What are the Community Access arrangements?

From 1 July 2015 changes will be introduced to the way clozapine can be prescribed and dispensed for maintenance treatment. Clozapine for maintenance therapy will be able to be prescribed and dispensed in the community, with a stronger role for community pharmacies.

These changes do not impact on the way clozapine initial treatment is provided in a hospital setting, or by a community-based prescriber with linkages to hospital psychiatric services.

The new community access arrangements apply to selected medicines in the Highly Specialised Drugs Programme. From 1 July 2015, these medicines include HIV antiretroviral therapies, medicines used in the treatment of Hepatitis B, and clozapine when being used in maintenance therapy.

What are the changes?

Prior to 1 July 2015, medical practitioners prescribing clozapine for maintenance therapy were required to be affiliated with specialist hospital units and clozapine was generally available from hospital pharmacies only.

Under the new arrangements clozapine may be prescribed by authorised general practitioners or other community prescribers and be dispensed in community pharmacies.

Note that Clozapine can continue to be prescribed and dispensed under the existing hospital arrangements.

What is meant by ‘maintenance therapy’?

For the purposes of PBS subsidy for clozapine continuing/maintenance therapy, the following clinical criteria will apply:

- Previous initial treatment under a psychiatrist for a period of no less than 18 weeks AND
- The treating psychiatrist agrees the patient is suitable for community-based management and prescribing AND
- The patient’s clozapine dosage is considered stable by the treating psychiatrist AND
- Treatment is under the supervision and direction of the psychiatrist reviewing the patient at regular intervals.

What is changing for patients?

From 1 July 2015, patients will have greater choice about where they access their medicines, through either a community pharmacy, or a private or public hospital pharmacy.
It will be easier for patients to access clozapine once therapy has been initiated and stabilised in a hospital setting, as they will no longer need to be receiving care at or from a hospital to be prescribed these medicines. Being able to have prescriptions dispensed at a local pharmacy will be very convenient for many patients particularly in areas where it is difficult to access a hospital.

Patient eligibility criteria are unchanged. Patients will continue to pay a patient co-payment which will contribute to the PBS Safety Net Record. In 2015, the PBS general patient co-payment is up to $37.70 and the PBS concessional patient co-payment is $6.10.

**How do patients know which pharmacy to attend to have their prescriptions dispensed?**

Involving community pharmacies in the supply of clozapine is expected to be introduced and managed at a local level, in consultation with the mental health care team, or private psychiatrist, responsible for initial patient therapy.

**What is changing for prescribers?**

Under the new arrangements, authorised general practitioners and eligible community based prescribers will be able to prescribe clozapine once the treating psychiatrist believes that the patient is suitable for community based management and prescribing. Eligible prescribers will now be able to prescribe clozapine without the need to demonstrate an association with a hospital, in accordance with State or Territory accreditation/authorisation requirements.

All prescribers will be required to use the STREAMLINED authority approval process when prescribing clozapine. More detailed information on the streamlined authority approval process is at: [http://www.humanservices.gov.au/health-professionals/services/pbs-for-prescribers/streamlined-authority-process](http://www.humanservices.gov.au/health-professionals/services/pbs-for-prescribers/streamlined-authority-process).

Prescribers and patients must be registered with the appropriate clozapine patient monitoring system. Prescribers must also order a blood test and review the results before each occasion of prescribing clozapine. The two monitoring systems can be accessed at [https://www.ecpms.com.au/](https://www.ecpms.com.au/) (for Clozaril) or [https://www.clopine.com.au/](https://www.clopine.com.au/) (for Clopine). Treatment centres, and individual patients, prescribers, and pharmacists must be registered with the appropriate patient monitoring system before prescribing or dispensing of clozapine can occur.

While the maximum quantity of tablets for PBS prescriptions will remain at 200, prescribers should consider prescribing a sufficient quantity for a month of therapy (or less depending on the blood result) rather than the full PBS maximum quantity, as patients require a blood test at least every 28 days, prior to each prescription. Specifying that the patient receive clozapine in staged supply portions from the pharmacist can improve the quality use of medicines for some patients.

**What is changing for pharmacies?**

Community pharmacies are able to dispense clozapine for maintenance therapy regardless of where the medicine was prescribed. However, with respect to safe supply of clozapine, pharmacists must meet all relevant PBS, state and clozapine monitoring system.
requirements in order to participate. When supplying clozapine, a patient’s pathology results must be checked and details entered into the brand-specific clozapine patient monitoring database prior to dispensing and subsequent claiming.

The two monitoring systems can be accessed at [https://www.ecpms.com.au/](https://www.ecpms.com.au/) (for Clozaril) or [https://www.clopine.com.au/](https://www.clopine.com.au/) (for Clopine). Treatment centres, and individual patients, prescribers, and pharmacists must be registered with the appropriate patient monitoring system before prescribing or dispensing of clozapine can occur.

Clozapine for maintenance therapy is now included with other PBS medicines that are classified ‘Authority required STREAMLINED’.

Community pharmacists must use the streamlined Authority code indicated on the prescription by the prescriber for dispensing.

*How should prescriptions written prior to 1 July 2015 be treated?*

Prescriptions for clozapine and any repeats from those prescriptions, written prior to 1 July 2015 will need to be dispensed by a hospital pharmacy in accordance with the previous arrangements.

*Should prescriptions be written for brand-specific Clozapine?*

Yes. Under the PBS a prescriber is able to specify the brand of medicine by endorsing the prescription if brand substitution is not permitted.

While the two brands of clozapine are ‘a-flagged’ in the Pharmaceutical Benefits Schedule, patients should be maintained on a single brand throughout therapy. Patients are initiated on a particular brand of clozapine within the hospital sector, and mandatory monitoring is conducted via the clozapine monitoring system set up and maintained by the pharmaceutical sponsor for that brand.