5.19 CLOZAPINE,
Tablet 12.5 mg (orally disintegrating),
Tablet 25 mg (orally disintegrating),
Tablet 50 mg (orally disintegrating),
Tablet 100 mg (orally disintegrating),
Tablet 200 mg (orally disintegrating),
Clozaril ODT®,
Viatris Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission requested listing of new orally disintegrating tablet (ODT) forms of clozapine for the treatment of patients with treatment-resistant schizophrenia who are non-responsive or intolerant to other antipsychotic therapies, under the same restrictions as the currently listed tablet forms on the PBS Section 100 Highly Specialised Drugs (S100 HSD) Program.

1.2 Listing was requested based on a cost-minimisation approach for clozapine ODT compared against existing oral tablet forms of clozapine and their equivalent strengths listed on the PBS.

2 Background

2.1 Current PBS listings for clozapine include 25 mg, 50 mg, 100 mg and 200 mg oral tablets (Clopine®, Clozitor®, and Clozaril® brands), and 50 mg/mL oral liquid (Versacloz® and Clopine® Suspension brands). A 12.5 mg oral tablet is not currently PBS-listed. Clozapine is listed on the S100 HSD Program (Community Access, Public and Private) as an Authority Required (STREAMLINED) listing for patients with schizophrenia that is non-responsive or intolerant of other neuroleptic agents.

Registration status

2.2 Clozaril ODT was TGA registered on 30 March 2026 for treatment-resistant schizophrenia.

Previous PBAC consideration

2.3 The PBAC has not previously considered clozapine ODT (Clozaril ODT®) for the treatment of schizophrenia.

3 Requested listing

3.1 The proposed listings for initiation and continuing treatment phases for Clozaril ODT are listed below and mirror the restrictions for current PBS listings of clozapine oral tablets.

3.2 The submission requested the following new listings of Clozaril ODT for the treatment of schizophrenia on the S100 HSD Program:

Add new medicinal product as follows:

MEDICINAL PRODUCTmedicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CLOZAPINE					
clozapine 25 mg orally disintegrating tablet, 100	NEW (HS) NEW (HB) MP	2	200	0	Clozaril ODT
clozapine 50 mg orally disintegrating tablet, 100	NEW (HS) NEW (HB) MP	2	200	0	Clozaril ODT
clozapine 100 mg orally disintegrating tablet, 100	NEW (HS) NEW (HB) MP	2	200	0	Clozaril ODT
clozapine 200 mg orally disintegrating tablet, 100	NEW (HS) NEW (HB) MP	2	200	0	Clozaril ODT

Restriction Summary / Treatment of Concept	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Streamlined) [new]
	Authority type: ☒ Non-complex Authority Required (non-CAR)
	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.
	Indication: Schizophrenia
	Treatment Phase: Initial treatment
	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.
	Prescribing Instructions: The name of the consulting psychiatrist should be included in the patient's medical records.
	Prescribing Instructions: A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CLOZAPINE					
clozapine 12.5 mg orally disintegrating tablet	NEW (HS) NEW (HB) MP	1	10	0	Clozaril ODT

Restriction Summary / Treatment of Concept	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Streamlined) [new]
	Authority type: ☒ Non-complex Authority Required (non-CAR)
Prescribing rule	**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.
	Indication: Schizophrenia
	Treatment Phase: Initial treatment
	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.
	Prescribing Instructions: The name of the consulting psychiatrist should be included in the patient's medical records.
	Prescribing Instructions: A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CLOZAPINE					
clozapine 25 mg orally disintegrating tablet, 100	NEW (CA) MP	2	200	0	Clozaril ODT
clozapine 50 mg orally disintegrating tablet, 100	NEW (CA) MP	2	200	0	Clozaril ODT
clozapine 100 mg orally disintegrating tablet, 100	NEW (CA) MP	2	200	0	Clozaril ODT
clozapine 200 mg orally disintegrating tablet, 100	NEW (CA) MP	2	200	0	Clozaril ODT

Restriction Summary / Treatment of Concept	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Streamlined) [new]
	Authority type: ☒ Non-complex Authority Required (non-CAR)
Prescribing rule	**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.
	Indication: Schizophrenia
	Treatment Phase: Continuing treatment
	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
	Clinical criteria:
	Patient must have completed at least 18 weeks therapy
	AND
	Clinical criteria:
	Patient must be on a clozapine dosage considered stable by a treating psychiatrist
	AND
	Clinical criteria:
	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.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CLOZAPINE					
clozapine 12.5 mg orally disintegrating tablet	*NEW (CA)* MP	1	10	0	Clozaril ODT
Restriction Summary / Treatment of Concept					
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (Streamlined) [new]				
	Authority type: ☒ Non-complex Authority Required (non-CAR)				
Prescribing rule	**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..				
	Indication: Schizophrenia				
	Treatment Phase: Continuing treatment				
	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				
	Clinical criteria:				
	Patient must have completed at least 18 weeks therapy				
	AND				
	Clinical criteria:				
	Patient must be on a clozapine dosage considered stable by a treating psychiatrist				
	AND				
	Clinical criteria:				
	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.				

4 Comparator

4.1 The submission proposed a new form of clozapine ODT and compared this to the currently listed clozapine oral tablets.

4.2 The PBAC noted that the TGA accepted bioequivalence of Clozaril ODT to Clozaril tablets. The submission claimed that Study CLOZ-ODT-1002, a single-dose oral bioequivalence study of clozapine ODT 12.5 mg versus 12.5 mg dose (delivered as half a tablet) of clozapine 25 mg tablet, demonstrated bioequivalence of clozapine ODT 12.5 mg with the same strength of clozapine tablet (half a 25 mg tablet).

4.3 The PBAC advised under Section 101 (3BA) of the *National Health Act 1953* that Clozaril ODT should be treated as interchangeable ('a' flagged) with the equivalent strength of clozapine oral tablets.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no sponsor hearing for this item.

Consumer inputs

5.2 The PBAC noted that no consumer inputs were received for this item.

Clinical evidence

5.3 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

Economic analysis

5.4 As a Category 4 submission, the economic analysis has not been independently evaluated.

5.5 The submission presented a cost-minimisation approach of clozapine ODT compared with clozapine oral tablets. The PBAC considered the modelling approach to be appropriate.

Estimated PBS usage and financial implications

5.6 The requested price was based on the AEMP of clozapine oral tablets currently listed on the PBS. Table 1 provides a summary of estimated use and financial implications. The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of Clozaril ODT is a saving of around $0 to < $10 million over six years. The estimated saving was proposed to result from reduced wastage of 25 mg tablets when used for initiation, due to the listing of the 12.5 mg ODT pack. The PBAC considered that the proposed listing would likely result in a nil financial impact to the PBS.

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed[a]	[redacted][1]	[redacted][2]	[redacted][3]	[redacted][4]	[redacted][4]	[redacted][5]
Estimated financial implications of Clozaril ODT						
Cost to PBS less co-payment ($)	[redacted][6]	[redacted][7]	[redacted][8]	[redacted][9]	[redacted][8]	[redacted][9]
Cost to RPBS less co-payment ($)	[redacted][6]	[redacted][7]	[redacted][8]	[redacted][9]	[redacted][8]	[redacted][9]
Estimated financial implications of clozapine oral tablets						
Cost to PBS less co-payment ($)	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]
Cost to RPBS less co-payment ($)	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]
Net financial implications						
Net cost to PBS/RPBS ($)	-[redacted][10]	-[redacted][10]	-[redacted][10]	-[redacted][10]	-[redacted][10]	-[redacted][10]

[a] Assuming number of scripts per year as estimated by the submission.
Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Clozaril UCM, sheet 5
The redacted values correspond to the following ranges:
[1] *20,000 to < 30,000*
[2] *40,000 to < 50,000*
[3] *80,000 to < 90,000*
[4] *100,000 to < 200,000*
[5] *200,000 to < 300,000*
[6] *$0 to < $10 million*
[7] *$10 million to < $20 million*
[8] *$20 million to < $30 million*
[9] *$30 million to < $40 million*
[8] *$40 million to < $50 million*
[9] *$50 million to < $60 million*
[10] *net cost saving*

Quality use of medicines

5.7 The proposed restriction includes a requirement for the patient to be registered in the relevant clozapine patient monitoring program for the brand.

6 PBAC Outcome

6.1 The PBAC recommended the listing of clozapine orally disintegrating tablets (Clozaril ODT®) on the PBS for the treatment of schizophrenia in patients who are non-responsive to, or intolerant of, other neuroleptic agents, under the same restrictions as the currently listed clozapine oral tablets.

6.2 The PBAC noted that Clozaril ODT® is a new formulation of clozapine and noted that it would provide an additional dosage form for patients requiring clozapine treatment, without changing the place in therapy of clozapine, the eligible patient population, or the expected utilisation of clozapine.

6.3 The PBAC noted that the submission was presented on a cost-minimisation basis compared with currently listed clozapine oral tablets and considered this approach appropriate for a Category 4 submission. The PBAC advised that the orally

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disintegrating tablet formulation should be treated as equivalent to the corresponding strength of currently listed clozapine oral tablets for pricing purposes.

6.4 The PBAC advised that the equi-effective dose should be clozapine 1 mg oral tablets to clozapine 1 mg ODT. Noting that a 12.5 mg oral tablet was not a currently PBS-listed dose and that there was a slight variance in the cost per mg between different strengths of clozapine tablets listed, the PBAC advised that the price proposed for the 12.5 mg ODT in the submission was based on cost-minimisation to currently listed clozapine oral tablets.

6.5 The PBAC advised that Clozaril ODT® should be treated as interchangeable on an individual patient basis with other oral tablet clozapine products, subject to the requirements of the relevant clozapine patient monitoring program.

6.6 The PBAC noted that the 12.5 mg ODT form did not have an equivalent pack size currently available on the PBS. The PBAC recommended that the 10 pack of the 12.5 mg ODT form be made available under the 'initial' and 'continuing' treatment phase.

6.7 The PBAC noted that this submission is not eligible for an Independent Review as it had received a positive recommendation.

Outcome:
Recommended

7 Recommended listing

Add new item:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CLOZAPINE					
clozapine 25 mg orally disintegrating tablet, 100	NEW (HS) NEW (HB) MP	2	200	0	Clozaril ODT
clozapine 50 mg orally disintegrating tablet, 100	NEW (HS) NEW (HB) MP	2	200	0	Clozaril ODT
clozapine 100 mg orally disintegrating tablet, 100	NEW (HS) NEW (HB) MP	2	200	0	Clozaril ODT
clozapine 200 mg orally disintegrating tablet, 100	NEW (HS) NEW (HB) MP	2	200	0	Clozaril ODT

Restriction Summary / Treatment of Concept	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Streamlined) [new]
	Authority type: ☒ Non-complex Authority Required (non-CAR)
Prescribing rule	**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..
	Indication: Schizophrenia
	Treatment Phase: Initial treatment
	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.
	Prescribing Instructions: The name of the consulting psychiatrist should be included in the patient's medical records.
	Prescribing Instructions: A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CLOZAPINE					
clozapine 12.5 mg orally disintegrating tablet	NEW (CA) MP	1	10	0	Clozaril ODT
Restriction Summary / Treatment of Concept					
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (Streamlined) [new]				
	Authority type: ☒ Non-complex Authority Required (non-CAR)				
Prescribing rule	**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.				
	Indication: Schizophrenia				
	Treatment Phase: Continuing treatment				
	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				
	Clinical criteria:				
	Patient must have completed at least 18 weeks therapy				
	AND				
	Clinical criteria:				
	Patient must be on a clozapine dosage considered stable by a treating psychiatrist				
	AND				
	Clinical criteria:				
	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.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CLOZAPINE					
clozapine 25 mg orally disintegrating tablet, 100	NEW (CA) MP	2	100	0	Clozaril ODT
clozapine 50 mg orally disintegrating tablet, 100	NEW (CA) MP	2	100	0	Clozaril ODT
clozapine 100 mg orally disintegrating tablet, 100	NEW (CA) MP	2	100	0	Clozaril ODT
clozapine 200 mg orally disintegrating tablet, 100	NEW (CA) MP	2	100	0	Clozaril ODT

Restriction Summary / Treatment of Concept	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Streamlined) [new]
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Prescribing rule	**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.
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	Clinical criteria:
	Patient must have previously received PBS-subsidised therapy with this drug for this condition
	AND
	Clinical criteria:
	Patient must have completed at least 18 weeks therapy
	AND
	Clinical criteria:
	Patient must be on a clozapine dosage considered stable by a treating psychiatrist
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	Clinical criteria:
	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.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CLOZAPINE					
clozapine 12.5 mg orally disintegrating tablet	NEW (CA) MP	1	10	0	Clozaril ODT

Restriction Summary / Treatment of Concept	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program - Community Access (Code CA)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Streamlined) [new]
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Prescribing rule	**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.
	Indication: Schizophrenia
	Treatment Phase: Continuing treatment
	Treatment criteria:
	Must be treated by a psychiatrist; or
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	Clinical criteria:
	Patient must have previously received PBS-subsidised therapy with this drug for this condition
	AND
	Clinical criteria:
	Patient must have completed at least 18 weeks therapy
	AND
	Clinical criteria:
	Patient must be on a clozapine dosage considered stable by a treating psychiatrist
	AND
	Clinical criteria:
	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.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available

through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.