error message to tell me my options including the new option to write a Written order to have the pharmacist dispense clozapine using an Emergency Registration override during non-duty NCCC hours, holidays and weekends only for a one-time emergency dispense of 4 days if the patient had normal ANC results. |
| *The only new requirement for CPRS is that the message box that displays to the Provider when a patient is not actively registered, is updated to alert the Provider that if this a non-emergent situation, they can contact NCCC or if this is an emergency during non-duty NCCC hours, a written order to the Pharmacy will allow a temporary local authorization number to be assigned. A normal ANC result (≥1500) is required.* |

Table 30: Requirement for Emergency Registration Local Override – CPRS

| **RRC#** | **Emergency Registration Override – Update Message** |
| --- | --- |
| 701441 | In CPRS, when a patient is not registered, the system shall display the following message to the Provider and issue a hard stop:  Message:  \*\*\* This patient is not registered in the clozapine treatment program or has been discontinued from the program. A new registration number must be assigned. If this is not an emergency, contact the NCCC. For emergency registration during non-NCCC duty hours, a written order to the pharmacist can be used to process a registration override. \*\*\*  cid:image001.png@01D194C7.33EDCBC0 |

### STORY 8 – Auto-Notify NCCC when Patient Status is Changed to Discontinued

|  |
| --- |
| As an NCCC analyst, I want to ensure that the system stores and sends a patient status update to the NCCC when a clozapine patient’s status is changed from “active” to “discontinued” in the local VistA system, so that I can maintain an accurate record of all clozapine patients’ statuses. |
| *The NCCC will receive notification via VistA MailMan in the nightly batch roll-up when a patient status has changed to ‘Discontinued’.* |

Table 31: Requirement for Auto-notify when Patient Status Changes to Discontinued

| **RRC#** | **Auto Notify when Patient Status Changes** |
| --- | --- |

|  |  |
| --- | --- |
| 691811 | The patient status shall automatically change from ‘Active’ to ‘Discontinued’ based on any of the following triggers:   * A new clozapine patient has not filled their order within 28 days of being marked ‘Active’ * A current clozapine patient has not filled their order within 56 days * A temporary local authorization number assigned to a clozapine patient has expired after 4 days and the NCCC has not issued a permanent authorization number |
| 720268 | The system shall report the patients automatically changed to ‘Discontinued’ status within the last 24 hours, in the nightly roll-up of clozapine data to include the following:   * Site number * Patient name * Last 4 digits of patient SSN * Trigger (28 days, 56 days or temporary authorization expiration) |

### STORY 9 – Reporting Clozapine Patient Data to NCCC (Replace Weekly Rollup)

|  |
| --- |
| As an NCCC analyst, I want to ensure that both the Outpatient Pharmacy and Inpatient Medications applications transmit patient data to the national clozapine data files (to include the Reason for Override code) when the pharmacist dispenses or finishes a clozapine order so that I can be sure that the necessary information is available for the NCCC to process and send to the FDA. |
| *When a pharmacy order is complete/verified,the system will store the order’s clozapine data in a local XTMP variable file. The system will send the XTMP data to the National Clozapine data files nightly. Nightly batch roll-ups should be run during non-peak hours to limit impact to users – recommended time is 2 am, which is configurable by the local coordinator and includes the previous 24 hours of patient data. The XTMP data file contains the patient information and is retained for one year in the event that the data needs to be recreated and/or re-sent. If the nightly batch fails or if the system is down, when it is back up, Taskman will re-send the data.*  *The Reason for Lockout field is populated with a number that corresponds with the system-generated reason code:*  *7 -* NCCC AUTHORIZED  8 - REGISTER NON-DUTY HR/WEEKEND (MAX4DAY)  *9 -* PRESCRIBER APPROVED 4 DAY SUPPLY  10 - MILD NEUTROPENIA PRESCRIBER APPROVED  *In the case of Special Conditions, an additional Prescriber-approved code is used to append to #9 above:*  ***Outpatient-specific***  *1 – Weather related condition*  *2 – Mail order delay of clozapine*  *3 – Inpatient going on leave*  ***Inpatient-specific***  *4 – IP Order Override with Oustide Lab Results*  *For instance: Reason code 9 + Prescriber code 1 = 91, etc.* |

Table 32: Requirements for nightly batch roll-up data transfer

| **RRC#** | **Nightly batch roll-up reporting to NCCC** |
| --- | --- |
| 690240 | When the pharmacist completes the clozapine order in either OP or IP pharmacy, the system shall store the data in a local XTMP variable file and provide a nightly batch roll-up data transfer of patient data to the National Clozapine data files, including reason for override (Reason for Lockout field – which is populated with numeric values corresponding to the Override reason (7, 8, 9, 10) and in the case of Special Conditions, also includes the Prescriber’s reason 1, 2, 3, or 4 appended to 9 to equal 91, 92, 93, or 94).  -- ABS Gran #  -- ABS Gran Date  -- Blood Sample Drawn  -- City  -- Clozaril Dosage (Total daily dose)  -- Clozaril Status (Patient clozapine status being reported for Active patients)  -- Date Prescribed (Date/time order was placed)  -- Date Received  -- Gran Test Name (Neutrophil)  -- Hospital Zip  -- NDC  -- Patient Initials  -- Patient SSN  -- Pharmacy DEA Number  -- Physician  -- Physician DEA Number  -- Reason for Lockout  -- Registration Number  -- RX Number  -- Site  -- Site Name  -- Site Number  -- State  -- Street Line 1  -- Street Line 2  -- Total WBC Count  -- WBC Test Name  -- Zip Code |
| 720411 | Following dispense of clozapine, the system shall store the data in a local XTEMP variable file to be sent as a nightly roll-up via MailMan to the National Clozapine data files. |
| 720430 | The VistA Mental Health package shall transmit the last 24 hours of clozapine pharmacy data nightly via MailMan message to the National Clozapine data files to include the contents of the local XTMP variable file. (Default transmit time is 2 am, but this variable is configurable by local coordinator). |

### STORY 10 – Auto-Notification when Override is Dispensed or Finished

|  |
| --- |
| As a clozapine client, I want to ensure that both the prescribing Provider and overriding Approving Member of the clozapine team receive notification when a clozapine order with an override is dispensed or finished, so that I know that they have been notified when the order with an override is complete. |
| *Any time an override is required, the Pharmacist selects an Approving Member of the clozapine team so that two signers are included in the order. An auto-notification via VistA Alerts is sent to both Provider who wrote the order and the second Approving member of the clozapine team.VistA Alerts are accessible in both the CPRS GUI and Backdoor Pharmacy..* |

Table 33: Requirement for Auto-notification via VistA Alerts

| **RRC#** | **Auto-notification to Provider and Approving Member** |
| --- | --- |
| 689696 | The system shall send an auto-notification via VistA Alerts to both the prescribing Provider and the active Approving Member of the clozapine team with PSOLOCKCLOZ key that an order has been activated/ verified. |

Table 34: Requirements for VistA Alert Messages

| **RRC#** | **VistA Alert Message** |
| --- | --- |
| 720270 | The system shall generate a non-actionable VistA Alert to the Provider and Approving Member of the clozapine team when an override is used to process a clozapine prescription/order and is made available in both the GUI and VistA Backdoor Pharmacy to include the following:   * Patient name with the concatenated last 4 digits of the patient SSN * Alert Date/Time * Message: CLOZAPINE OVERRIDE RX PROCESSED with Alert Date/Time added to the end of the message |

### STORY 11 – Update the Clozapine Pharmacy Manager Reporting Menu Option

|  |
| --- |
| As a Pharmacy Manager, I want to be able to use Inpatient Pharmacy menus to access the same Clozapine Pharmacy Manager tools currently available in the Outpatient Pharmacy so that I have can effectively follow the treatment of Inpatients who are on clozapine. |
| *The Clozapine Inpatient Medications Manager menu includes options that are similar to what is currently in OP, but enhanced to run in the IP environment. There are 4 menu items.* |

Table 35: Requirements for New Inpatient Clozapine Pharmacy Manager Tools

| **RRC#** | **Pharmacy Manager Tools** |
| --- | --- |
| 709378 | A new menu for the IP Pharmacy Manager shall give the same capabilities to the IP pharmacy as the existing “Clozapine Pharmacy Manager” menu does for clozapine outpatients. The new menu “Clozapine Inpatient Medications Manager” contains two existing options from the outpatient menu and two new inpatient options:   * Register Clozapine Patient * Display Inpatient Lab Tests and Results * List Inpatient Clozapine Overrides * Edit Data for a Patient in the Clozapine Program |
| 709379 | When the “Register Clozapine Patient” option is selected from the menu, the system shall allow the Inpatient Pharmacy Manager to register both Clozapine inpatients and outpatients in the local system’s Pharmacy files (Files #603.01 and #55) . |
| 709380 | When the “Display Inpatient Lab Tests and Results” option is selected from the menu, the system shall prompt the user to enter filtering information to retrieve results:   * Beginning fill date: * Ending last fill date: * Earliest date for lab results: * Keyword for drug name: (e.g. Clozapine) * Laboratory Test Name: (e.g., NEUTROPHILS ABSOLUTE) * Specimen Used (e.g., serum, plasma, blood) |
| 709381 | When the “Display Inpatient Lab Tests and Results” returns results, the system shall include the following information for the each clozapine inpatient medication order:  Name of Provider, ID#, Fill Date, Lab Date, Results |
| 709382 | When the “List Inpatient Clozapine Overrides” option is selected from the menu, the system shall prompt the IP Pharmacy Manager to enter filtering information to retrieve specific results based on selected date range (beginning fill date and ending last fill date) |
| 709383 | When the “List Inpatient Clozapine Overrides” displays, the system shall include the following information for the IP Pharmacy Manager:  Date, Order Number (IP), Patient, Drug/Dose, Entered by (Doctor who ordered clozapine), Approved by (Pharmacist who processed order), Lockout Reason (System generated reason code, e.g., MILD NEUTROPENIA PRESCRIBER APPROVED), and Comments. |
| 709384 | When the “Edit Data for a Patient in the Clozapine Program” option is selected from the menu, the system shall prompt the IP Pharmacy Manager to select an active or inactive clozapine patient name. This option gives the IP pharmacist the ability to edit data for a previously enrolled patient in the clozapine treatment program. \*This is typically used to reregister a patient whose treatment has been suspended and who has rejoined the program. |

### Future Development

The following Stories and requirements are planned for future development.

**STORY 5** – **Add Special Conditions Local Override to CPRS - FUTURE**

|  |
| --- |
| As a Provider, I want to have the option in CPRS to use a Special Conditions Local Override to dispense a 4-day supply of clozapine when a registered clozapine patient has no ANC results in the last 7 days. |

**STORY TBD** – **Add Emergency Registration Local Override to CPRS - Future**

|  |
| --- |
| As a Provider, I want to have the option in CPRS to use an Emergency Registration Local Override to prescribe a 4 day supply when a patient is not a locally registered clozapine patient but does have an ANC ≥1500. (No other overrides are allowed in conjunction with this override.) |

**STORY TBD** – **Update Inpatient and Outpatient Doses - Future**

|  |  |
| --- | --- |
| As a Provider, I want to be able to modify the current inpatient or outpatient clozapine dose for a clozapine patient as long as the most recent lab results are still within the required dispense frequency blood testing interval. | |
| **RRC#** | **Override Blood Testing when Patient admitted to IP** |
| 691026 | In the event an Outpatient is admitted to Inpatient, the system shall not require new ANC blood tests to be drawn based on the following two conditions:   * There are No Changes, No Increase or No Decrease in the Dose per Day * The length of the new IP order does not exceed the patient’s current dispense frequency |
| 691027 | The system shall distinguish between existing Outpatient dose and the new Inpatient order and notify the pharmacist if safe ANC blood test results can be found within the past 7 days. |
| **RRC#** | **Override Blood Testing when Patient admitted to IP** |
| 691028 | The system shall recognize when there is **No Change** in Dose per Day for an Outpatient with an existing clozapine order who is admitted to Inpatient with a new IP prescription, and not require a new ANC result when the either of the following conditions exist:   * Existing safe ANC result within the last 7 days of patient’s admittance \*\*OR\*\* * There is a valid blood test result from the last scheduled clozapine blood test and the prescription does not exceed the dispense frequency |
| 691029 | The system shall recognize when there is a **Decrease** in Dose per Day for an Outpatient with an existing clozapine order who is admitted to Inpatient with a new IP prescription, and not require a new ANC result when the either of the following conditions exist:   * Existing safe ANC result within the last 7 days of patient’s admittance \*\*OR\*\* * There is a valid blood test result from the last scheduled clozapine blood test and the prescription does not exceed the dispense frequency |

### Enterprise Specifications

Adherence to enterprise-level requirements is a requirement of enhancements to the enhancements to support the National Clozapine Coordination Center software. All system functionality implemented in NCC enhancements project must be engineered to adhere to enterprise-level requirements, as specifically addressed in the **Enhancements to Support the National Clozapine Coordination Center New Service Request (NSR) 20100703** **Requirements Elaboration Document** (RED). This section traces to ENTR11, ENTR8, ENTR7, ENTR10, ENTR19, ENTR78, ENTR63, & ENTR31.

The Enterprise requirements support Veterans Health Administration (VHA) Blueprint for Excellence by supporting:

* Theme 1: Improve Performance
  + Strategy One: Operate a health care network that anticipates and meets the unique needs of enrolled Veterans, in general, and the service disabled and most vulnerable Veterans, in particular.
* Theme 3: Advance Healthcare innovation for Veterans and the Country
  + Strategy Six: Advance health care that is personalized, proactive, and patient-driven, and engages and inspires Veterans to their highest possible level of health and well-being.
* Theme 4: Increase Operational Effectiveness and Accountability
  + Strategy Ten: Modernize management processes in human resources, procurement, payment, capital infrastructure, and information technology to operate with benchmark agility and efficiency.

This request is in direct alignment with the VHA mission statement which is to “Honor America’s Veterans by providing exceptional health care that improves their health and well-being.”

### Identity Management Specifications

A significant part of VA’s mission is to assure that information and systems are protected from unauthorized access. It is essential that it be designed into the infrastructure. Sensitive information must be protected on a need to know basis.

For reference, the Federal Identity, Credential, and Access Management (FICAM) Roadmap details additional rationale for adopting an identity and access services framework to support business and/or objectives. Identity and Access Management (IAM) services provide a framework for identity, credential, and access services. IAM services also provide compliance, increased security, improved interoperability, enhanced customer self-service, and increased protection of personally identifiable information (PII).

The NCC project is enhancing legacy VistA applications and will rely on existing VistA access controls. The clozapine processing code uses the YSCL-Authorized security key to restrict which Providers are authorized to prescribe clozapine and the PSOLOCKCLOZ key to restrict which pharmacist and clozapine treatment team members are authorized to process clozapine overrides.

### Privacy

All VA privacy and security requirements will be adhered to. Based on Federal Information Processing Standard 199 and National Institute of Standards and Technology (NIST) SP 800-60, the recommended Security Categorization is Medium.

The Security Categorization will drive the initial set of minimal security controls required for NCC project. Minimum security control requirements are addressed in NIST SP 800-53 and VA Handbook 6500.

The NCC project will incorporate NIST Standards into the NCC enhancements as appropriate.

### HIPAA Compliance

Collection and storage of both PII and PHI are vital to the VA's mission; to maintain public trust, the VA must show that it can protect this information. Protection of PII and PHI includes not just implementing the security controls to limit access to the data, but also to be able to track who has had access to specific data. This means being able to reconstruct who had access to data requires that requests for access to data be logged. VA can only show that access to PII and PHI is appropriate if such access can be audited after the fact, which again can only be done if the accesses are logged.

Relevant Health Insurance Portability and Accountability Act (HIPAA) security and privacy requirements shall be followed. An extract of HIPAA requirements is available from the VA SRSC. An extract of HIPAA security requirements to be implemented in health care-related projects is available from VHA Health Care Security Requirements.

Clozapine software enhancements will comply with all relevant HIPAA security and privacy requirements. CPRS and VistA software will log all access to PII and PHI; log will be subject to audits. Appropriate controls will be implemented and enforced. User PHA and PII will be secure.

### HL7 Messaging

This section is not applicable.

### Patient Safety

All relevant patient safety requirements will be adhered to. VHA recognizes that these are Enterprise requirements for all developed Electronic & Information Technology. These requirements are applicable to any application that adds, edits, or performs lookups on persons (patients, practitioners, employees, IT Users) to systems within the VHA. To ensure that these requirements are met, they are addressed through the Enterprise-level requirements maintained by VHA Health Information Technology, Software Engineering and Integration, and Enterprise Requirements Management.

## Graphical User Interface (GUI) Specifications

There are no GUI non-functional specifications identified for this project.

## Multi-divisional Specifications

There are no multi-divisional non-functional specifications identified for this project.

## Performance Specifications

The clozapine software solution will execute performance, capacity, and independent testing of its product, and as part of Software Quality Assurance (SQA) analysis and testing. Recurring discussions with the Systems Engineering and Design Review (SEDR) workgroup are in progress to articulate requirements for performance and capacity transactions.

Relevant nonfunctional requirements from the Requirements Elaboration Document (RED) are traced to and expanded upon in Appendix A.

## Quality Attributes Specifications

The clozapine software system solution will rely upon infrastructure components, data models, and services that support an open, modular, extensible Electronic Health Record (eHER) platform, allowing VA to provide high-quality solutions at increased speed and decreased cost. In addition, the clozapine software solution will be flexible and agile, accommodating new technology advances and achieving optimal results more efficiently.

The clozapine software solution complies with the quality specifications set forth by the VA Project Management Accountability System (PMAS) Quality specifications. The following types of testing will be performed to assess the quality of the solution:

* Unit testing
* Integration / functional testing
* User Acceptance Testing (UAT)
* Section 508 testing
* Performance testing

The following quality specifications are also applicable to this solution:

* The system is composed of tools, applications, and software that conform to VA’s standard server and database operating systems. The VA Technical Reference Model (TRM) provides more information.
* The system is designed to operate in VA’s standard virtualized operating system environment according to the VA TRM.

Relevant non-functional requirements from the BRD are traced to and expanded upon in Appendix B.

## Reliability Specifications

The following summarize requirements for clozapine software reliability specifications.

* Availability – the clozapine software shall be available 24/7.
* Accuracy – The clozapine software shall return entries exactly as they were passed with no modification. The lab test results reported with the patient’s prescription/order will the same lab test results that the Pharmacist used to process the prescription.
* Defect repair – It is expected that all defects related to the implementation get resolved during initial development and subsequent testing.
* When the system goes live in production the NCC project development team will address defects of a critical nature that are deemed “show stoppers.” Enhancement requests made after go-live will be logged for consideration in a future, coordinated clozapine software release.

Refer to Appendix B.

## Scope Integration

The NCC Project involves integration of multiple applications and interfaces which includes changes to existing VistA functionality related to Mental Health, Inpatient Medications, and Outpatient Pharmacy applications. Some of the changes are enhancements to existing system processes, while others are additions based on the current business processes. Refer to System Design Document (SDD) associated with this project for detailed integration descriptions. The major application integration and purpose is outlined in the following table:

Table 36: Integration Scope of Multiple Applications

| **Application** | **Description** |
| --- | --- |
| CPRS | CPRS is a VistA computer application that enables doctors and medical professionals to initiate a clozapine order utilizing the Order or Meds Tab. Prior to initiating the order, CPRS utilizes the Mental Health software to perform checks to see if the patient is registered and has a clozapine authorization number. Once an order is initiated, it is sent to a Pharmacy application depending on a patient’s status either as an Inpatient Medications or an Outpatient Pharmacy for processing. |
| Inpatient Medications | The Inpatient Medications package provides a method of management, dispensing, and administration of inpatient drugs within the hospital. When orders are processed using Inpatient Medications, the Mental Health software is used to perform checks to see if the patient is registered and has a clozapine authorization number. Inpatient Medications is also used to register patients within the clozapine program. Once an order passes safety checks, the order is activated by the Pharmacist. The clozapine data is transmitted to the national clozapine data files. |
| MailMan | The VistA MailMan software is designed to allow users, or VistA software applications, to send and receive mail from individuals or groups, electronically, through communication lines, modems, and other networks. |
| Mental Health | The Mental Health module provides computer support for both clinical and administrative patient care activities associated with mental health care. The Mental Health software contains the YSCL server that provides the capability for the NCCC to interact (both read and write) with a local VistA system’s clozapine-related files through MailMan messages. This software also contains clozapine-related software, such as the CLAPI and other clozapine APIs.  CLAPI is called by CPRS and the Pharmacy applications, when a patient’s ANC lab results must be checked. CLAPI interfaces with the Laboratory system to obtain a patient’s WBC and ANC lab results, calculates if clozapine can safely be dispensed, and returns the results to CPRS, and the Pharmacy applications. |
| Outpatient Pharmacy | Outpatient Pharmacy provides a method for managing the medications given to Veterans who have visited a clinic or who have received prescriptions upon discharge from the hospital. When orders are processed, Outpatient Pharmacy utilizes the Mental Health software to perform checks to see if the patient is registered and has a clozapine authorization number. Outpatient Pharmacy is also used to register patients within the clozapine program, dispense orders, and transmit clozapine data to the national clozapine data files. |

## System Features

Features and functionality of the various systems involved in building new functionality and integrating enhancements are outlined in Sections 1.2 Scope and 2.6 Functionality Specifications. For more detailed system design, see the NCC Project’s supporting System Design Documents for Outpatient Pharmacy, Inpatient Medications, and Mental Health (MH).

## Usability Specifications

There are no specific usability specifications identified for this project.

# Purchased Components

No components will be purchased to support this project.

# Estimation

Estimates are derived by the Functional Analysts, Developers, Testers, and Database Analysts involved in the implementation of this project. The design, development, implementation, and release management of the proposed project will be managed using the Agile Scrum methodology.

Table 37: Project Software Functional Size and Size-Based Effort and Duration Estimate

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Item | A | B | C | | D | E | | Totals |
| Counted Function Points |  |  |  | |  |  | |  |
| Estimated Scope Growth |  |  |  | |  |  | |  |
| Estimated Size at Release |  |  |  | |  |  | |  |
| Size-Based Effort Estimates | | | | Labor Hours | | | Probability | |
| Low-Effort Estimate – With indicated probability, project will consume no more than: | | | |  | | |  | |
| High-Effort Estimate – With indicated probability, project will consume no more than: | | | |  | | |  | |
| Size-Based Duration Estimates | | | | Labor Hours | | | Probability | |
| Low-Duration Estimate – With indicated probability, project will consume no more than: | | | |  | | |  | |
| High-Duration Estimate -- With indicated probability, project will consume no more than: | | | |  | | |  | |

# Approval Signatures

REVIEW DATE: <date>

SCRIBE: <name>

Signed:

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**Integrated Project Team (IPT) Co-Chair / Project Manager** Date

Kristen A. Templet

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**Integrated Project Team Co-Chair / Business Sponsor** Date

National Mental Health Director for Informatics, Mental Health Services

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OI&T Mental Health Program Manager

2. Epic 1 Mission Critical Systems

| **Epic 1 : The VistA Mental Health, Inpatient Medications, and Outpatient Pharmacy systems relied upon for clozapine dispensing are mission-critical systems; a contingency plan and data back-up and restore procedures must be documented to ensure data integrity and 24x7 backup in the event of a disaster or system crash.** | | | | |
| --- | --- | --- | --- | --- |
| NEED/ OWNR# | BRD Trace | User Stories (Narratives) | User Tasks | Business Acceptance Criteria (Requirements) |
| NONF1766 | A notification of an event that poses a risk of extending a scheduled maintenance period that requires the service to be offline or which may degrade system performance shall be disseminated to the user community. | 1.1: As a user, I want a notification of any scheduled system maintenance prior. | 1.1.1: Develop and store a baseline approved version of the contingency plan in the document repository. | All support documentation for the clozapine software shall be stored in a document repository containing the most current officially approved document versions. |
| NONF1767 | Unscheduled outages and events that degrade system functionality and/or performance shall require notification to the user community within 30 minutes of the occurrence. The notification shall include the information described in the current Automated Notification Reporting (ANR) template maintained by the VA Service Desk. The business impact must be noted. | 1.2: As an information technology (IT) staff or user, I want a back-up and data recovery process so that I can ensure data recovery and back-up procedures are properly executed during maintenance or when the system experience unexpected technical issues or “down-time.” | 1:2:1: Develop a reporting functionality that will send notification to all users of unscheduled system outages and other events that degrade system functionality and/or performance.  1.2.2: Create workflow that will send notification to users within 30 minutes of the occurrence.  1.2.3: Report should include the following:  Automated Notification Reporting (ANR) template  Specific Business impact. | The users are notified of unscheduled system outages and other events that degrade the system functionality and or performance within 30 minutes of the occurrence. The report will include information described in the current Automated Notification Reporting (ANR) template maintained by the VA Service Desk. The specific business impact must be noted in order for OI&T to provide accurate data in the service impact notice of the ANR. |
| NONF1768 | The system shall provide a back-up plan for when the system is brought off line for maintenance or technical issues/problems. | 1.3: As an IT staff or user, I want to ensure measures are taken to protect the data/information so that I can request timely data restores in the future. | 1.3.1: Implement the back-up and data recovery procedures when warranted by technical or maintenance issues. | The data protection measures are scheduled and implemented for a mission critical system. |