6.09 Lamotrigine for bipolar disorder

1 Purpose of item

That the Pharmaceutical Benefits Advisory Committee (PBAC):

1.1 **Provide advice** on the cost estimates to the Pharmaceutical Benefits Scheme (PBS) of a new Restricted Benefit listing for lamotrigine (LTG) for bipolar disorder (the "proposed listing").

1.2 **Provide advice** on the PBS restriction for the proposed listing.

1.3 **Note** the pre-PBAC responses.

2 Background

2.1 At its September 2020 meeting, the PBAC recommended amending the PBS restrictions to allow for the first-line use of levetiracetam (LEV) and LTG in women of childbearing potential. These restriction changes took effect on 1 January 2021. These restriction changes followed feedback from the Epilepsy Society of Australia (ESA) on best practice clinical management of epilepsy for women of childbearing potential. The PBAC noted that the previous PBS restrictions for LEV and LTG restricted access to those who had failed to have their epilepsy controlled with other anti-epileptic drugs (AEDs) and may have resulted in prescribers continuing to use valproate among women of childbearing potential when safer options were available. The PBAC also requested that the Department provide to the Drug Utilisation Sub-Committee (DUSC):

- utilisation data and any further evidence on the broader use of other second-line AEDs, and;
- estimates of cost to the PBS of allowing first-line use of LEV and LTG in the remaining population with epilepsy (i.e., males and females of all ages).

2.2 In September 2023, the DUSC considered the *Utilisation analysis of PBS-listed AEDs in a cohort of epilepsy patients*. The DUSC was also requested to advise the Department on the development of the cost estimates to the PBS of allowing first-line use of LEV and LTG in the remaining population with epilepsy (i.e., males and females of all ages).

2.3 In April 2024, the Department commissioned the Centre for Medicine Use and Safety (CMUS), Monash University to:

- undertake a systematic literature review to identify relevant clinical guidelines for the use of AEDs for the treatment of epilepsy and compare these to the PBS restrictions and Therapeutic Goods Administration (TGA)-approved indications for these medicines, and;
- estimate the cost to the PBS of expanding the restrictions for the second-line AEDs LEV and LTG to allow their first-line use in the general Australian population with epilepsy.

2025 PBAC and DUSC consideration

2.4 The *Review of clinical guidelines and cost estimates for the use of AEDs for the treatment of epilepsy* report was considered by the DUSC at its April 2025 meeting and by the PBAC at its May 2025 Intracycle meeting.[1]

2.5 Overall, the PBAC accepted the key findings from the Review of AEDs including the estimates of cost to the PBS of allowing first-line use of LEV and LTG in the general Australian population with epilepsy (the "proposed listings"). The PBAC noted the findings of the review of clinical guidelines that two Australian guidelines and most international guidelines recommend LEV and/or LTG as first-line antiseizure medications in adults with focal and/or generalised seizures.

2.6 The PBAC considered the estimated cost to the R/PBS of allowing first-line use of LEV and LTG in the general Australian population with epilepsy was reasonable ($1.2 million in 2025 increasing to $4.4 million in 2030). In addition, the proposed listings were expected to have a minimal impact on the utilisation of the more expensive third-line antiseizure medications.

2.7 The PBAC recommended amending the PBS restrictions for LEV (tablets and liquid forms) and LTG (tablets) to Restricted Benefit listings for "epileptic seizures" and removal of the following clinical criteria from the current listings: "The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR Patient must be a woman of childbearing potential." This restriction change was implemented on 1 November 2025 and allowed the subsidised first-line use of these medicines in the general Australian population with epilepsy.

2.8 The PBAC noted the analysis of the private market which was used to estimate the current extent of private (non-PBS) use of LEV and LTG. The PBAC agreed the private market for LEV appears to be small, while the private market for LTG appears to be significantly larger than LEV; likely due to LTG use in conditions such as bipolar disorder and trigeminal neuralgia.

2.9 The PBAC considered there may be an unmet need to subsidise LTG for mental illnesses such as bipolar disorder. The PBAC recommended in principle extending subsidy of LTG to this indication and requested that the Department undertake further work to estimate the cost to the R/PBS of a separate Restricted Benefit listing for LTG for bipolar disorder for its consideration at a future meeting.

Sponsor and stakeholder consultation

2.10 On 7 October 2025, the PBAC overview paper was distributed to sponsors of LTG, the Royal Australian and New Zealand College of Psychiatrists (RANZCP), the Royal Australian College of General Practitioners (RACGP), and the National Aboriginal Community Controlled Health Organisation (NACCHO), inviting them to submit a pre-PBAC response in line with standard PBAC processes and timelines.

[1] https://www.pbs.gov.au/info/reviews/review-of-clinical-guidelines-and-cost-estimates-for-the-use-of-aeds

3 Proposed listing

3.1 LTG is currently listed on the PBS for "epileptic seizures" in the following dosage forms:

- lamotrigine 5 mg tablet, 56
- lamotrigine 25 mg tablet, 56
- lamotrigine 50 mg tablet, 56
- lamotrigine 100 mg tablet, 56
- lamotrigine 200 mg tablet, 56

3.2 The following outlines the proposed new Restricted Benefit listing for LTG for bipolar disorder.

Restricted Benefit Indication: Bipolar disorder Treatment criteria: Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner

3.3 The proposed listing is supported by Australian clinical guidelines. For example, the electronic Therapeutic Guidelines (eTG) recommends LTG as first-line monotherapy for the treatment of bipolar depression; and as second-line monotherapy for the prophylaxis of bipolar disorder in adults and young people according to the following regimen:

Lamotrigine 25 mg orally, at night for 2 weeks; increase to 50 mg at night for 2 weeks; increase to 100 mg at night for 1 week; increase to 200 mg at night. Maximum daily dose of 400 mg. Continue for at least 6 to 12 months to prevent relapse, then assess if prophylaxis is required.[2]

In addition, three of the eight brands of LTG listed on the PBS are TGA-approved for the prevention of depressive episodes in patients with bipolar disorder as well as for the treatment of partial and generalised seizures in adults and children (Lamictal®, Lamotrigine GH® and Sandoz Lamotrigine®).

3.4 The PBAC was asked to consider and provide advice on several aspects of the proposed restriction for LTG for bipolar disorder, including:

- Whether the 5 mg tablet form of LTG should be included in the listing, given that the recommended starting dose for this indication is 25 mg at night for two weeks.
- The appropriateness of a 60-day PBS listing for this indication, noting that a 60-day listing has been available for LTG for epileptic seizures since 1 March 2024.
- Whether nurse practitioners should be permitted to prescribe LTG for bipolar disorder under the PBS, consistent with the current prescribing arrangements for epileptic seizures.

[2] https://tgldcdp.tg.org.au/viewTopic?etgAccess=true&guidelinePage=Psychotropic&topicfile=depressive-episodes-bipolar-disorder&guidelinename=Psychotropic&sectionId=toc_dle569#toc_dle569. Accessed 12 September 2025.

- Whether an Unrestricted Benefit listing would be more appropriate than a Restricted Benefit listing, noting that an Unrestricted Benefit listing may increase PBS-subsidised use of LTG for conditions beyond epilepsy and bipolar disorder (such as for trigeminal neuralgia).

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Financial impact to the R/PBS of the proposed listing

Market analysis

4.1 To estimate the total size of the LTG market, data on the number of LTG units supplied by wholesalers to retail pharmacies between 2020 and 2024—broken down by strength (5 mg, 25 mg, 50 mg, 100 mg, and 200 mg)—was sourced from the Australian Pharmacy Index (API) dataset provided by IQVIA (see Table 1). The API dataset captures sell-in data from pharmaceutical wholesalers and manufacturers supplying directly to retail pharmacies and covers approximately 96% of wholesalers.

Table 1: Lamotrigine units supplied by wholesalers to retail pharmacies (total market)

	2020	2021	2022	2023	2024
LTG 5mg	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
LTG 25mg	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
LTG 50mg	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
LTG 100mg	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
LTG 200mg	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total	**839,291**	**925,507**	**998,057**	**1,036,146**	**1,109,326**

4.2 The number of units for each strength of LTG supplied through the R/PBS from 2020 to 2024 was determined using the number of R/PBS scripts supplied for LTG (see Table 2). These figures were sourced from the Department's R/PBS Section 85 Date of Supply Data and includes under co-payment prescriptions. With the introduction of 60-day listings for LTG on 1 March 2024, each R/PBS script from 2020–2023 was counted as one unit. In 2024, one 30-day script was considered equivalent to one unit, while one 60-day script was counted as two units of LTG.

Table 2: Lamotrigine units supplied via the R/PBS (R/PBS market)

	2020	2021	2022	2023	2024
LTG 5mg	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
LTG 25mg	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][3]
LTG 50mg	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]
LTG 100mg	[redacted][3]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]
LTG 200mg	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]
Total	**525,419**	**547,600**	**571,826**	**579,754**	**646,246**

The redacted values correspond to the following ranges:
[1] 500 to < 5,000
[2] 60,000 to < 70,000
[3] 70,000 to < 80,000
[3] 100,000 to < 200,000
[4] 200,000 to < 300,000

4.3 The size of the private market for each strength of LTG (in units) from 2020 to 2024 was determined by subtracting the number of R/PBS units from the total market units.

Projections for private LTG units by strength from 2025 to 2031 were then estimated using a linear forecast based on the 2020–2024 data (see Table 3).

Table 3: Lamotrigine units supplied in the private (non-PBS) market

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
LTG 5mg	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
LTG 25mg	[redacted][2]	[redacted][3]	[redacted][4]	[redacted][4]	[redacted][3]	[redacted][4]	[redacted][4]	[redacted][3]	[redacted][3]	[redacted][4]	[redacted][3]	[redacted][3]
LTG 50mg	[redacted][2]	[redacted][3]	[redacted][4]	[redacted][5]	[redacted][5]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]
LTG 100mg	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]
LTG 200mg	[redacted][3]	[redacted][5]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]	[redacted][6]
Total	**313,872**	**377,907**	**426,231**	**456,392**	**463,080**	***520,567***	***545,486***	***573,156***	***606,517***	***643,600***	***669,994***	***703,589***

The redacted values correspond to the following ranges:
[1] 500 to < 5,000
[2] 60,000 to < 70,000
[3] 70,000 to < 80,000
[4] 80,000 to < 90,000
[5] 90,000 to < 100,000
[6] 100,000 to < 200,000
[7] 200,000 to < 300,000

Cost estimates

4.4 The utilisation and cost model (UCM) workbook was used to estimate the cost to the R/PBS of the proposed listing for the period 2026–2031. In this model, the private script volume for each strength of LTG was assumed to match the number of LTG units supplied in the private market from 2026 to 2031 (see Table 3 above). The base-case analysis assumed that 95% of private LTG scripts are used for bipolar disorder and that the uptake rate of the proposed listing would be 95% (i.e., 95% of private scripts for bipolar disorder would transition to R/PBS scripts as a result of the proposed listing). For each strength of LTG, the split between 30-day and 60-day scripts was assumed to be 55%/45% in 2026 (Year 1), 42%/58% in 2027 (Year 2), and 37%/63% from 2028-2031 (Years 3–6). These proportions were informed by the Impact analysis: Lowering the costs of medicines through changes to maximum dispensing quantities (2022, p.26).[3] The dispensed price for maximum quantity (DPMQ) applied in the financial modelling for each LTG strength was aligned with the DPMQs used for epileptic seizures.

4.5 The key inputs and assumptions used in the financial modelling are summarised in Table 4.

[3] https://oia.pmc.gov.au/sites/default/files/posts/2023/05/Impact%20Analysis_3.pdf

Table 4: Key inputs and assumptions used in the financial modelling

Assumption/input	Value used in base-case analysis	Value/s used in sensitivity analyses	Rationale/source
Proportion of private LTG scripts for bipolar disorder	95% for each LTG strength	90% & 100% for each LTG strength	Estimate. LTG is TGA-approved for epilepsy and bipolar disorder. The eTG also recommends LTG for trigeminal neuralgia, in addition to epilepsy and bipolar disorder indications. The prevalence of bipolar disorder in Australia is approximately 2.2%.[1] The prevalence of trigeminal neuralgia is 0.01%.[2] Therefore, most private use of LTG currently is expected to be for patients with epilepsy who do not meet the current PBS criteria and for patients with bipolar disorder.
Uptake rate	95% for each LTG strength	90% & 100% for each LTG strength	Estimate. If LTG is PBS-listed for bipolar disorder it is expected that nearly all patients currently receiving this medication privately for this indication would switch to PBS-subsidised use.
30-day versus 60-day PBS script split as a result of the proposed listing	55%/45% in 2026 (Year 1), 42%/58% in 2027 (Year 2), and 37%/63% from 2028-2031 (Years 3-6) for each LTG strength	N/A	'Impact analysis: Lowering the costs of medicines through changes to maximum dispensing quantities (2022, p.26).'[3]
DPMQ for each LTG strength	Same as the DPMQ for each LTG strength for epileptic seizures	N/A	PBS schedule.[4]
PBS patient co-payments	2025 co-payment values:[5] General co-pay = $31.60 Concessional co-pay = $7.70	2026 co-payment values:[6] General co-pay = $25 Concessional co-pay = $7.70	If the proposed listing is recommended by the PBAC, it will likely be implemented in 2026 when the general co-payment will be $25 and the concessional co-payment $7.70.

Abbreviations: DPMQ = dispensed price for maximum quantity; eTG = electronic Therapeutic Guidelines; LTG = lamotrigine; PBAC = Pharmaceutical Benefits Advisory Committee; PBS = Pharmaceutical Benefits Scheme; TGA = Therapeutic Goods Administration.

[1] https://psychology.org.au/for-the-public/psychology-topics/bipolar-disorder (2025)

[2] https://melbourneheadachecentre.com.au/conditions/trigeminal-neuralgia/ (2025)

[3] https://oia.pmc.gov.au/sites/default/files/posts/2023/05/Impact%20Analysis_3.pdf (2022)

[4] https://www.pbs.gov.au/pbs/search?term=lamotrigine

[5] https://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee

[6] https://www.health.gov.au/sites/default/files/2025-03/budget-2025-26-cheaper-medicines_0.pdf

4.6 In the base-case analysis, the estimated net cost to the R/PBS resulting from the proposed listing was $0 to < $10 million per year from 2026 to 2031, with a total projected cost of $40 million to < $50 million over the six-year period (see Table 5).

Table 5: Net cost to the R/PBS resulting from the proposed listing (base-case analysis)

	2026	2027	2028	2029	2030	2031	Total
Cost to PBS	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][4]
Less co-payments	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]
Net cost to PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][3]
Cost to RPBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Less co-payments	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Net cost to RPBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Net cost to R/PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][3]

Source: UCM workbook.

The redacted values correspond to the following ranges:

[1] *$0 to < $10 million*

[2] *$10 million to < $20 million*

[3] *$40 million to < $50 million*

[4] *$60 million to < $70 million*

Sensitivity analyses

4.7 As shown in Table 6, sensitivity analyses were performed to test key model inputs and assumptions. The results indicate that the total cost of the proposed listing is projected to range from $45 million to < $55 million over the 2026–2031 period.

Table 6: Net cost to the R/PBS resulting from the proposed listing (sensitivity analyses)

	2026	2027	2028	2029	2030	2031	Total	% change from base-case
Base-case analysis: Proportion of private LTG scripts for bipolar disorder (95%); uptake rate (95%); 2025 patient co-payments								
Net cost to R/PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][3]	-
Sensitivity analysis 1: Proportion of private LTG scripts for bipolar disorder (**90%**); uptake rate (95%); 2025 patient co-payments								
Net cost to R/PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][3]	-5.3%
Sensitivity analysis 2: Proportion of private LTG scripts for bipolar disorder (**100%**); uptake rate (95%); 2025 patient co-payments								
Net cost to R/PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][4]	+5.3%
Sensitivity analysis 3: Proportion of private LTG scripts for bipolar disorder (95%); uptake rate (**90%**); 2025 patient co-payments								
Net cost to R/PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][3]	-5.3%
Sensitivity analysis 4: Proportion of private LTG scripts for bipolar disorder (95%); uptake rate (**100%**); 2025 patient co-payments								
Net cost to R/PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][4]	+5.3%
Sensitivity analysis 5: Proportion of private LTG scripts for bipolar disorder (**100%**); uptake rate (**100%**); 2025 patient co-payments								
Net cost to R/PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][4]	+10.8%
Sensitivity analysis 6: Proportion of private LTG scripts for bipolar disorder (95%); uptake rate (95%); **2026** patient co-payments								
Net cost to R/PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][4]	+2.2%

Source: UCM workbook.

The redacted values correspond to the following ranges:

[1] *$0 to < $10 million*

[2] *$10 to < $20 million*

[3] *$40 million to < $50 million*

[4] *$50 million to < $60 million*

5 PBAC outcome

5.1 The PBAC noted pre-PBAC responses from the RANZCP, the RACGP, the NACCHO and one sponsor.

5.2 The PBAC recalled that in May 2025 it considered the *Review of clinical guidelines and cost estimates for the use of AEDs for the treatment of epilepsy* report and considered there may be an unmet need to subsidise LTG for mental illnesses such as bipolar disorder. The PBAC recommended in principle extending subsidy of LTG to this indication and requested that the Department undertake further work to estimate the cost to the R/PBS of a separate Restricted Benefit listing for LTG for bipolar disorder (the "proposed listing") for its consideration at a future meeting.

5.3 The PBAC recommended creating a new Restricted Benefit listing for all PBS-listed strengths of LTG tablets (i.e. 5 mg, 25 mg, 50 mg, 100 mg and 200 mg) for the treatment of bipolar disorder, to be priced equivalently to the existing LTG listings for

epileptic seizures. This recommendation was supported by stakeholders, who endorsed the subsidised use of LTG for this indication. Furthermore, Australian clinical guidelines (eTG) recommend LTG as a first-line monotherapy for bipolar depression and as a second-line monotherapy for the prevention of bipolar disorder in both adults and young people.

5.4 The PBAC noted that, although both the RANZCP and NACCHO supported an Unrestricted Benefit listing, only three of the eight brands of LTG available on the PBS (Lamictal, Lamotrigine GH, and Sandoz Lamotrigine) are approved by the TGA for the treatment of bipolar disorder. Consequently, the PBAC recommended that the new Restricted Benefit listing should be limited to these three brands only.

5.5 The PBAC recommended that, despite the eTG specifying an initial dose of 25 mg of LTG daily for bipolar disorder, the PBS listing should also include the 5 mg tablet strength. This decision was informed by advice from the RANZCP, which highlighted that the availability of the 5 mg tablet would provide clinicians with the flexibility to tailor dosing more precisely for their patients.

5.6 The PBAC noted that the UCM workbook was used to estimate the cost to the R/PBS of the proposed listing from 2026-2031. The PBAC accepted the findings of the base-case analysis and considered the estimated net cost to the R/PBS of the proposed listing reasonable.

5.7 The PBAC noted that, although the cost-effectiveness of LTG for bipolar disorder had not been formally established, it is likely that this medicine represents reasonable value for money for this indication for the following reasons:

- LTG is recommended as a first-line treatment for bipolar disorder in Australian clinical guidelines, suggesting its clinical effectiveness is comparable (non-inferior) to other PBS-listed alternatives.
- LTG is likely to offer improved safety and tolerability compared to other PBS-listed medicines for bipolar disorder, with a lower risk of teratogenic effects than alternatives such as valproate.
- Cost comparisons per defined daily dose (DDD) indicate that LTG is similar in price to other PBS-listed treatments for bipolar disorder, such as quetiapine.
- As an F2 medicine, LTG is subject to statutory price reductions, price disclosure, and supply guarantees under the *National Health Act 1953*. Consequently, its cost-effectiveness for bipolar disorder is expected to improve further as prices decrease over time.

5.8 The PBAC recommended that, consistent with the existing listings for LTG for epileptic seizures, a 60-day listing should also apply to LTG for bipolar disorder. Furthermore, the committee advised that the proposed listing would be appropriate for prescribing by nurse practitioners.

5.9 The PBAC recommended that the Department monitor the use of LTG following implementation of the new listing and advised that it would be prepared to reconsider the appropriateness of an Unrestricted Benefit listing for this medicine at a future meeting.

Outcome:
Recommended

6 Recommended listing

6.1 Add new listing for bipolar disorder as follows:

30-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LAMOTRIGINE					
lamotrigine 5 mg tablet, 56	New	1	56	5	Lamictal Lamotrigine GH Sandoz Lamotrigine
lamotrigine 25 mg tablet, 56	New	1	56	5	
lamotrigine 50 mg tablet, 56	New	1	56	5	
lamotrigine 100 mg tablet, 56	New	1	56	5	
lamotrigine 200 mg tablet, 56	New	1	56	5	
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒Medical Practitioners ☒Nurse practitioners					
Restriction type: ☒Restricted Benefit					
Restriction Summary New1 / Treatment of Concept: New1A					
Indication: Bipolar disorder					
Treatment criteria:					
Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner					

60-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LAMOTRIGINE					
lamotrigine 5 mg tablet, 56	New	2	112	5	Lamictal Lamotrigine GH Sandoz Lamotrigine
lamotrigine 25 mg tablet, 56	New	2	112	5	
lamotrigine 50 mg tablet, 56	New	2	112	5	
lamotrigine 100 mg tablet, 56	New	2	112	5	
lamotrigine 200 mg tablet, 56	New	2	112	5	
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒Medical Practitioners ☒Nurse practitioners					
Restriction type: ☒Restricted Benefit					
Restriction Summary New2 / Treatment of Concept: New2A					
Indication: Bipolar disorder					
Clinical criteria					
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient					
AND					
Treatment criteria:					
Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner					

7 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.