



FDA REGULATORY CHANGES FOR CLOZAPINE OUTPATIENT PHARMACY

RELEASE NOTES

PSO*7*222

Version 7.0
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1. Introduction

This document provides a brief description of enhancements required to meet revisions in the Food and Drug Administration (FDA) requirements for blood monitoring in patients being treated with Clozapine.



Note: The information referenced in this document pertaining to Clozapine dispensing functionality is available through Backdoor Pharmacy with the installation of the PSO*7*222 patch. Corresponding changes in the Computerized Patient Record System (CPRS) will be available as part of Patch OR*3*243.



Note: The PSO*7*222 patch is associated with the Mental Health patch YS*5.01*90. Patch YS*5.01*90 is a required patch for PSO*7*222.

Successful implementation of the Mental Health patch YS*5.01*90 is very important for Pharmacy and CPRS. The Mental Health Clinician, with the help of the LAB ADPAC, have to ensure that the LAB tests, White Blood Count (WBC) and Absolute Neutrophil Count (ANC), are set up correctly in the Mental Health package using the CLOZAPINE MULTI TEST LINK option. Also, with the release of YS*5.01*90, providers must also hold the YSCL AUTHORIZED security key.

2. New Features, Functions, and Enhancements

This enhancement allows for a Monthly (28-Day) supply of Clozapine for patients that meet specific criteria.

The following table displays the number of refills allowed for each range of prescription fills.

Clozapine Refills Allowed

Patient Status	Maximum Prescription Fills	Refills Allowed
Monthly	7-Day	3
	14-Day	1
	28-Day	0
Bi-Weekly	7-Day	1
	14-Day	0
Weekly	7-Day	0

This Outpatient Pharmacy patch contains the following enhancements for Clozapine dispensing:

- Adjust the business rules to disallow prescription processing without override if $3500/\text{mm}^3 > \text{WBC} > 3000/\text{mm}^3$ and $2000/\text{mm}^3 > \text{ANC} > 1500/\text{mm}^3$. Prior to this patch, override restrictions were very lenient. Once this patch is installed, dispensing is no longer allowed if the $\text{WBC} < 3000/\text{mm}^3$ or $\text{ANC} < 1500/\text{mm}^3$. However, if the WBC is between $3000/\text{mm}^3$ and $3500/\text{mm}^3$ or if ANC is between $1500/\text{mm}^3$ and $2000/\text{mm}^3$, dispensing will be allowed with an overriding reason. These levels require twice weekly blood testing until the WBC stabilizes above $3500/\text{mm}^3$ and ANC above $2000/\text{mm}^3$ with no signs of infection.
- Recognize the new 28-day prescription fill status and apply the appropriate restrictions for LAB draw checks.
- Add a new field to store ANC value and require both a WBC and ANC be drawn and reported before drug dispensing is allowed.
- Prevent local users from editing the Patient Status within the Clozapine module.

3. Updated Fields

A new ANC RESULTS field (#304) is created in the PRESCRIPTION file (#52) to store the ANC value.

The REASON FOR LOCKOUT field (#4) in the CLOZAPINE PRESCRIPTION OVERRIDES file (#52.52) is changed to REASON FOR OVERRIDE field (#4). The set of codes have been modified and three new codes (5, 6, 7) were added to accommodate the override conditions for the new ANC LAB test:

- '1' FOR NO WBC IN LAST 7 DAYS
- '2' FOR NO VERIFIED WBC
- '3' FOR LAST WBC RESULT < 3500
- '4' FOR 3 SEQ. WBC DECREASE
- '5' FOR LAST ANC RESULT < 2000
- '6' FOR 3 SEQ. ANC DECREASE
- '7' FOR NCCC AUTHORIZED.

4. New Messages for Clozapine Drug Selection

When the Clozapine drug has been selected, the following messages have been introduced for dispensing Clozapine according to the scenarios shown in the examples below.



Note: All messages are processed through communication with Mental Health patch YS*5.01*90.



Note: The “NEUTROPHIL MATURITY, MEAN (ANC) results” verbiage shown in these examples is for illustration only. This can vary, depending on the site definition for ANC calculation.

Example 1: Patient not registered (not eligible) in the Clozapine program

```
Now doing drug interaction and allergy checks. Please wait...

Permission to dispense clozapine has been denied. Please contact the
Director of the VA National Clozapine Coordinating Center
(REDACTED)
```

Example 2: Patient discontinued from the Clozapine program

```
Now doing drug interaction and allergy checks. Please wait...

*** This patient has been discontinued from the clozapine treatment program ***
*** and must have a new registration number assigned ***

Permission to dispense clozapine has been denied. Please contact the
Director of the VA National Clozapine Coordinating Center
REDACTED
```

Example 3: Clozapine Patient with no LAB work in the past 7 days or if labs are available which have not been entered in VistA, the site will receive the following warning

```
Now doing drug interaction and allergy checks. Please wait...

Permission to dispense clozapine has been denied. If the results of the latest
Lab Test drawn in the past 7 days show WBC>3000/mm3 and ANC>1500/mm3 and
you wish to dispense outside the FDA and VA protocol WBC/ANC limits, document
your request to Director of the VA National Clozapine Coordinating Center
REDACTED for a one-time override permission.

A CBC/Differential including WBC and ANC Must Be Ordered and Monitored on a
Twice weekly basis until the WBC STABILIZES above 3500/mm3 and ANC above
2000/mm3 with no signs of infection.

Also make sure that the LAB tests, WBC and ANC are set up correctly in the
Mental Health package using the CLOZAPINE MULTI TEST LINK option.
```

If the Patient has paper documentation to prove laboratory tests were done (for example, outside the VA system) and the results were within accepted limits, the NCCC can authorize a onetime override. After the NCCC has received and approved this documentation, the following message will display.

Example 4: Onetime override authorized by NCCC

```
Now doing drug interaction and allergy checks. Please wait...

Permission to dispense clozapine has been authorized by NCCC

Override reason being: NCCC AUTHORIZED

Do you want to override and issue this prescription? N//
```


Example 5: When the Patient's WBC <3500 (range 3000 to 3500 for overriding)

```
Now doing drug interaction and allergy checks. Please wait...

*** Most recent WBC and NEUTROPHIL MATURITY, MEAN (ANC) results ***
    performed on JUL 27,2006 are:

    WBC: 3100
    ANC: 1900

*** Last Four WBC and ANC results were:
                                WBC      ANC
05/20/2006@14:53      Results: 4900 - 2800
05/27/2006@14:53      Results: 1900 - 2500
06/27/2006@14:53      Results: 3900 - 2500
07/27/2006@15:06      Results: 3100 - 1900

Override reason being: LAST WBC RESULT < 3500
```



Note: Up to four of the last LAB results can be displayed in the message.

Example 6: When the Patient's WBC is above range but ANC <2000 (range 1500 to 2000 for overriding)

```
Now doing drug interaction and allergy checks. Please wait...

*** Most recent WBC and NEUTROPHIL MATURITY, MEAN (ANC) results ***
    performed on JUL 26,2006 are:

    WBC: 3900
    ANC: 1900

*** No previous results to display ***

Override reason being: LAST ANC RESULT < 2000

Do you want to override and issue this prescription? N//
```



Note: In Example 6, previous LAB results did not exist.

Example 7: Patient meets all criteria

Now doing drug interaction and allergy checks. Please wait...

*** Most recent WBC and NEUTROPHIL MATURITY, MEAN (ANC) results ***
performed on JUL 27,2006 are:

WBC: 3900

ANC: 2000

CLOZAPINE dosage (mg/day) ? : (12.5-3000):