

Guidance for care of people prescribed clozapine in care homes

This document was developed jointly by the Scottish Mental Health Pharmacy Strategy Group and the Care Inspectorate

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Clozapine – key facts



Clozapine therapy requires mandatory full blood counts due to risks of lowering white blood cells.

Without a valid blood result, clozapine cannot be supplied.

The frequency of blood tests depends on the length of treatment; weekly, fortnightly, or monthly.

If clozapine treatment is stopped for more than 48 hours, it must be re-titrated. This increases the risk of a relapse in symptoms.



The results of the full blood count are referred to using a traffic light system.

Green - white blood cell count is normal

Amber - white blood cell count is slightly low (requires extra bloods)

Red - white blood cell count is too low (clozapine must stop with urgent daily blood samples)

Clozapine like all medicines has side effects.

Individuals on clozapine should be closely monitored for side effects especially constipation which can be severe and potentially life threatening.



Smoking lowers levels of clozapine in the blood by around 50%. If there are changes in someone's smoking habit, their clozapine dose may need adjusted.

In the event of signs of infection e.g., sore throat, raised temperature; get an extra full blood count to check that the white cell count is not too low.



Guidance for the care of people prescribed clozapine in care homes

Clozapine is the 'gold standard' antipsychotic for the people with treatment resistant schizophrenia.

Unfortunately, it is associated with a range of troublesome side-effects, some of which can have a profound effect on a person's on-going physical health.

As a potentially life-long treatment, robust processes are therefore needed to ensure the necessary physical health monitoring is undertaken systematically, regardless of the care setting.

A small but growing number of people prescribed the medicine clozapine are being cared for in care homes across Scotland by nursing and/or social care staff.

This document describes high level guidance intended to support all care homes caring for residents prescribed clozapine.

Background

What is clozapine?

Clozapine is an antipsychotic used to treat people with schizophrenia who have not responded to other antipsychotics. This is sometimes called Treatment Resistant Schizophrenia. It is also used for people with Parkinson's disease who are experiencing psychosis. Very occasionally it is used in other mental health conditions out with the manufacturer's licensed indications.

What is unique about clozapine?

About 2-3 people in every 100 people taking clozapine will develop *neutropenia* or *agranulocytosis* (a decreased white blood cell count). If this happens, the individual may not be able to fight infections effectively. Because of this, **every person taking clozapine is registered with the clozapine manufacturer's monitoring service.** The person is required to have a blood sample taken for a full blood count before each supply of clozapine is issued. **Clozapine will not be supplied unless the blood result is satisfactory.**

In some parts of Scotland clozapine is only supplied from the hospital pharmacy that is registered to supply clozapine to that person; in other parts community pharmacies are also involved in the supply of clozapine. Care homes should check with local mental health pharmacy services which applies in their locality. Care homes should ensure clozapine supply and use is recorded on the medicines administration recording chart.

Importance of blood tests

Regular tests are necessary to check that the person’s blood counts are in the correct range. Some people may attend local clozapine clinics if they’re able, CPNs may come into care homes or care homes may arrange it themselves.

For the blood result to be ‘valid’ it must be within a recent specific time frame in relation to the supply.



Importance of continued supply

If clozapine treatment is stopped, the person is at risk of relapsing. If clozapine is stopped for more than 48 hours, it is termed a ‘treatment break’. Clozapine needs to be re-titrated following a treatment break. This means clozapine treatment will have to be started again at a low starting dose and the dose increased gradually to the dose the person was previously getting. Most often this will require an admission to hospital.



It is therefore vital that full blood counts are taken at the stipulated frequency and whenever extra blood tests are requested by the clozapine monitoring service, pharmacy or the mental health or learning disability team.

What the full blood test results mean

The manufacturers of clozapine all use a traffic light system to indicate the status of the blood result. *(See table 1)*

Table 1: Clozapine blood result traffic light system

| Result | Meaning | Action | Supply |
|--------------|--|--|--|
| Green | White blood cell count is normal | Continue with routine tests | Clozapine will be supplied |
| Amber | White blood cell count is slightly low | Twice weekly blood tests are necessary until the white blood count level results return to green range. | Clozapine will be supplied <u>but</u> additional blood tests <u>MUST</u> be carried out. |
| Red | White blood cell count is too low | Another blood result is required <u>urgently and every day</u> until the white blood cells return to green range. The patient’s psychiatrist will be informed and clozapine must be stopped. | Clozapine will <u>not</u> be supplied |

How often should blood samples for full blood counts be taken?

- ❖ Every week for 18 weeks (sometimes longer) at start of treatment.
- ❖ Then every 2 weeks for the rest of the first year (sometimes longer).
- ❖ And then every 4 weeks.
- ❖ And when instructed by the mental health or learning disability team or hospital pharmacy (urgent)
- ❖ And when the person shows signs of infection e.g., sore throat or raised temperature* (urgent)

*Signs of infection may indicate that the person's white blood cell counts are falling so as a precaution this needs to be checked. Notify the mental health or learning disability team, clozapine clinic or care home charge nurse, so arrangements can be made for a blood sample to be taken to check this out.

The risks of developing neutropenia or agranulocytosis decreases with time therefore blood tests can be changed to every 2 weeks after 4-5 months and then every 4 weeks after one year. But only if the person's white blood cell count has been consistently in the green range.

Other blood tests

Occasionally, the mental health or learning disability team may want to find out the level of clozapine in the person's blood. This can be useful in helping the team decide if the clozapine dose needs adjusted. If the level is too high, side effects are more likely; too low and the clozapine may not be effective enough.

The mental health or learning disability team will also arrange for a number of other health checks to be undertaken at appropriate intervals in line with the NHS Scotland Clozapine Physical Health Monitoring Standards.

[http://www.sehd.scot.nhs.uk/cmo/CMO\(2017\)04.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2017)04.pdf)

Other clozapine side effects to watch out for

Table 2: common clozapine side effects

| Side effect | What to do |
|--|---|
| <p>Constipation</p> <p>It is important to ensure the person on clozapine does not get constipated.</p> <p>This is because if constipation is not treated early, it can become so severe, that the bowels will become blocked. This can be life threatening.</p> <p>For more information a handy fact sheet on clozapine and constipation is available at www.choiceandmedication.org/nhs24</p> | <p>Encourage the person to drink enough fluid and take a diet with plenty of fibre.</p> <p>Encourage exercise e.g., walking or sitting exercises for those unable to walk.</p> <p>Monitor bowels using Bristol stool chart (appendix 1)</p> <p>If stool consistency is type 1 or type 2 on the Bristol Stool chart, refer to GP who may prescribe a laxative e.g. osmotic laxative, to be prescribed on a regular basis. Ensure adequate fluid intake with osmotic laxatives to ensure they are</p> |

| | |
|--|---|
| <p style="text-align: center;">*****</p> <p style="text-align: center;">If constipation has continued for several days <u>or</u> is accompanied by being sick <u>or</u> bloated abdomen <u>or</u> liquid diarrhoea</p> <p style="text-align: center;">*****</p> | <p>working.</p> <p style="text-align: center;">*****</p> <p style="text-align: center;">SEEK URGENT MEDICAL ADVICE</p> <p style="text-align: center;">Tell the medical team that the person is on clozapine.</p> <p style="text-align: center;">*****</p> |
| <p>Sedation/sleepiness</p> <p>Clozapine can cause sedation. If the person is feeling or appearing sleepy, drowsy, or sluggish it may impact on their quality of life.</p> | <p>Talk to the mental health or learning disability team to see if the timings or the dose needs to be changed.</p> <p>Sometimes the doses can be split differently so there is more given in evening than the morning to decrease the likelihood of daytime sleepiness.</p> |
| <p>Hypersalivation</p> <p>Clozapine can cause hypersalivation where the person may dribble or drool (more than usual if this is an existing problem) or their mouth may be full of saliva. Often the pillow can be wet in the morning. This can be upsetting for the person.</p> <p>For more information a handy fact sheet on clozapine and hypersalivation is available at www.choiceandmedication.org/nhs24</p> | <p>Propping up pillows at night helps some people. You may be able to purchase an absorbent pillow.</p> <p>Talk to the mental health or learning disability team as hyoscine hydrobromide tablets (sometimes patches) can be prescribed to help dry up the saliva.</p> <p>Ensure the GP is aware of any hypersalivation if the person is prone to aspirating, as this can be a high risk to health.</p> |
| <p>Weight gain</p> <p>The person may gain weight when on clozapine and may want to eat more.</p> <p>For more information there are handy fact sheets on preventing and managing weight gain at www.choiceandmedication.org/nhs24</p> | <p>Monitor the person's weight.</p> <p>Encourage a diet full of vegetables and fibre as this may help prevent weight gain and help with reducing risk of constipation.</p> <p>Ensure soft drinks are no sugar.</p> <p>Encourage exercise e.g., walking or sitting exercises for those unable to walk</p> |

Other things to look out for

Smoking

Smoking lowers the level of clozapine in the blood by up to 50%. It is important to let the mental health or learning disability team know if there is any sustained change in smoking habit for five days or more, as the dose of clozapine may need to be adjusted. A clozapine level blood test may be carried out to help decide on a new dosage.

- ❖ If the person has stopped smoking but then starts to smoke again then clozapine levels may fall and the person may relapse.
- ❖ If the person stops smoking or decreases the amount they are smoking then the clozapine levels may rise, increasing the risk of side effects.
- ❖ Nicotine replacement therapy, vaping devices and e-cigarettes do not alter clozapine levels. It's the chemicals in cigarette smoke that causes the problem.
- ❖ Tell the mental health or learning disability team as soon as you are aware the person has or is intending to start or stop smoking.

Other information sources

Good information on clozapine and other mental health medicines and conditions is available at www.choiceandmedication.org/nhs24. There are handy fact sheets on different aspects of clozapine including managing side effects.

GASS for clozapine

If the person receiving care gets their blood sample taken at a clozapine clinic, they will also be monitored there for side effects using GASS (Glasgow Antipsychotic Side-effect Scale) for clozapine. Alternatively, the community psychiatric or learning disability nurse may use GASS for clozapine at the person's home to assess for side effects. If the person is living in a care home, the care home nursing staff may be asked to complete the GASS for clozapine. Ask the mental health or learning disability team for a copy of this scale and instruction for use. There is also an easy read version available.

Guidance

Other Education and training

Clozapine is a medicine which requires care home staff to have particular knowledge for monitoring of its use to ensure personal outcomes are met for any residents taking the medicine. Care homes are encouraged to engage with local specialist mental health services to receive more in-depth training for their staff as needed. This is in line with the **Health and Social Care Standards: My support, my life** (<https://www.gov.scot>)

3.14 *I have confidence in people because they are trained, competent and skilled, are able to reflect on their practice and follow their professional and organisational codes.*

4.27 *I experience high quality care and support because people have the necessary information and resources.*

Shared care and communication

People prescribed clozapine will remain under the care of mental health services for some aspects of their on-going care. It is therefore essential for mental health services and care home providers to agree for each person which service will be responsible for which aspects of their care, and so avoid any confusion in care. This will require good communication between organisations in line with the following **Health and Social Care Standards: My support, my life** (<https://www.gov.scot>)

3.19 *My care and support is consistent and stable because people work together well*

4.17 *If I am supported and cared for by a team or more than one organisation, this is well co-ordinated so that I experience consistency and continuity.*

4.18 *I benefit from different organisations working together and sharing information about me promptly where appropriate, and I understand how my privacy and confidentiality are respected.*

Care planning

Every person attending a registered care home must have a personal plan within 28 days of them starting to use the service - **The Social Care and Social Work Improvement Scotland (Requirements for Care Services) Regulations 2011, SSI 2011/210, Regulation 5: Personal Plan** – link below.

https://www.legislation.gov.uk/ssi/2011/210/pdfs/ssi_20110210_en.pdf

In accordance with the **Health and Social Care Standards: My support, my life** (<https://www.gov.scot>) the personal plan should detail how the relevant care needs are met.

1.15 *My personal plan (sometimes referred to as a care plan) is right for me because it sets out how my needs will be met, as well as my wishes and choices.*

Where the resident is prescribed clozapine the care plan should cover the following elements (**note: national standards for clozapine monitoring are available at this link** [www.sehd.scot.nhs.uk/cmo/CMO\(2017\)04.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2017)04.pdf)).

- **Routine and ad hoc full blood count monitoring:** Where, when and by whom routine and ad hoc full blood count monitoring is undertaken. Actions to take if a person is unable to attend for routine full blood counts.

- **Bowel function assessment:** The monitoring and recording of bowel activity, and who should be contacted for advice and support where an issue with the bowel function presents.
- **Side effect monitoring:** Which aspects of side effect monitoring will be undertaken in the care home and which by local services. E.g., routine pulse and BP might be undertaken in the care home but annual ECG and non FBC blood tests might be undertaken by local mental health services. Where the care home is monitoring side effects, the plan should detail when and how this should be escalated to local MH services.
- **Compliance with treatment:** Actions to take in the event of a missed dose or a treatment break.
- **Signs or symptoms suggestive of neutropenia:** Actions to take if the person displays signs of or symptoms suggestive of neutropenia, such as raised temperature, sore throat, or flu like symptoms.
- **Smoking status:** How to judge that the person's smoking habits have changed and who to report this to.
- **Weight management:** The agreed threshold for raising concerns about weight gain and who to report concerns to within local mental health services.
- **Mental state:** How to assess mental state and escalate concerns.

More information on care planning for adults can be found in the **Guide for providers on personal planning for adults** – (<https://hub.careinspectorate.com/media/4665/personal-plans-guide-adults-final-05112021.pdf>)

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The content of this document was adapted from guidance produced by the mental health pharmacy team in NHS Lanarkshire.

Appendix 1

Bristol Stool Chart

| | | |
|--------|---|--|
| Type 1 |  | Separate hard lumps, like nuts (hard to pass) |
| Type 2 |  | Sausage-shaped but lumpy |
| Type 3 |  | Like a sausage but with cracks on the surface |
| Type 4 |  | Like a sausage or snake, smooth and soft |
| Type 5 |  | Soft blobs with clear-cut edges |
| Type 6 |  | Fluffy pieces with ragged edges, a mushy stool |
| Type 7 |  | Watery, no solid pieces. Entirely Liquid |

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