



**Australian Government**  
**Department of Health**

# Supply of Clozapine in community settings

(prescribing and dispensing  
maintenance therapy only)

## Implementation issues

Change history			
Version Number	Release date	Author / compiler	Details
1	19 Jan 2015	Health (Cth)	Initial draft
2	21 Jan 2015	Health (Cth)	Stakeholder release
3			
4			

# Supply of Clozapine in community settings

## Background

The Australian Government has announced changes to the Pharmaceutical Benefits Scheme (PBS) to improve community access to:

- HIV antiretroviral therapies; and
- clozapine in the treatment of schizophrenia (maintenance therapy only).

These changes, expected to commence on 1 July 2015, reflect recommendations to Government by the Pharmaceutical Benefits Advisory Committee. This consultation document is intended to support implementation of the revised PBS arrangements for clozapine [CLOZARIL® and CLOPINE®], which seek to increase patients' independence and quality of life, in the context of safe use of clozapine.

No changes are proposed to the prescribing and dispensing of clozapine during the period in which therapy is initiated in a hospital setting.

## Invitation to comment

Input on implementation issues, including those in this document, is invited from state and territory regulators, mental health teams, Highly Specialised Drugs Program coordinators, pharmaceutical industry responsible persons (Hospira Pty Ltd and Novartis Pharmaceuticals Australia Pty Ltd), groups representing community and hospital pharmacy practice, prescriber groups, and healthcare consumers.

## Contact officer

The contact person for input to this document is:

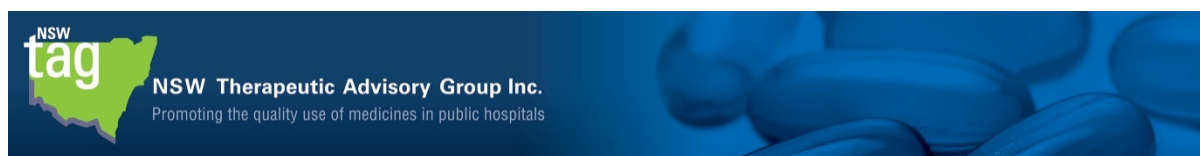
David Pearson  
Director, Specialised Supply  
Pharmaceutical Benefits Division  
Australian Government Department of Health  
Canberra

[david.pearson@health.gov.au](mailto:david.pearson@health.gov.au)

(02) 6289 2415

**Written submissions should be received by the contact officer by:**

**close of business Friday 20 February 2015**



The NSW Therapeutic Advisory Group (NSW TAG) is an independent not-for-profit association that promotes the Quality Use of Medicines (QUM) within and across the continuum of acute care. Our members are clinical pharmacologists, pharmacists, and other clinicians from each of the Drug and Therapeutics Committees (DTCs) in NSW public hospitals and Local Health Districts. Our goal is to promote QUM by sharing unbiased, evidence based information about drug therapy. Our objectives are to investigate and evaluate new initiatives in therapeutics, to support Drug and Therapeutics Committees and to promote rational, high quality, safe prescription, dispensing and administration of medicines in public hospitals and the wider community.

The NSW TAG welcomes the invitation to comment on the announced change to the PBS for clozapine in the maintenance management of schizophrenia. The responses represent those from its member local health district hospital pharmacists, with long histories and experience in the management of clozapine.

Contact: Dr Sasha Bennett

NSW Therapeutic Advisory Group

26 Leichhardt St

Darlinghurst, 2010

Email: [nswtag@stvincents.com.au](mailto:nswtag@stvincents.com.au)

Phone: 02 8382 2852

## 1. Definition of ‘maintenance therapy’

### **BACKGROUND**

Clozapine is currently prescribed and dispensed to patients through public and private hospital clinics where appropriate facilities and expertise are available. Hospital-based initiation of treatment includes close monitoring of cardiac and haematological parameters and patient response.

Once therapy has been initiated and stabilised in a specialist setting, patients in some state jurisdictions may enter formal shared care arrangements that support local access by patients to treatment. These arrangements may include:

- **Shared care in prescribing**, by community prescribers (general practitioners and public sector mental health prescribers working in community mental health units) under the supervision of a hospital psychiatrist. This enables patients to visit a designated community prescriber for assessment and monitoring, without attending a specialist at hospital on each occasion; and
- **Shared care in dispensing**, where some community pharmacies, selected by the hospital, act as agents of the public hospital to dispense and supply clozapine to eligible patients in the community setting.

### **ISSUE**

- The clinical treatment phase at which a patient is categorised as receiving maintenance therapy needs to be defined to identify when they are eligible to access the new community arrangements for ongoing treatment.
- Current definitions of maintenance therapy may differ across jurisdictions.
- This issue informs aspects of Issue 6 – PBS administration matters – in that separate PBS entries will be created for initiation and maintenance therapy.

### **POSITION / COMMENT**

Several definitions of “maintenance therapy” and patient suitability for maintenance therapy have been proposed. The overall definition would ideally combine a consideration of the major determinants. Given the complexity of determining eligibility for ‘maintenance’ therapy, the treating psychiatrist should determine whether/when therapy is ‘maintenance’.

#### From a prescribing perspective:

- There are many non-compliant and relapsing patients who will be re-admitted and re-initiated.
- To be considered for maintenance therapy, patients should not have had a recent hospital admission for a mental health-related issue.
- There are many patients who may not ever be suitable for community management. The treating psychiatrist would need to be involved in the assessment of the patient’s suitability, along with other members of the treatment team.

#### From a monitoring perspective:

A patient may be considered for maintenance if:

- A patient has completed the 18 week initiation period and is now stabilised and is having 28-day bloods or has been stabilised before 18 weeks if the dose has remained unchanged for 4 weeks; or
- A patient is stabilised on 28 day-bloods after 6 weeks of weekly bloods, following an interruption to therapy; or
- A patient has been clinically stable on 28-day bloods, but requires more intensive monitoring/ staged supply, due to a red or amber result.

From a medication- management perspective:

- Patients need to be able to self-govern and have sufficient cognitive function to reliably access a local GP and local pharmacist; or
- Patients should have a suitable carer capable of assisting the patient in medication-management.
- Patients should have a stable dosing structure as the initial response to clozapine can be highly variable; a good understanding of the safety process and the risks of clozapine; demonstrate a good medication-compliance history; good blood picture and cardiac function. These criteria should be able to be demonstrated over a period such as 6-months to ensure suitability. A patient who is stable enough to receive monthly therapy is not necessarily, by implication, capable of undertaking community-based treatment.

Other points to consider:

- The definition of “maintenance” therapy should be the same across jurisdictions. This ensures continuity of care is maintained in the scenario whereby a patient moves interstate, or if a patient is close to a border and is hospitalised in one state but has a community pharmacy in another.
- There should be clear guidelines for patients coming from overseas who are on maintenance treatment, on their eligibility for treatment in community setting; for instance, requirement to be reviewed in a hospital setting or immediate acceptance into the community setting.
- The agreed minimum eligibility criteria for community-based management should be made very clear to all involved.
- In current practice, there is a significant investment of time into the management and follow-up of a clozapine patient. The system will need to amply reimburse community prescribers/ dispensers or risk threats to uptake or patient management.
- There is a requirement for a system to deal with a previously stable patient on “maintenance” who has red or amber blood results and therefore potentially requires daily, twice-weekly or weekly supply. Possible solutions to maintenance patients receiving red or amber blood results:
  - A central clozapine-coordinator continues to synchronise the care of patients with red or amber results.
  - Patients receiving maintenance therapy with red or amber results potentially remain with maintenance therapy, but undergo more intensive monitoring with

the community pharmacies supplying clozapine via a staged supply on the one prescription. The patient would still be charged for the 28 days' supply overall.

- For involvement of community pharmacies in the management of red or amber patients, it would be necessary for:
  - Pharmacist training to include recognition of triggers to be able to refer clozapine patients back to the doctor or hospital; that is, how to recognise clinically deteriorating patients.
  - Pharmacist training on the duty of care to follow up red or amber bloods by contacting the clozapine-coordinator or the patient's specialist/ prescriber and/ or by checking the patient's clinical notes on the clozapine monitoring database before determining what to dispense.
  - Pharmacists knowing their duty of care once the appropriate checks have been performed, to provide ongoing supply (unless the doctor/ clinical notes suggest otherwise) and to generally supply only up until the next blood test is due date or to a maximum of 2 days beyond (as per the "48 hour rule").

## 2. Certification/eligibility of community-based prescribers

### **BACKGROUND**

Clozapine and antiretroviral therapies for HIV are supplied under the PBS through the Highly Specialised Drugs Program (HSDP). Community-based prescribing by accredited non-specialist prescribers has existed for some years for HIV ART. These arrangements are supported by jurisdictional protocols which, in turn, are supported by the Australasian Society for HIV Medicine's *National Standards for Accreditation of Community HIV s100 Prescriber Education, CPD, and Certification of HIV s100 Prescribers*.

No comparable national arrangement exists in respect of clozapine community-based prescribing.

Currently under the Highly Specialised Drugs Program, an eligible prescriber is defined as someone:

- who is an affiliated specialist medical practitioner; or
- who is, for the prescription of medication for maintenance therapy if it is impractical to obtain a prescription from the treating affiliated specialist medical practitioner and the treating staff hospital specialist has agreed to the prescription—a medical practitioner; or
- who is, for the prescription of medication for maintenance therapy—a medical practitioner whom the Commonwealth and the State or Territory Government has agreed may give such a prescription.

Community-based prescribers will need to register with the relevant clozapine monitoring system and be linked to the patient's Centre.

### **ISSUE**

- How should prescribers in the community be identified as 'eligible' to provide maintenance therapy for clozapine patients under the community access arrangements, consistent with HSD principles of patient safety and specialist oversight of care?

### **POSITION / COMMENT**

There is an advantage of attracting more clozapine-accredited prescribers, as under the current systems the number of patients who can be managed on clozapine is limited by the number of prescribers affiliated with the health service. With more accredited prescribers available, the potential number of patients who can be managed could be increased.

#### Eligible prescribers could include:

- Psychiatrists
- Psychiatry Registrars
- GPs who are already registered with a clozapine monitoring program and who prescribe under the supervision of a psychiatrist who the patient sees at least 6-monthly
- any GP who wishes to become an accredited prescriber of clozapine (and who will need to prescribe under the supervision of a psychiatrist who the patient sees at least 6-monthly)

There are several caveats to increasing the prescribing in the community.

- There could be a different registration code for community-based prescribers compared to specialists in the ClopineConnect/Clozaril database as they are providing difference services.
- A register of 'eligible' or 'registered' community prescribers should be maintained so it is readily available for reference when patient is ready to be transferred to community. This would assist with selecting a prescriber that is most accessible for the patient, increasing their independence and quality of life.
- GPs who are currently accredited prescribers may not be able to accept the extra workload of extra clozapine patients.
- Accredited GPs would need to be able to indicate their willingness and ability of their practice to cope with increasing numbers of patients prescribed clozapine.
- The issue of GP availability (either because of part-time hours, holidays or sickness) needs to be pro-actively covered in policy/ algorithms or guidelines as it is a real phenomenon and one that may lead to prescribing by non-accredited GPs (locums, partners, GP registrars, etc).
- GP practices that are not bulk billing practices are a barrier for access by patients;
- Community-based prescribers should then undergo formal assessment of their knowledge and understanding of the clozapine monitoring protocols, for accreditation.
- Details of approval/ accreditation/ eligibility of medical prescribers for clozapine should be available for pharmacists to check via an online system.
- Consideration could be given to the development of a National Standard of Accreditation of community S100 Clozapine prescribers (and pharmacists). This could be used to generate a clear list of registered prescribers as well registered community pharmacies and pharmacists and could limit purchasing from wholesalers of Clozapine. This would prevent anyone sourcing the medication privately.
- Community prescribers to continue to prescribe the clozapine brand the patient has achieved the "maintenance" status on.

#### Possible accreditation process (and see point 6)

- Training for accreditation to be provided by external professional organisations, potentially in conjunction with the two clozapine manufacturers, working collaboratively with GP organisations/ Primary Health Care networks/ local Mental Health Services. Interdisciplinary training could include the clozapine co-ordinators and mental health pharmacists (analogous to training and accreditation of GPs by psychologist to access mental health EPC items in 2000's)
- Coordinating joint GP/ community pharmacy/ mental health service training sessions for education, networking opportunities and to promote integration of the associated professional groups.
- The clozapine coordinator to develop supporting policy and guidelines which provide clear guidance as to the instances occasioning referral to the patient's psychiatrist, to be included in training materials and mandatory knowledge for accreditation.
- Prescribers should be assessed for competency at regular intervals.



### 3. Community pharmacy participation requirements

#### **BACKGROUND**

As noted above, in some jurisdictions a number of community pharmacies, selected by public hospitals, currently act as agents of the hospital to dispense and supply clozapine to eligible patients in the community setting. PBS claims for these supplies are made by the public hospital.

Under the proposed community access arrangements, pharmacies in the community will be permitted to source, supply, and make claims under the PBS for clozapine supplied to eligible patients. Pharmacists will need to meet all relevant PBS, state, and clozapine monitoring system requirements in order to participate.

For example, this means that pharmacies wishing to act as community supply points must register as a supplying pharmacy under the ClopineConnect™ or CLOZARIL Patient Monitoring System (CPMS), in respect of a particular patient/Centre. Individual pharmacists may be registered to multiple pharmacies. Pharmacists will need to confirm prescriptions are written by authorised prescribers, and are accompanied by appropriate, contemporary haematological test results. Pharmacists will also need to update the clozapine monitoring system database in respect of the test results and medicine supply.

Given the administrative requirements, the number of patients being prescribed clozapine, and existing specialisation by some community pharmacies with links to public hospitals, the Department of Health expects that the new arrangements may be of relevance to only a small proportion of the community pharmacy network. Nevertheless, participation requirements will need to be documented and made available to the sector for consideration.

Should pharmacies be chosen through state-based selection processes such as Expressions of Interest to ensure availability in the areas in which eligible patients live? How best can eligible community-based patients be informed of available pharmacies from which they can obtain clozapine (see also issue 4, below)?

Existing restrictions regarding public hospital HSD prescriptions being dispensed by community pharmacies will be addressed under the new arrangements (see issue 6).

Community pharmacies wishing to participate will need to source clozapine stock. Currently, mandatory stocking requirements for PBS benefits by pharmaceutical wholesalers do not extend to PBS items listed solely under section 100 of the *National Health Act 1953* (Cth), such as Highly Specialised Drugs.

Current remuneration levels for pharmacists approved under section 90 of the *National Health Act 1953* (Cth) for supplying Highly Specialised Drugs is given in clause 13 of the Fifth Community Pharmacy Agreement, due to expire on 30 June 2015.

#### **ISSUE**

- How should community pharmacy participation in the new arrangements be managed?

#### **POSITION / COMMENT**

##### Selection / recruitment of pharmacies

- Pharmacies who are currently participating in shared-care programs and who already have contracts in place with their local Mental Health service, could be automatically accredited.

- Expressions of interest should be sought from other interested pharmacies wishing to become accredited to dispense clozapine.
- From July 1st 2015, community *pharmacies* will need to be accredited to supply clozapine, not the individual pharmacists, as the pharmacy with the PBS approval number will claim PBS payment. Accreditation of pharmacies will be needed, whereas current systems require the registration of individual *pharmacists* with a particular drug company database. The workload and process may restrict which pharmacies will want to become accredited.
- Professional contracts for interested proprietors will need to be in place outlining their responsibility to always have a trained/ accredited clozapine pharmacist on duty and the pharmacy would need to agree to comply with all of the professional responsibilities/ duty of care that comes with clozapine dispensing. The constant availability of a clozapine-accredited pharmacist after-hours may be a limiting issue. Contracts could be potentially be available through PSA and/or SHPA.

#### Location of pharmacies

- Ideally, the location of the pharmacies responding to an expression of interest will cover most geographic areas nationally. Appropriate remuneration and incentives for the community pharmacies to participate in the program should ensure enough interest. If remuneration and the system are not cost-effective or overly burdened with administration then comprehensive geographical coverage may not occur
- A state-based selection process for choosing which pharmacies will participate could work against the PBAC's goal of improving equity of access in the community for clozapine patients. The selection of particular pharmacies to dispense clozapine may require clients to visit a particular pharmacy. If this is different one from where they regularly fill all the other scripts there may be issues with access as the patient has to fill the clozapine script within restricted time according to when a prescription is issued. Issue of access, transport, organising the task may prove difficult for some.

#### Competencies / accreditation of pharmacist /pharmacies

- There have been a number of occasions already where clozapine has been dispensed in the community on a streamlined authority prescription without following the mandatory monitoring requirements. Professional contracts for proprietors will need to outline the requirement to always have a trained/ accredited clozapine pharmacist on duty.
- Accredited pharmacists could also be assessed for competence at regular intervals, similar to the process for medical practitioners as outlined in Section 2.
- As this will be a clinical service in addition to a supply program and requires both professional and clinical expertise to be present at the pharmacy through a

trained/competent pharmacist, participating pharmacies should be regularly assessed for appropriateness to deliver the service. That is, remuneration for the community pharmacy should be based not solely on the supply of the clozapine medication but also incorporate the clinical review and checks performed by the pharmacist.

#### Informing patients (see section 4, also)

- The hospital/clozapine centre should consider whether a community dispensing point will be of value to their patients and if it is required, collaborate with one or two dispensing points. This will be important as the Centre co-ordinator needs to be able to track supply in case of an adverse event requiring discontinuation.
- A register is necessary of all local community pharmacies registered / accredited to monitor and dispense clozapine in the area surrounding the hospital or centre.
- The patient's community Mental Health team and Clozapine Co-ordinator can assist in steering patients to a the appropriate participating clozapine-accredited pharmacy.

#### Coordination of haematology, prescribing and dispensing

- If community pharmacists are to be required to update the clozapine monitoring system database they will need to have reliable and timely access to the haematological results so dispensing is not delayed. The dispensing of clozapine must take place within a 48 hour period as per current clozapine dispensing practice.
- There needs to be clear guidelines on what the community pharmacist can do in scenarios such as when a patient is unable to pick up their clozapine with the 48 hour period.
- It may be easier and safer for each clozapine clinic / prescriber to be affiliated with a limited number of pharmacies per area (apart from in individual circumstances).
- It is important for the pharmacist to be able to contact appropriate prescribers easily and promptly if there are any queries with the prescription.
- A pharmacist needs to contact ClopineConnect / CPMS to transfer a patient each time one attends a new point of dispensing. If patient is transferring from one brand to another, they need to be re-registered as a completely new patient with the new monitoring service, which is time-consuming, but necessary for the pharmacies to understand.
- Guidelines and possible algorithms need to consider:
  - The quantity of clozapine that is to be supplied if an amber result is obtained.
  - The process (and quantity to supply) if a red result is obtained but the prescriber wishes to continue treatment.
  - The process if the retail pharmacy is unable to access information such as previous dose, date of last dispensing, and quantity supplied.

## 4. Patient choice of supplier

### **BACKGROUND**

As noted previously, given the administrative requirements, the number of patients being prescribed clozapine, and existing specialisation by some community pharmacies with links to public hospitals, the new arrangements may be of relevance to only a small proportion of the community pharmacy network.

If this transpires, eligible community-based patients may not be able to attend ANY community pharmacy to have their clozapine maintenance therapy prescriptions dispensed. Rather, there may need to be specific lists of participating pharmacies to guide patients.

Current agency arrangements are often managed by the public hospital at which the patient's treatment is initiated. Should these arrangements be extended to community-based supply after 1 July 2015?

### **ISSUE**

- How best can eligible community-based patients be informed of available pharmacies from which they can obtain clozapine?

### **POSITION / COMMENT**

#### Informing patients

- As the program is aiming to increase patient's independence and quality of life, a register of registered pharmacies should be maintained and available to all hospital pharmacies, accredited prescribers, the centre co-ordinator and case managers. This would ensure the patient can be referred to a pharmacy that is most convenient to them.
- Patients not near a current clozapine-accredited pharmacy could be advised of the location of others that may be close to their other health professional contacts, for instance, the prescriber.
- For ease of access for the patient, develop a national list of participating community pharmacies on a website which patients or their healthcare providers can check.
- During the transition stage of the program, a leaflet could be developed for all current patients explaining changes and new program. The leaflet could also have a list of resources and phone numbers on it as well.

#### Changing pharmacies

- There are significant benefits for clozapine patients, in terms of communication, patient safety and quality of care, to be part of a completely collaborative shared-care model, where the patient/ carer knows to inform all parties, including their GP, treating team, case manager, before making any changes to their pharmacy.

- Changing to a pharmacy less experienced in clozapine dispensing could adversely impact on patients, so careful consideration should be given regarding what information is communicated to patients about choice of pharmacies. Patients who are already in a shared-care model and obtaining clozapine from a community pharmacy and who are stable, should be encouraged to remain with that pharmacy unless there are issues of access, transport etc.
- The many benefits of patients staying with the same pharmacy should be outlined to patients.

## 5. Brand substitution

### **BACKGROUND**

The two brands of clozapine available in Australia are 'A flagged' in the Schedule of Pharmaceutical Benefits. This indicates that the sponsors of these brands have submitted evidence of bioequivalence or therapeutic equivalence, or that justification for not needing bioequivalence or therapeutic equivalence has been provided to the Therapeutic Goods Administration.

While this might suggest that pharmacists may supply either brand on presentation of a valid 'maintenance therapy' prescription, in practice this is inappropriate. Patients are initiated on a particular brand of clozapine within the hospital sector, and monitoring is conducted via the clozapine monitoring system set up, and maintained, by the sponsor/responsible person for that brand. Continuity of brand is important for patients and prescribers, and assists the product sponsors/responsible persons meet the conditions of registration of the products in the Australian Register of Therapeutic Goods.

Choice of brand during initiation is usually subject to state pharmaceutical tendering arrangements. In these cases, patients in a jurisdiction such as New South Wales will all be initiated on the same brand of clozapine during the period of operation of the tender arrangements.

### **ISSUE**

- While the two brands of clozapine are 'A-flagged' on the PBS, how should the community access arrangements take account of brand continuity in order to maintain clear reporting and ensure patient safety?

### **POSITION / COMMENT**

Brand-switching should be avoided in the treatment period as there are a number of disadvantages. It may cause confusion for the patients, affecting patient safety. Also, the monitoring of patient's haematological results would not be clear and continuous if results are alternated within the two databases ClopineConnect and Clozaril.

Possible ways to avoid brand-switching could include:

- The prescription should contain the brand name that patient is currently maintained / registered with and the prescriber should always utilise and ticks the "Brand Substitution Not Permitted" box on the PBS prescription.
- The PBS could remove the 'A' flag for Clozaril® and Clopine® brands. The situation might be similar to situation with Coumadin/ Marevan warfarin brands not being interchangeable.
- The patient's clozapine brand could be linked to their Medicare number, which uniquely identifies the patient. This would avoid the patient receiving duplicate brands, for instance, it would avoid patients being registered at one pharmacy with one brand and at another pharmacy with the other brand.
- However, the brands will need to be interchangeable if one company is out of stock and pharmacies are forced to use the other brand.

### **Combining databases**

Linking/ combining databases:

- The PBAC could approach Novartis and Hospira about the possibility of the two companies jointly developing software that is just one database. Then the brand could be chosen at the time of dispensing. This would allow pharmacies the freedom to choose brands but also maintain an accurate patient record. This would also avoid the potential issue of a patient being registered at two pharmacies each of which use a different database.
- The software would need to be linked to local shared-care models. The pharmaceutical company used by local hospitals/ shared-care providers should be chosen on their ability to deliver the optimal software and training/ technical support.
- If a single patient database is not possible the following may be an option:
  - Both clozapine databases be linked to the PBS, so the PBS only allows dispensing of the brand that matches the database on which the patient is enrolled. The pharmacist ticks that they have verified the blood results in the same database.
  - For example: a patient is registered on the Clopine® database but pharmacist wants to switch patient to Clozaril® brand. The pharmacist uploads bloods (if necessary) and selects in the Clopine® database that bloods have been viewed. This sends a message to the PBS.
    - if pharmacist tries to dispense Clozaril® brand, there is a PBS rejection a red cross will occur
    - pharmacist will only get a green tick/ approval from PBS if they dispense the Clopine® brand.

## 6. PBS administration matters

### **BACKGROUND**

Under the current arrangements, the process by which a prescriber obtains the appropriate PBS Authority to Prescribe approval differs depending on the setting. Prescribers operating in public hospitals use a STREAMLINED authority code when prescribing clozapine under the PBS. For patients in private hospital settings, prescribers are required to obtain phone authority approval from the Department of Human Services – Medicare, prior to prescribing.

These arrangements will be harmonised from 1 July 2015, with all prescribers using PBS Authority Required (STREAMLINED) processes, irrespective of prescribing setting. Valid prescriptions for clozapine will be able to be dispensed in public and private hospital pharmacies, and community pharmacies. No hospital provider number will be required on prescriptions.

PBS systems will differentiate between clozapine being prescribed in initial treatment, from maintenance treatment.

Pharmacists will still be required to ensure the patient's pathology results are within appropriate parameters prior to dispensing; this is facilitated through the use of the relevant patient monitoring database.

No amendment to PBS dispensing systems is envisaged (other than changes to PBS Item Codes to give effect to the changes described above.)

Changes will be given effect through amendments to the **National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010** (Cth).

### **ISSUE**

- Stakeholders may wish to comment on practical aspects of the PBS administration matters raised.

### **POSITION / COMMENT**

#### Authority system, codes, PBS and prescriptions

One harmonised single streamlined authority system for public and private hospital and community pharmacies to system is welcomed, however:

- The addition of a streamlined code for PBS differentiation of initiation and maintenance therapies may not be sufficient for the safe management of clozapine patients as such proposal assumes that dispensing and management in the maintenance phase is always routine. Patients may require smaller quantities because of blood results, potential for self-harm or may have to be re-initiated for other reasons.
- In the situation of the prescriber choosing the incorrect code, that is, non-maintenance instead of maintenance, continuing supply to the patient may be threatened if the community pharmacy's ability to dispense is restricted.
- The type of prescription allowable requires clarification. NSW public hospital pharmacists generally understand that they cannot dispense a prescription that has been written in a private setting on a PBS stationary (e.g. from specialists' rooms not associated with public hospital; or GP clinic) and can only dispense from public



hospital prescription stationary. Clarification is required as to the ability of hospital pharmacies to dispense a PBS script on PBS prescription stationary with the correct (maintenance) code selected but generated by a community prescriber from a practice or clinic that has no association with the hospital, after July 1<sup>st</sup>, 2015.

- Prescribing software will require updating to allow/ default to a quantity of 28 days' supply when a dose/ strength is chosen, instead of the current default of 100 tablets or PBS max of 200 tablets per strength. It is currently the responsibility of pharmacists to dispense only 28 days, which has taken substantial training by clozapine liaison pharmacists within the present shared-care model. After July 1st 2015, community pharmacists may dispense exactly what is prescribed, such as full packs for scripts of 100 or 200 tablets, as is the current practice for most other PBS medicines.
- After July 1<sup>st</sup>, 2015, the maximum notice possible from the PBS (i.e. greater than the usual 7 days' notice) around any changes to PBS Streamlined Authority codes is recommended to allow appropriate communication of any new codes to prescribers, otherwise this may hold up dispensing by the community pharmacies or effect patient charges.

#### Coordination of haematology results and dispensing

- The dispensing pharmacy will need to receive a copy of the patient's blood results, via fax or directly from the Pathology Provider to the patient's clozapine database, or potentially, the pharmacy. This will rely on the prescriber correctly identifying the recipient of the results and consideration of secure messaging of patient data.
- A process of ensuring the pharmacist has sighted and reviewed the bloods results is required to be electronically recorded before PBS dispensing is allowed.
- A system/ guideline is required to be developed for times when either of the databases are down; that is, at times when the clozapine monitoring system is down or times when the PBS is down. The pharmacists may still be able to manually check the blood results, but can't dispense until the green PBS approval tick is given.

#### Co-payments

Before the system is altered, it is necessary for agreement in advance as to how co-payments will be applied:

- Usually, \$100 medications are charged as one co-payment per strength and per dispensing. For instance, if a patient requires three strengths of clozapine tablets for their dose, they are – in some cases- charged three co-payments each time the medication is dispensed. If a patient is prescribed only one week's supply of clozapine (e.g. if an amber blood result is obtained), there is a charge each time the medication is dispensed.
- Presently, as a "duty of care" consideration to improve compliance, in some public hospitals, one co-payment is charged per month, regardless of the number of strengths of clozapine supplied and number of times dispensed that month. Other

co-payment costs are absorbed by the hospital. Such practices may differ in other clozapine centres.

- Due to limited resources and in consideration of "duty-of-care", there is currently little or no follow up of outstanding co-payments for clozapine by some hospital pharmacies. Payment is frequently outstanding for clozapine supplies that have not been collected by the patient themselves, where an invoice has been generated. This may become an issue for the patient.
- In summary, the PBS requirement for patient contribution may need to be reviewed for this patient population, consider either nil co-payments or a single co-payment each month, not per strength of medication issued. Co-payment may be to be a driver for non-compliance and a risk for admission.

## 7. Health professional education / training

### **BACKGROUND**

In 2012, the then Highly Specialised Drugs Working Party drafted *principles for shared care arrangements* that included (inter alia):

- the safety of patients must be assured;
- HSD medicines are by nature specialised and this status must be acknowledged;
- specialist oversight of care must be maintained in some fashion;
- prescribing and dispensing should occur by appropriately competent professionals; and
- there should be no loss of quality of service surrounding HSDs for health consumers.

These draft principles, and the background given in issues 2 and 3, support the use of formal education and certification for community based prescribers and dispensers.

There is no national existing material on clozapine that is comparable to the Australasian Society for HIV Medicine's *National Standards for Accreditation of Community HIV s100 Prescriber Education, CPD, and Certification of HIV s100 Prescribers*.

### **ISSUE**

- what education material should be available to support certification of community-based prescribers and dispensers to participate in the new community access arrangements?
- who should manage these processes?

### **POSITION / COMMENT**

#### Multidisciplinary training and assessments

Community prescribers and pharmacists could undergo joint training sessions with some use of on-line modules. Interdisciplinary sessions would additionally enable opportunities for networking between hospital and community prescribers and pharmacists and mental health teams. Education and training could be provided by relevant professional bodies; for pharmacists by SHPA and/or PSA and possibly NPS or the Australian Commission on Safety and Quality in Healthcare, with assessment undertaken initially and regularly thereafter.

Other system-based approaches to mitigate potential harm to patients are:

- the inclusion of a mandatory field in the PBS dispensing process, so dispensing cannot proceed until the pharmacist ticks that the patient's FBC results have been sighted and/ or that these are in appropriate range; and the due date for the next FBC is checked;
- mandatory safety alerts to be built in to prescribing and dispensing software; and
- flagging of the need for the patient, prescriber and pharmacist to be accredited/ registered with the relevant clozapine program.

#### Community prescribers

- Accreditation requirements could be communicated to prescribers by organisations such as RACGP or via a national *Position Statement on Clozapine* from a Chief Psychiatrist's professional body. Alternatively, a joint National Position Statement on

clozapine prescribing/ S100 dispensing (similar style to HIV National Standards document) could be developed.

- Clozapine prescribers need to be trained to specify each strength and quantity so that 28 days' supply is not exceeded.

### Pharmacists

Specific training required regarding:

- requirement of 28 days' dispensing quantities, at the most or only up until the next blood test due date or to a maximum of 2 days beyond (as per 48 hour rule);
- optimal management of red/ amber patient blood results by contacting the clozapine co-ordinator or the patient's specialist/ prescriber or by checking patient's clinical notes on the clozapine monitoring database before determining what to dispense;
- knowing when to refer clozapine patients back to the prescriber / hospital and how to recognise clinically deteriorating patients (clear guidelines are required);
- specific training appropriate to the brands of clozapine being dispensed and the relevant databases; and
- consideration should be given to training pharmacists on the level of disability associated with schizophrenia, understanding patient's concerns and the level of follow-up needed to encourage compliance.

## 8. Other

### Clozapine co-ordinator

This consultation concerning the clozapine community program after July 1<sup>st</sup>, 2015, assumes that the vital role of the clozapine co-ordinator is retained at a regional and local level. This is strongly recommended. The co-ordinator:

- will remain responsible for blood results; that is, results that are missing or out of range will be forwarded to the coordinator for action. This is a position currently supplied in NSW by hospitals or parts of NSW Health;
- will be required to communicate with several community pharmacies, pharmacists and prescribers in addition to the hospital pharmacy, case worker and psychiatrist. More resources will be required for the Clozapine Centre co-ordinator in keeping track of the various authorised personnel and possible dispensing points for patients;
- will be required to track when patients are due for their appointments or provide guidance as to the follow-up and relevant responsibilities of community healthcare professionals.

Overall clinical governance of the patient is presumably to remain with the specialist psychiatrist and the personnel associated with the hospital/Clozapine Centre. If there is a failure in the proposed system in the wider Community and something does go wrong, there is the question of liability.

### Resources during the transition

There is likely to be an extensive transition period resulting from the hospital's handover to the new community model of care, after July 2015, which will require mental health hospital pharmacy resources being available to provide ongoing support in a troubleshooting capacity.

### Management of adverse events

A systems-based approach is required to be developed before the transition to community-care to the recognition and management of adverse events, such as agranulocytosis. Algorithms and guidelines are mandatory to inform the process of ceasing therapy and ensuring that medication is not accessible for the patient, but also that referral pathways are followed. Follow-up monitoring and reporting may be more difficult when the prescribing and dispensing information is fragmented.

## Glossary of abbreviations used:

MH	Mental Health
GP	General Practitioner
COB	Close of Business
PBS	Pharmaceutical Benefits Scheme
PBAC	Pharmaceutical Benefits Advisory Committee
PSA	Pharmaceutical Society of Australia
SHPA	Society of Hospital Pharmacists of Australia
RACGP	Royal Australian College of General Practitioners
CATAG	Council of Australian Therapeutic Advisory Groups
PDL	Pharmaceutical Defence Limited
FBC	Full Blood Count