

Protocol for the Dispensing of Clozapine by Community Pharmacies

**For the Integrated Community Pharmacy
Services Agreement**

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The aim of this protocol is to ensure the safe dispensing of clozapine and that appropriate processes are in place for the monitoring of blood results. This protocol will be reviewed and updated by the DHBs from time to time in consultation with you and/or representative body.

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All District Health Boards

1 Dispensing Clozapine

1.1 Dispensing of Clozapine

On receipt of a prescription form for clozapine.

1.2 Check patient details

If the service user is a new patient, obtain the following information:

- (a) Name of service user and/or caregiver
- (b) Address
- (c) Contact telephone numbers
- (d) NHI (required to access the blood monitoring database)
- (e) Date of birth (DOB)
- (f) Community Services Card (CSC) status
- (g) High Use Health Card (HUHC) status
- (h) Prescriber's name and contact telephone number
- (i) Name of liaison person agreed with prescriber together with contact telephone numbers (if appropriate)
- (j) Community mental health team that the service user is under together with contact telephone numbers (if appropriate)
- (k) Current dosage of clozapine
- (l) Other prescribed and over the counter medications
- (m) Date and result of the most recent blood test
- (n) Due date for next blood test
- (o) Name of laboratory where blood test results can be obtained together with contact telephone numbers
- (p) Baseline blood test (that is, test prior to and within seven days of commencing clozapine treatment). Available from the supplier(s) of clozapine or an agent thereof
- (q) Stage in treatment (that is, how many weeks has the patient been receiving clozapine). Available from the supplier(s) of clozapine or an agent thereof.

Record this information on a file for each service user (see Section 3 below).

1.3 Check the patient is registered with the supplier(s) of clozapine

This may be achieved by contact with the supplier(s) of clozapine or an agent thereof either:

- (a) By accessing their database.
- (b) By contacting them directly.

This is to safeguard against dispensing clozapine to service users who have been excluded from treatment with clozapine because of a previous incidence of agranulocytosis, hypersensitivity reactions or other medical and clinical conditions.

Prescribers are responsible for registering the service user with the relevant supplier(s) or agent thereof but the pharmacist must check this has in fact been done. If the service user does not appear to be registered with the relevant supplier(s) or agent thereof, inform the prescriber or, if appropriate, the liaison person agreed with the prescriber. The pharmacist

is required to enter the date of any dispensing on the website for a complete record to be available to all providers.

Do not dispense clozapine to unregistered service users.

1.4 Check that the prescription form is written by an authorised prescriber

- (a) The Ministry of Health has directed that clozapine may only be prescribed by:
 - (i) Prescribers who are vocationally registered under the HPCA Act and certified as competent in the branches of psychological medicine or psychiatry by the Medical Council of New Zealand.
 - (ii) Registrars in psychological medicine or psychiatry who are under the supervision of persons of the kind referred to in sub-clause (i) above.
- (b) You are required to check that the prescriber is either a specialist or registrar in psychological medicine or psychiatry. You will be provided with a list of the appropriate registrars in your area.

1.5 Check blood test results

No clozapine prescriptions are to be dispensed unless a satisfactory blood test result is available. (See process for blood test monitoring which is outlined in Section 2 below.)

1.6 Quantity of clozapine that may be dispensed

- (a) Clozapine will generally be dispensed in lots of 7, 14 or 28 days as dictated by the frequency of blood monitoring or the date of the next blood test.
- (b) The quantity of clozapine dispensed must not exceed that which is required to take the patient from the date of dispensing to the date of the next blood test.
- (c) Where the date of the blood test coincides with the date of dispensing then the following applies:
 - (i) For service users in the first 18 weeks of treatment you must only dispense a sufficient quantity of clozapine for seven days.
 - (ii) For service users having blood tests at four-weekly intervals you must only dispense a sufficient quantity of clozapine for 28 days.
- (d) Where the date of the blood test precedes the date of dispensing the quantity of clozapine dispensed should only be sufficient to take the service user up to the date of their next blood test.
- (e) For service users in the first 18 weeks of treatment with clozapine and where the date of the most recent blood test precedes the date of dispensing by two days (48 hours) you must only dispense a sufficient quantity of clozapine for five days.
- (f) For service users having blood tests at four-weekly intervals and where the date of the most recent blood test precedes the date of dispensing by two days (48 hours) you must only dispense a sufficient quantity of clozapine for 26 days.

1.7 Interval between blood test and dispensing

Dispensing should generally take place within 24-72 hours of the date of the most recent blood test for the relevant service user. This requirement may vary according to the hospital

or health service protocol that applies in your locality. You may need to customise procedures for your pharmacy accordingly.

1.8 Maximum supply is limited to 28 days

In relation to the dispensing of clozapine, one month's supply is equal to 28 days. This is to regularise the period of dispensing with the blood testing regime and to avoid the involvement of weekends.

1.9 Record information regarding dispensing on patient files

Information must include the following:

- (a) Dispensing date
- (b) Total daily dosage
- (c) Number of days supplied
- (d) Date when next supply is due.

1.10 Label the container

Apply **Cautionary** and **Advisory** labels 1 and 9:

- (a) Label 1 states that "This medicine may make you sleepy and make it dangerous to drive or operate machinery. Limit alcohol intake".
- (b) Label 9 states "Do not stop taking this medicine without consulting your doctor".

1.11 Patient advice and counselling

- (a) Discuss with the individual service user for whom the prescription is issued or with the carer of such service user essential advice and counselling on the directions for safe and effective use of clozapine. Advice and counselling must be given in accordance with legal and professional requirements. In this particular case, you should also discuss the:
 - (i) Importance of compliance
 - (ii) Requirement to consult their prescriber immediately at the first signs of a cold, influenza, sore throat or other infection.
 - (iii) Importance of having their next blood test on the day it falls due.
 - (iv) Importance of safe storage of clozapine.
- (b) You must also inform the service user or their caregiver where a reduced quantity of clozapine has been supplied to coincide with the date of the next blood test.

1.12 Record and monitor the next dispensing date

Record the service user's name and the date of the next dispensing in the clozapine diary.

Check the clozapine diary daily and follow up on any service users who have not had clozapine dispensed by contacting the prescriber or, if appropriate, the liaison person agreed with the prescriber.

1.13 Arrangements for collection or delivery

Put aside for collection or arrange for delivery where this is required.

2 Blood Test Monitoring

Check that a satisfactory blood test is available for the relevant service user before dispensing clozapine.

2.1 Obtaining blood test results

- (a) Blood results may accompany the prescription form. A copy of an official laboratory reporting form may be attached to the prescription form.
- (b) Blood results may be written on the actual prescription form in the prescriber's own handwriting. Check that the results are the attest blood test results for that service user and that the date of the test is annotated on the prescription form.
- (c) Blood results may be obtained direct from the laboratory. In this case a copy of the results must be faxed to the pharmacy for verification.
- (d) Blood results may be obtained directly from an appropriate electronic clinical data repository (such as Test Safe or the blood monitoring database monitored by the supplier(s) of clozapine (or an agent thereof)) where the pharmacy has access to such an electronic data repository.

2.2 Definition of a recent blood test

As a general guide the most recent blood test results should not be older than 24-72 hours at the time of dispensing clozapine. This timeframe may vary according to hospital and health service protocol applying in your locality. You may need to customise your pharmacy's procedures.

2.3 No blood test is available

If no applicable blood results are available then a blood test should be requested through the prescriber. Clozapine should not be dispensed until a satisfactory blood result is obtained. Dispense only as advised by the prescriber.

2.4 Record blood test results

Information on blood tests should be entered on a separate record sheet for each service user. The following information should be recorded:

- (a) Date of blood test.
- (b) White blood cell count (WBC).
- (c) Neutrophil count.
- (d) Date when the next blood test is due.

2.5 If laboratory results are normal

Dispense a sufficient quantity of clozapine as required to take the service user up to the date of their next blood test. You will need to refer to the instructions on the prescription form and also to the dispensing requirements for clozapine which are outlined in Section 1 above.

2.6 Determining the date of the next blood test

- (a) For service users in the first 18 weeks of treatment with clozapine, the date of the next blood test will be seven days from the last test.
- (b) For service users having tests at four-weekly intervals, the date of the next blood test will be 28 days (four weeks) from the last test.
- (c) As a general guide the monitoring frequency is reduced to four-weekly intervals after the first 18 weeks if no abnormalities are detected. This may vary so please refer to the hospital and health service protocol applying in your area.
- (d) Monitoring of blood at four-weekly intervals should remain in place as long as clozapine treatment continues. More frequent monitoring is required whenever blood tests indicate borderline results.

2.7 If the laboratory results are abnormal

If the WBC falls below $3.5 \times 10^9/L$ ($<3500\text{mm}^3$) for a service user in the first 18 weeks of therapy, **or** below $3.0 \times 10^9/L$ ($<3000\text{mm}^3$) for a service user beyond the first 18 weeks **and/or** neutrophil count falls below $2.0 \times 10^9/L$ ($<2000\text{mm}^3$) for a service user in the first 18 weeks of therapy, or below $1.5 \times 10^9/L$ ($<1500\text{mm}^3$) for a service user beyond the first 18 weeks **or** either have dropped by a substantial amount from the baseline. A substantial drop is defined as a single drop of $3.0 \times 10^9/L$ or more in the WBC

and/or there are any signs or symptoms of infection occurring

THEN DO NOT DISPENSE CLOZAPINE.

YOU MUST CONSULT THE PRESCRIBER.

- (a) Patients may need to have a differential white blood cell test.
- (b) Dispense only as instructed by the prescriber.
- (c) Notify the relevant supplier(s) or agent thereof in cases where treatment with clozapine is withheld.
- (d) Patients in whom clozapine has been discontinued for haematological reasons must not be re-exposed to the medicine.

3 Service User Information Record

- (a) Every service user receiving clozapine should have a separate file. These should be kept in alphabetical order and in a secure location within the dispensary of your pharmacy.
- (b) The information that should be kept on each service user's file shall include the following:
 - (i) Service user details (as referred to in Section 1.2 above).
 - (ii) Copies of blood test results from laboratories, kept in order according to date.
 - (iii) Recording sheets for blood test results and dispensing details.
 - (iv) Delivery details.
- (c) All actions undertaken in association with the collection, retention and disclosure of health information about a patient receiving clozapine must comply with statutory requirements.

- (d) The supplier's clozapine website needs to be updated with the date of dispensing each time this occurs.

4 Special Circumstances

4.1 Missed doses

If you become aware that clozapine therapy has been interrupted and that a service user has missed more than two days of treatment then the pharmacist must notify the prescriber.

Treatment should be re-initiated using the original dose titration schedule. It is important that the first few doses are low. However it may be possible to titrate upwards more quickly than was the case when clozapine was initially begun.

4.2 Extended supply

In exceptional circumstances (for example, public holidays) the period of supply may be extended by one or two days. This will only be carried out after consultation with the prescriber.

The maximum quantity of clozapine that can be dispensed at one time must not exceed 28 days' supply.

4.3 Replacement doses

If a service user loses their supply of clozapine you must contact the prescriber. The prescriber may decide to issue another prescription form. Document the situation on the service user's file. Annotate on the prescription form that the medication was lost. The amount dispensed must only be enough to carry the service user through until the date of their next blood test. Keep in mind the potential risks if this medicine is being hoarded.

4.4 Prescriber is not available

In the event that the prescriber cannot be contacted some of the following actions may be useful:

- (a) Try to obtain an alternative contact for the prescriber (for example, mobile number).
- (b) Contact the medical practitioner who is standing in for the prescriber.
- (c) Contact the liaison person agreed with the prescriber.
- (d) Contact the Mental Health Service which the service user is under. Ask to speak to either the psychiatric registrar or house surgeon on call or the key worker/case manager where appropriate.

4.5 Patient admitted to hospital

If you become aware that the service user has been admitted to hospital at any stage during treatment this matter should be noted on the service user's file. It may be useful for you to contact the hospital pharmacy to confirm the service user's clozapine treatment record.

After the service user has been discharged it may be useful to question the service user or their caregiver as to whether they have any clozapine which is surplus to their requirements and encourage them to return it to the pharmacy for destruction.