

MINOR LISTINGS AND CHANGES TO LISTINGS PROCESSED BY THE SECRETARIAT FOR CONSIDERATION BY THE COMMITTEE

14.02 CLOZAPINE

Oral liquid 50 mg per mL, 100 mL, Versacloz[®], Pfizer Australia Pty Ltd

1 Purpose of Application

- 1.1 The submission requested temporary Authority Required and Authority Required (STREAMLINED), Section 100 Highly Specialised Drugs Program (HSD) Public Hospital, Private Hospital and Community Access listings of clozapine (Versacloz[®]) on the Pharmaceutical benefits Schedule (PBS) as an alternative to the currently listed clozapine (Clopine Suspension[®], 50 mg per mL clozapine suspension), to address the current supply shortage issue.

2 Requested Listing

- 2.1 The submission requested identical listing price, pack size and authority conditions as Clopine Suspension[®].

3 Background

- 3.1 On 29 March 2018, the Therapeutic Goods Administration (TGA) approved the importation and supply of Versacloz[®] (clozapine, 50 mg/mL oral suspension) in Australia, under Section 19A(1) of the *Therapeutic Goods Act 1989*.
- 3.2 A letter of request from the sponsor was reviewed by the PBAC Secretariat in April 2018 to request a temporary PBS listing of Versacloz[®] clozapine 50 mg/mL oral suspension in the interest to address a supply shortage in Australia.
- 3.3 Versacloz[®] is a USA-based product, which has the same form and strength as the existing clozapine oral suspension on the PBS.

4 Pricing considerations

- 4.1 There will be no pricing implications, as the sponsor proposed the same price as the currently listed clozapine (AEMP \$135) and this listing is not expected to grow the market.

5 PBAC Outcome

- 5.1 The PBAC recommended the temporary Section 100 Highly Specialised Drugs Program (HSD) and Section 100 Community Access listings of clozapine (Versacloz®) on the Pharmaceutical Benefits Scheme (PBS) to address the current supply shortage of clozapine (Clopine Suspension®, 50 mg per mL clozapine suspension).
- 5.2 The PBAC considered that there is a clinical need for the supply of clozapine to be maintained on the PBS. The PBAC considered that the listing should remain during the validity of the Section 19A(1) approval by the TGA.
- 5.3 The PBAC considered that listings should have the same authority conditions as Clopine Suspension® Authority Required or streamlined listings and is not suitable for inclusion for prescribing by nurse practitioners, similar to existing listings. The PBAC noted the name of the patient monitoring program previously attached to the former Hospira brand of clozapine (Clopineconnect) had changed to Pfizer ClopineCentral (following a company merger), and considered this should be amended for the listing of the Versacloz® brand and flowed on to all Clopine® listings as they are now sponsored by Pfizer Australia Pty Ltd.

Outcome:

Recommended

6 Recommended Listing

Add new item – same restrictions for item 10341G (S100 HSD Community Access), 5630H (S100 HSD Public) and 9632Y (S100 HSD Private). Amend administrative note for all clozapine listings to update patient monitoring system terminology as follows:

“Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: ~~Novartis Mylan Clozaril Patient Monitoring System (eCPMS)~~ or *Pfizer ClopineCentral Hospira Clopineconnect*.

Public Summary Document – July 2018 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
CLOZAPINE Oral liquid 50 mg per mL, 100 mL	1	0	Versacloz®	Pfizer Australia Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program – Public and Private Hospitals
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Schizophrenia
PBS Indication:	Schizophrenia
Treatment phase:	Initial treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing (Private) <input checked="" type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required – Electronic (Private) <input checked="" type="checkbox"/> Streamlined (Public)
Treatment criteria:	Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.
Clinical criteria:	Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents.
Prescribing instructions:	Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.
Administrative advice:	Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

Public Summary Document – July 2018 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
CLOZAPINE Oral liquid 50 mg per mL, 100 mL	1	0	Versacloz®	Pfizer Australia Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program – Community Access
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Schizophrenia
PBS Indication:	Schizophrenia
Treatment phase:	Continuing treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing (Private) <input type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic (Private) <input checked="" type="checkbox"/> Streamlined (Public)
Treatment criteria:	Must be treated by a psychiatrist; OR Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.
Clinical criteria:	Patient must have previously received PBS-subsidised therapy with this drug for this condition, AND Patient must have completed at least 18 weeks therapy, AND Patient must be on a clozapine dosage considered stable by a treating psychiatrist, AND The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.
Prescribing instructions:	A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.
Administrative advice:	Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.