9.02 Review of clinical guidelines and cost estimates for the use of anti-epileptic drugs (AEDs) for the treatment of epilepsy

1 Purpose of item

1.1 That the Pharmaceutical Benefits Advisory Committee (PBAC):

- **Note** and **comment** on the key findings of the Review of clinical guidelines and cost estimates for the use of AEDs for the treatment of epilepsy draft report ("the Report").
- **Provide advice** on the cost estimates to the Pharmaceutical Benefits Scheme (PBS) of allowing first-line use of levetiracetam (LEV) and lamotrigine (LTG) in the general Australian population with epilepsy (hereafter referred to as the "proposed listings").
- **Provide advice** on the PBS restrictions for the proposed listings and any recommendations to change the current PBS listings for LEV and/or LTG (Section 4).
- **Consider** updating the terminology used in the PBS restrictions for other PBS-listed medicines to align with the terminology used by the International League against Epilepsy (ILAE) since 2017 as follows:
    - Change references to "partial epileptic seizures" to "focal onset seizures,"
    - Change references to "anti-epileptic drug/s" to "antiseizure medication/s."
- **Note** the April 2025 Drug Utilisation Sub-Committee (DUSC) Minutes for this item.
- **Note** the pre-sub-committee responses (PSCRs) and 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 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 AEDs and may have resulted in prescribers continuing to use valproate (VAL) among women of childbearing potential when safer options were available. The PBAC also requested that the Department provide to the 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*.[1] 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.

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.

2.4 On 7 March 2025, the TGA published a safety alert[2] for VAL, warning of the possible risk of learning, communication and behaviour problems in children born to men taking this medicine.

Sponsor and stakeholder consultation

2.5 Sponsors of PBS-listed AEDs, the ESA, and the Australian and New Zealand Association of Neurologists (ANZAN), were consulted on the draft Report and utilisation and cost model (UCM) workbook prior to the April 2025 DUSC meeting. These organisations were provided with the revised draft Report, UCM, and DUSC Minutes for this item on 23 April 2025, and invited to provide a pre-PBAC response in line with standard PBAC processes and timelines.

3 Review of clinical guidelines and cost estimates for the use of AEDs for the treatment of epilepsy

3.1 There were two parts to this review as presented below.

Part 1: Review of clinical guidelines

Objectives

3.2 To conduct a search of peer reviewed literature and a systematic search of the grey literature to identify relevant key Australian and international clinical guidelines for the use of AEDs for the treatment of epilepsy (Research Question 1).

3.3 To compare recommendations in the guidelines identified in Research Question 1 to PBS restrictions and TGA-approved indications (Research Question 2).

[1] N.B. This project was on hold for 24 months to allow the collection of sufficient PBS utilisation data following the 1 January 2021 restriction changes to LEV and LTG.

[2] https://www.tga.gov.au/news/safety-alerts/valproate-safety-alert

Key findings

3.4 Across the included guidelines, carbamazepine (CBZ) is commonly recommended as a first-line treatment for focal seizures and VAL for generalised seizures. However, for females who are of childbearing potential, LEV or LTG are recommended as alternatives to VAL.

3.5 Two Australian guidelines recommended LEV and LTG as a first-line AED for the treatment of adults with focal and/or generalised seizures. These recommendations were consistent with the recommendations in the majority of the international guidelines.

3.6 The second-line AEDs recommended by the included Australian guidelines are similar to the TGA-approved and PBS-listed ones except for LEV and LTG. Two Australian hospital-based guidelines recommended LEV and LTG as a first-line AED for the treatment of epilepsy.

Part 2: Utilisation review and cost estimates

Objectives

3.7 To estimate the cost to the PBS of expanding the restrictions for LEV and LTG to allow their first-line use in the general Australian population with epilepsy (Research Question 3).

3.8 To model how the first-line use of LEV and LTG in the general population will impact on the utilisation of the third-line AEDs (i.e., brivaracetam, perampanel, lacosamide, cannabidiol and stiripentol) (Research Question 4).

Key findings

3.9 A utilisation review of PBS-listed AEDs was undertaken under Part 2 of the review. The utilisation review involved an analysis of PBS data from 2014-2023. The purpose was to provide the DUSC and PBAC with additional data on the utilisation of AEDs and any further evidence on the broader use of other second-line AEDs as requested by the PBAC in September 2020.

3.10 The utilisation review was intended as a supplement to the *Utilisation analysis of PBS-listed AEDs in a cohort of epilepsy patients* that was considered by the DUSC in September 2023. It should be noted that there were differences in the methodology between the 2023 utilisation analysis and the utilisation analysis presented in the Report. In the 2023 analysis, patients were only included in the patient cohort if 50% or more of their PBS-subsidised AED prescriptions (supplied between 1 January 2018 and the end of January 2023) were indicated for epilepsy after excluding prescriptions with an unknown indication (i.e. unrestricted benefits or missing authority information). The utilisation review presented in the Report was less restrictive and only excluded the following dispensing data:

- all dispensings for nitrazepam and gabapentin where the PBS item code was not for epilepsy;
- all dispensings for topiramate where the authority code was specific to migraine, and;

- all dispensings for CBZ where the PBS item code was for dentist prescribing.

3.11 The key findings from the utilisation review are presented below:

- 920,512 patients were supplied a PBS-listed AED between 2014 and 2023; 485,532 (53%) females and 434,790 (47%) males.
- 27,261,781 prescriptions for AEDs were supplied via the PBS between 2014-2023. VAL was the most frequently supplied AED in 2014, accounting for 743,455 (31%) of all prescriptions. In 2023, VAL use had declined to 687,128 prescriptions (23%) and LEV became the most dispensed AED with 849,522 prescriptions (28%). LTG was the third most frequently dispensed AED in 2023 with 566,345 (15%) prescriptions.
- 564,746 patients initiated on a PBS-listed AED between 2015 and 2023. The number of incident patients declined over time from 75,541 patients in 2015 to 55,776 patients in 2023.
- In 2023, women of childbearing potential (aged 15-49 years) were more than twice as likely to initiate AED treatment with LEV or LTG compared to males of the same age. Males aged 15-49 years most frequently initiated with VAL while women most frequently initiated with LTG.
- 27.3% of patients who initiated on VAL or CBZ in the primary care setting had a recorded epilepsy diagnosis based on POpulation Level Analysis & Reporting (POLAR) primary care data from 2018 to 2023.
- Approximately 15% of patients who initiate AED treatment received sequences of two or more different AEDs during the study period (2015-2023).
- The two most frequent drug sequences were from VAL to LEV (n=4,373) and from LEV to VAL (n=4,188).

3.12 The UCM workbook was used to estimate changes in utilisation and the cost to the R/PBS if PBS restrictions for LEV and LTG were changed to allow their first-line use for epilepsy in the general Australian population (referred to as the "proposed listing"). The key findings from the base-case analysis were:

- R/PBS utilisation of CBZ and VAL is expected to decrease by 69,043 prescriptions in 2025, and by 234,974 prescriptions in 2030.
- R/PBS utilisation of LEV and LTG is expected to increase by 64,045 prescriptions in 2025, up to 219,360 prescriptions in 2030.
- The estimated net cost to the R/PBS as a result of the proposed listing is $1.2 million in 2025 increasing to $4.4 million in 2030, or a total of $16.9 million over the 6-year period (2025-2030).

3.13 Sensitivity analyses were conducted to test key model inputs and assumptions and to estimate how the proposed listing would impact on the utilisation of third-line AEDs (i.e., brivaracetam, perampanel, lacosamide, cannabidiol and stiripentol). These analyses showed that:

- By increasing the substitution rate of VAL and CBZ tablets and liquid from 10% in 2025 with additional 10% each year up to 2030 (base-case) to 15% (with additional 15% each year), the cost to the R/PBS increased by 48% to $25.0 million over 2025-2030.
- By decreasing the substitution rate of VAL and CBZ tablets and liquid from base-case to 5% (with additional 5% each year), the cost to the R/PBS decreased by 50% to $8.4 million over 2025-20230.
- By decreasing the substitution rate of VAL and CBZ liquid forms with LEV and LTG oral liquid from base-case (10% with increase of 10% per annum) to 5% or 2.5% (with additional 5% and 2.5% each year, respectively), the cost to the R/PBS decreased by 68% and 102%, respectively. Therefore, the 2.5% substitution rate scenario results in a net cost to the R/PBS which is lower than the cost of the current listing.
- Increasing the proportion of people using CBZ and VAL for epilepsy from the base-case of 27.3% to variables between 37.3% up to 80% (to account for the potential underreporting of epilepsy diagnoses in the POLAR data) decreased the cost to the R/PBS by 13% up to 79%.
- The flow-on effect to third-line AEDs is estimated to be minimal. Compared to the base-case model (no flow-on effects), the net cost to R/PBS decreases by 0.61% in the lowest cost scenario (from LEV 1g to lacosamide 100mg) and increases by 6.83% in the highest cost scenario (from LTG 50mg to perampanel 8mg).

4 Proposed listings

4.1 A key objective of the Report was to estimate the cost to the PBS of expanding the restrictions for LEV and LTG to allow their first-line use in the general Australian population with epilepsy (the "proposed listing"). The proposed listings for LEV and LTG are presented below.

Levetiracetam (LEV)

4.2 LEV is currently listed on the PBS for "partial epileptic seizures" in the following dosage forms:

- levetiracetam 100 mg/mL oral liquid, 300 mL
- levetiracetam 1 g tablet, 60
- levetiracetam 250 mg tablet, 60
- levetiracetam 500 mg tablet, 60

4.3 The box below shows the proposed PBS restriction criteria for the LEV *tablet* dosage forms. Proposed deletions for the current restriction are indicated in ~~strikethrough~~.

~~Authority Required (STREAMLINED)~~ Restricted Benefit

~~11116~~

~~Partial epileptic~~ Epileptic seizures

Clinical criteria:

- ~~The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR~~
- ~~Patient must be a woman of childbearing potential,~~

~~**AND**~~

- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

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*

4.4 The box below shows the proposed PBS restriction criteria for the LEV *liquid* dosage forms. Proposed deletions for the current restriction are indicated in ~~strikethrough~~.

~~Authority Required (STREAMLINED)~~ Restricted Benefit

~~11077~~

~~Partial epileptic~~ Epileptic seizures

Clinical criteria:

- ~~The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR~~
- ~~Patient must be a woman of childbearing potential,~~

~~**AND**~~

- Patient must be unable to take a solid dose form of levetiracetam,

AND

- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

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*

4.5 The PBAC was requested to consider the proposed restriction for LEV and provide advice on whether a Restricted Benefit listing (with a broader epilepsy indication) may be more appropriate than the current Authority Required (STREAMLINED) listing for "partial epileptic seizures." The review of clinical guidelines found that two Australian guidelines (one from a Victorian major tertiary referral teaching hospital and the other from a Tasmanian non-governmental primary health care organisation) recommended using LEV and/or LTG as a first-line AED in adults with focal and/or generalised seizures. LEV is also TGA-approved for types of epilepsy that are broader than its PBS indication. For example, LEV is TGA-approved as an add-on therapy in the treatment of primary generalized tonic-clonic seizures in adults and children from 4 years of age with idiopathic generalized epilepsy.

Lamotrigine (LTG)

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

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

4.7 The box below shows the proposed PBS restriction criteria for LTG. Proposed deletions for the current restriction are indicated in ~~strikethrough~~.

~~Authority Required (STREAMLINED)~~ Restricted Benefit

~~11081~~

Epileptic seizures

~~**Clinical criteria:**~~

- ~~The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR~~
- ~~Patient must be a woman of childbearing potential.~~

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*

4.8 The PBAC was requested to consider the proposed restriction for LTG. The proposed Restricted Benefit listing may increase the risk of LTG use for the treatment of conditions other than epilepsy, such as bipolar disorder (depressive episodes and prophylaxis) and trigeminal neuralgia (see Section 5).

5 Extent of private (non-PBS) use of LEV and LTG

5.1 LTG is TGA-approved for the prevention of depressive episodes in patients with bipolar disorder. In addition, Australian clinical guidelines[3] recommend LTG for bipolar disorder (depressive episodes and prophylaxis) and trigeminal neuralgia. Australian clinical guidelines[3] recommend LEV for forms of epilepsy that are broader than its PBS-listed indication such as tonic-clonic seizures. LEV has also shown promise as a treatment for patients with bipolar I disorder during the manic phase.[4] As such, the proposed listings may increase the risk of LEV and LTG use for the treatment of conditions other than epilepsy or for broader forms of epilepsy. LEV and LTG are currently PBS-listed as Authority Required (STREAMLINED) listings which do not require prior approval from Services Australia. Therefore, it is possible that use beyond the PBS restrictions is already occurring.

[3] https://tgldcdp.tg.org.au/ (accessed 11 March 2025)
[4] https://pmc.ncbi.nlm.nih.gov/articles/PMC9227682/ (accessed 11 March 2025)

5.2 To estimate the current extent of private (non-PBS) use of LEV and LTG, an analysis of R/PBS scripts supplied versus units supplied by wholesalers was undertaken for each medicine from 2020-2023. The number of R/PBS scripts supplied for LEV and LTG was extracted from the Department's R/PBS Section 85 Date of Supply Data by the DUSC Secretariat, which includes data on under co-payment prescriptions. The number of units of LEV and LTG supplied by wholesalers to retail pharmacies was obtained from the Australian Pharmacy Index (API) dataset sourced by IQVIA. The API dataset is updated monthly and contains the sell-in data sourced from pharmaceutical wholesalers and subscribing manufacturers who sell direct into retail pharmacies. Approximately 96% of wholesalers are included in the API dataset.

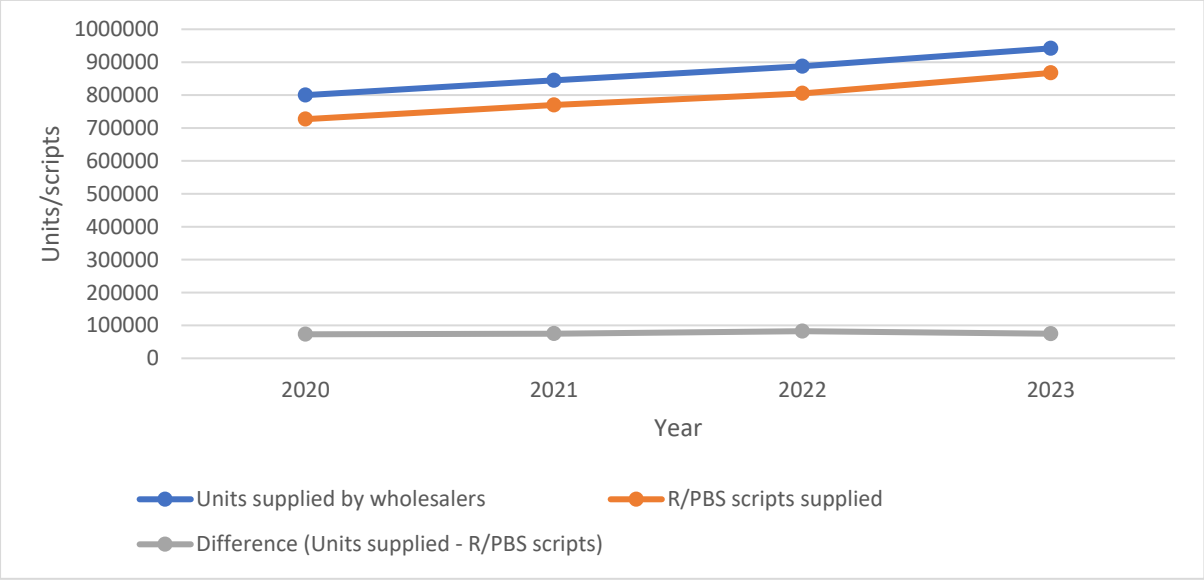
5.3 As shown in Table 1, the ratio of units supplied by wholesalers to R/PBS scripts supplied for LEV was 1.1 on average from 2020-2023 (i.e. 10% more units were supplied to pharmacies than were dispensed on the PBS). It is acknowledged that not all units supplied to pharmacies will be dispensed via the PBS within a given year; however, relative differences in the ratio of units supplied by wholesalers to R/PBS scripts supplied may provide an indication of the size of the private market for a medicine.

Table 1: R/PBS scripts supplied vs. units supplied by wholesalers for levetiracetam – ALL STRENGTHS (2020-2023)

	2020	2021	2022	2023	Average
Units supplied by wholesalers	799,864	844,649	887,627	942,105	868,561
R/PBS scripts supplied	726,817	769,802	805,201	867,300	792,280
Difference (Units supplied - R/PBS scripts)	73,047	74,847	82,426	74,805	76,281
Ratio (Units supplied : R/PBS scripts)	1.10	1.10	1.10	1.09	1.10

5.4 The difference between R/PBS scripts supplied for LEV (all strengths) vs. units supplied by wholesalers is presented in Figure 1.

Figure 1: R/PBS scripts supplied vs. units supplied by wholesalers for levetiracetam – ALL STRENGTHS (2020-2023)



5.5 As shown in Table 2 below, the ratio of units supplied by wholesalers to R/PBS scripts supplied for LTG was 1.71 on average from 2020-2023 (i.e. 71% more units were supplied to pharmacies than were dispensed on the PBS). This finding suggests that the private (non-PBS) market for LTG is significantly larger than the private market for

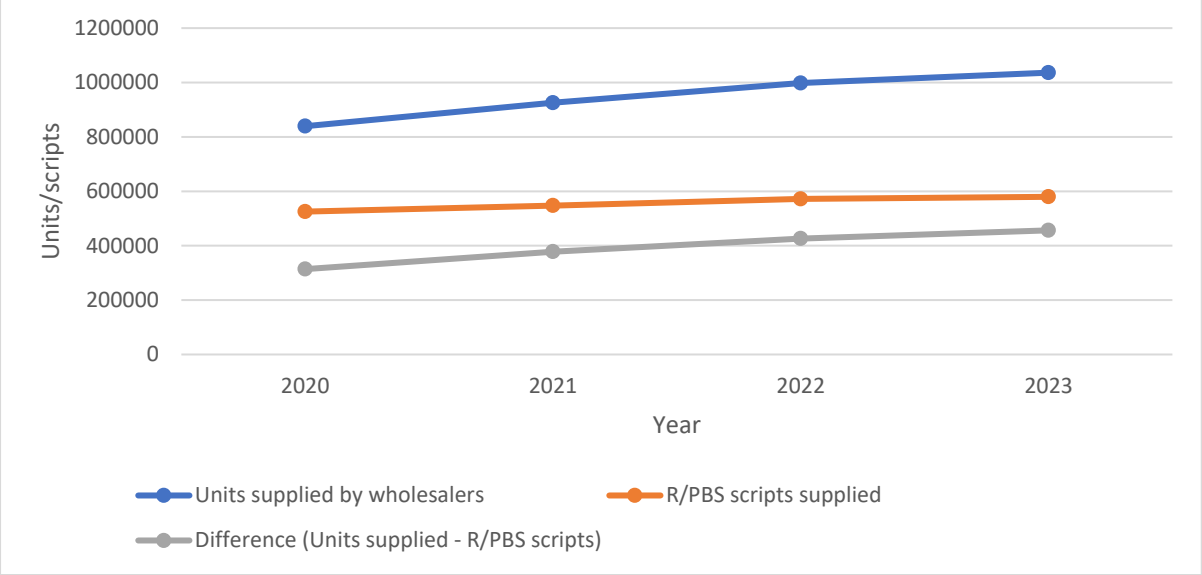
LEV. The private market for LTG has increased over the 2020-2023 period as indicated by an increase in the ratio from 1.6 in 2020 to 1.79 in 2023.

Table 2: R/PBS scripts supplied vs. units supplied by wholesalers for lamotrigine – ALL STRENGTHS (2020-2023)

	2020	2021	2022	2023	Average
Units supplied by wholesalers	839,291	925,507	998,057	1,036,146	949,750
R/PBS scripts supplied	525,419	547,600	571,826	579,754	556,150
Difference (Units supplied - R/PBS scripts)	313,872	377,907	426,231	456,392	393,601
Ratio (Units supplied : R/PBS scripts)	1.60	1.69	1.75	1.79	1.71

5.6 The difference between R/PBS scripts supplied for LTG (all strengths) vs. units supplied by wholesalers is presented in Figure 2.

Figure 2: R/PBS scripts supplied vs. units supplied by wholesalers for lamotrigine – ALL STRENGTHS (2020-2023)



6 PBAC outcome

6.1 The PBAC noted the PSCRs and pre-PBAC responses received from sponsors, the ESA, the ANZAN and individual clinicians.

6.2 The PBAC considered the *Review of clinical guidelines and cost estimates for the use of AEDs for the treatment of epilepsy* draft report ("the Report"). Overall, the PBAC accepted the key findings from the clinical guidelines review, the utilisation review (which supplemented the September 2023 *Utilisation analysis of PBS-listed AEDs in a cohort of epilepsy patients* considered by the DUSC in September 2023) and the cost estimates to the PBS of allowing first-line use of LEV and LTG in the general Australian population with epilepsy (the "proposed listings).

6.3 The PBAC noted that the proposed listings (see Section 4) sought to amend the PBS restrictions for LEV and LTG to allow their first-line use in the general population with epilepsy (i.e. males and females of all ages), and that the changes were supported by clinicians, clinical groups and sponsors.

6.4 The PBAC noted that the review of clinical guidelines found 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. The PBAC

noted that the current Authority Required (STREAMLINED) listings for LEV and LTG (for "partial epileptic seizures" and "epileptic seizures" respectively) restrict access to patients who have failed to have their epilepsy controlled with other antiseizure medications (unless the patient is a woman of childbearing potential) and are inconsistent with clinical guideline recommendations.

6.5 The PBAC considered the estimated cost to the R/PBS of allowing first-line 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 (i.e., brivaracetam, perampanel, lacosamide, cannabidiol and stiripentol). The PBAC also 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.

6.6 The PBAC considered that the cost-effectiveness of LEV and LTG as first-line agents for epilepsy had not been formally established by the Review, however it was likely that these medicines now provide comparable value for money in this setting due to decreasing prices and improved safety/tolerability over older first-line antiseizure medications. The PBAC noted that the market for LEV and LTG was highly genericised which would assist in mitigating financial risk, the utilisation was increasing overall independently of this change and that the more expensive antiseizure medications remained third-line.

6.7 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 will allow the subsidised first-line use of these medicines in the general Australian population with epilepsy.

6.8 The PBAC noted that the liquid form of LEV is considerably more expensive than tablet formulations, with a cost comparable to other antiseizure liquid medicines listed on the PBS as unrestricted benefits (e.g. ethosuximide). The PBAC considered that a reduction in restriction level from Authority Required (STREAMLINED) will have minimal impact on utilisation due to the small size of the LEV market.

6.9 The PBAC noted that LTG is currently PBS-listed as an Authority Required (STREAMLINED) listing, which does not require prior approval from Services Australia. The PBAC considered that a reduction in restriction level will have minimal impact on the utilisation of this medicine and recommended a Restricted Benefit listing for "epileptic seizures."

6.10 The PBAC recommended the terms "focal onset seizures" replace "partial seizures" and "antiseizure medication/s" replace "anti-epileptic drug/s" to avoid prescriber confusion, and that this change should be flowed on to the terminology used in all other PBS restrictions, including second- and third-line antiseizure medications.

6.11 The PBAC considered that the size of the private market for LTG may indicate an unmet need to subsidise this medicine for mental illnesses such as bipolar disorder. The PBAC noted that estimating the financial impact to the R/PBS for LTG for bipolar disorder was outside the scope of the current Report. 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.

6.12 The PBAC noted a sponsor's request for four to six months' notice of any proposed restriction change to its medicine to enable minimum stock holding requirements to be met.

Outcome:
Recommended

7 Recommended listing

7.1 Amend existing listing as follows (additions are in *italics* and deletions are in strikethrough):

Levetiracetam

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LEVETIRACETAM					
levetiracetam 250 mg tablet, 60	8654L	1	60	5	Keppra 11 other brands *4 other brands
levetiracetam 500 mg tablet, 60	8655M	1	60	5	
levetiracetam 1 g tablet, 60	8656N	1	60	5	
*levetiracetam 100 mg/mL oral liquid, 300 mL	*9169N	1	1	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒~~Authority Required (STREAMLINED) [11116]~~ *Restricted Benefit*
Restriction Summary [new] / Treatment of Concept: [new]	
~~14148~~ New	**Indication:** ~~Partial e~~*E*pileptic seizures
	~~Clinical criteria:~~
~~14281~~	~~The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or~~
~~26647~~	~~Patient must be a woman of childbearing potential~~
	AND
	***Clinical criteria**
*14284	*Patient must be unable to take a solid dose form of levetiracetam
	AND
	Clinical criteria
21893	The treatment must not be given concomitantly with brivaracetam, except for cross titration
	Treatment criteria
32845	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

*Note: Criteria denoted with an * (asterix) refer to the oral liquid formation only.*

Levetiracetam 60-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LEVETIRACETAM					
levetiracetam 250 mg tablet, 60	8654L	2	120	5	Keppra 11 other brands *4 other brands
levetiracetam 500 mg tablet, 60	8655M	2	120	5	
levetiracetam 1 g tablet, 60	8656N	2	120	5	
*levetiracetam 100 mg/mL oral liquid, 300 mL	*13993L	2	2	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒~~Authority Required (STREAMLINED) [14964/14988]~~ *Restricted Benefit*
Restriction Summary [new] / Treatment of Concept: [new]	
~~14148~~ New	**Indication:** ~~Partial e~~*E*pileptic seizures
	Clinical criteria:
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	~~**Clinical criteria:**~~
~~14281~~	~~The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or~~
~~26647~~	~~Patient must be a woman of childbearing potential~~
	~~**AND**~~
	***Clinical criteria**
*14284	*Patient must be unable to take a solid dose form of levetiracetam
	AND
	Clinical criteria
21893	The treatment must not be given concomitantly with brivaracetam, except for cross titration
	Treatment criteria
32845	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

*Note: Criteria denoted with an * (asterix) refer to the oral liquid formation only.*

Lamotrigine

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LAMOTRIGINE					
lamotrigine 5 mg tablet, 56	8063J	1	56	5	Lamictal 7 other brands
lamotrigine 25 mg tablet, 56	2848X	1	56	5	
lamotrigine 50 mg tablet, 56	2849Y	1	56	5	
lamotrigine 100 mg tablet, 56	2850B	1	56	5	
lamotrigine 200 mg tablet, 56	2851C	1	60	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒~~Authority Required (STREAMLINED) [11081]~~ *Restricted Benefit*
Restriction Summary [new] / Treatment of Concept: [new]	
14148	**Indication:** Epileptic seizures
	~~**Clinical criteria:**~~
~~14281~~	~~The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or~~
~~26647~~	~~Patient must be a woman of childbearing potential~~
	Treatment criteria

32845	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

Lamotrigine 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	14047H	2	112	5	Lamictal 7 other brands
lamotrigine 25 mg tablet, 56	13842M	2	112	5	
lamotrigine 50 mg tablet, 56	13975M	2	112	5	
lamotrigine 100 mg tablet, 56	14052N	2	112	5	
lamotrigine 200 mg tablet, 56	13843N	2	112	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒~~Authority Required (STREAMLINED) [14964/14988]~~ *Restricted Benefit*
Restriction Summary [new] / Treatment of Concept: [new]	
14148	**Indication:** Epileptic seizures
	Clinical criteria:
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	~~**Clinical criteria:**~~
~~14281~~	~~The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or~~
~~26647~~	~~Patient must be a woman of childbearing potential~~
	~~**AND**~~
	Clinical criteria
21893	The treatment must not be given concomitantly with brivaracetam, except for cross titration
	Treatment criteria
32845	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

Flow on changes

7.2 The PBAC recommended the following changes to existing listings of PBS listed AEDs. The following amendments to the existing restriction are shown in *italics* and strikethrough.

Gabapentin

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
GABAPENTIN					
gabapentin 100 mg capsule, 100	8505P	1	100	5	Neurontin (various other brands)
gabapentin 300 mg capsule, 100	1834M	1	100	5	
gabapentin 400 mg capsule, 100	1835N	1	100	5	
gabapentin 600 mg tablet, 100	8559L	1	100	5	
gabapentin 800 mg tablet, 100	8389M	1	100	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)

Restriction Summary New / Treatment of Concept: New	
14148	**Indication:** ~~Partial epileptic~~ *Focal onset* seizures
	Clinical criteria:
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*
	Treatment criteria
32845	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

Tiagabine

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
TIAGABINE					
tiagabine 5 mg tablet, 50	8221Q	2	100	5	Gabitril
tiagabine 10 mg tablet, 50	8222R	2	100	5	
tiagabine 15 mg tablet, 50	8223T	2	100	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
14148	**Indication:** ~~Partial epileptic~~ *Focal onset* seizures
	Clinical criteria:
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*
	Treatment criteria
32845	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

Tiagabine – 60-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
TIAGABINE					
tiagabine 5 mg tablet, 50	8221Q	4	200	5	Gabitril
tiagabine 10 mg tablet, 50	8222R	4	200	5	
tiagabine 15 mg tablet, 50	8223T	4	200	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
14148	**Indication:** ~~Partial epileptic~~ *Focal onset* seizures
	Clinical criteria:
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	Clinical criteria:
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*
	Treatment criteria

32845	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

Zonisamide

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ZONISAMIDE					
zonisamide 25 mg capsule, 56	9388D	1	56	5	Zonegran
zonisamide 50 mg capsule, 56	9389E	1	56	5	
zonisamide 100 mg capsule, 56	9390F	2	112	5	
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners				
	Restriction type: ☒Authority Required (STREAMLINED)				
Restriction Summary New / Treatment of Concept: New					
14148	**Indication:** ~~Partial epileptic~~ *Focal onset* seizures				
	Clinical criteria:				
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*				
	Treatment criteria				
32845	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				

Zonisamide – 60-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ZONISAMIDE					
zonisamide 25 mg capsule, 56	13853D	2	112	5	Zonegran
zonisamide 50 mg capsule, 56	13988F	2	112	5	
zonisamide 100 mg capsule, 56	13854E	4	224	5	
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners				
	Restriction type: ☒Authority Required (STREAMLINED)				
Restriction Summary New / Treatment of Concept: New					
14148	**Indication:** ~~Partial epileptic~~ *Focal onset* seizures				
	Clinical criteria:				
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient				
	AND				
	Clinical criteria:				
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*				
	Treatment criteria				
32845	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				

Vigabatrin

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
VIGABATRIN					

vigabatrin 500 mg tablet, 100	2667J	1	100	5	Sabril
vigabatrin 500 mg powder for oral liquid, 60 sachets	2668K	1	60	5	
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners				
	Restriction type: ☒Authority Required (STREAMLINED)				
Restriction Summary New / Treatment of Concept: New					
14148	**Indication:** ~~Partial epileptic~~ *Focal onset* seizures				
	Clinical criteria:				
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*				
	Treatment criteria				
32845	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				

Vigabatrin – 60-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
VIGABATRIN					
vigabatrin 500 mg tablet, 100	13919N	2	200	5	Sabril
vigabatrin 500 mg powder for oral liquid, 60 sachets	13974L	2	120	5	
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners				
	Restriction type: ☒Authority Required (STREAMLINED)				
Restriction Summary New / Treatment of Concept: New					
14148	**Indication:** ~~Partial epileptic~~ *Focal onset* seizures				
	Clinical criteria:				
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient				
	AND				
	Clinical criteria:				
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*				
	Treatment criteria				
32845	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				

Oxcarbazepine

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
OXCARBAZEPINE					
oxcarbazepine 150 mg tablet, 100	8584T	1	100	5	Trileptal
oxcarbazepine 300 mg tablet, 100	8585W	1	100	5	
oxcarbazepine 600 mg tablet, 100	8586X	1	100	5	
oxcarbazepine 60 mg/mL oral liquid, 250 mL	8588B	2	2	5	
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners				

Concept ID (for internal Dept. use)	**Restriction type:** ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
14370	**Indication:** Seizures
	Clinical criteria:
14371	Patient must have ~~partial epileptic~~ *focal onset* seizures; or
14380	Patient must have primary generalised tonic-clonic seizures
	Clinical criteria:
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*
	Treatment criteria
32845	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

Oxcarbazepine – 60-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
OXCARBAZEPINE					
oxcarbazepine 150 mg tablet, 100	14562K	2	200	5	Trileptal
oxcarbazepine 300 mg tablet, 100	14033N	2	200	5	
oxcarbazepine 600 mg tablet, 100	13935K	2	200	5	
oxcarbazepine 60 mg/mL oral liquid, 250 mL	13936L	4	4	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
14370	**Indication:** Seizures
	Clinical criteria:
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	Clinical criteria:
14371	Patient must have ~~partial epileptic~~ *focal onset* seizures; or
14380	Patient must have primary generalised tonic-clonic seizures
	Clinical criteria:
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*
	Treatment criteria
32845	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

Topiramate

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
TOPIRAMATE					
topiramate 25 mg tablet, 60	8163P	1	60	5	Topamax
topiramate 50 mg tablet, 60	8164Q	1	60	5	(Various other brands)

topiramate 100 mg tablet, 60	8165R	1	60	5	
topiramate 200 mg tablet, 60	8166T	1	60	5	
*topiramate 15 mg capsule, 60	8371N	1	60	5	Topamax Sprinkle
*topiramate 25 mg capsule, 60	8372P	1	60	5	
*topiramate 50 mg capsule, 60	8520K	1	60	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
14370	**Indication:** Seizures
	Clinical criteria:
14371	Patient must have ~~partial epileptic~~ *focal onset* seizures; or
14380	Patient must have primary generalised tonic-clonic seizures. or
	Patient must have seizures of the Lennox-Gastaut syndrome,
	Clinical criteria:
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*
	AND
	***Clinical criteria:**
*14313	*Patient must be unable to take a solid dose form of topiramate
	Treatment criteria
32845	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

*Note: Criteria denoted with an * (asterix) refer to the capsule/sprinkle formation only.*

Topiramate – 60-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
TOPIRAMATE					
topiramate 25 mg tablet, 60	13969F	2	120	5	Topamax (Various other brands)
topiramate 50 mg tablet, 60	13913G	2	120	5	
topiramate 100 mg tablet, 60	14008G	2	120	5	
topiramate 200 mg tablet, 60	14009H	2	120	5	
*topiramate 15 mg capsule, 60	14063E	2	120	5	Topamax Sprinkle
*topiramate 25 mg capsule, 60	13905W	2	120	5	
*topiramate 50 mg capsule, 60	13878K	2	120	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
14370	**Indication:** Seizures
	Clinical criteria:
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	Clinical criteria:
14371	Patient must have ~~partial epileptic~~ *focal onset* seizures; or
14380	Patient must have primary generalised tonic-clonic seizures. or
14376	Patient must have seizures of the Lennox-Gastaut syndrome,
	AND

	Clinical criteria:
14281	The condition must have failed to be controlled satisfactorily by *at least one* other ~~anti-epileptic drugs~~ *antiseizure medication*
	AND
	***Clinical criteria:**
*14313	*Patient must be unable to take a solid dose form of topiramate
	Treatment criteria
32845	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

*Note: Criteria denoted with an * (asterix) refer to the capsule/sprinkle formation only.*

Brivaracetam

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
BRIVARACETAM					
brivaracetam 25 mg tablet, 56	11328F	1	56	5	Briviact
brivaracetam 50 mg tablet, 56	11334M	1	56	5	
brivaracetam 75 mg tablet, 56	11356Q	1	56	5	
brivaracetam 100 mg tablet, 56	11339T	1	56	5	
brivaracetam 10 mg/mL oral liquid, 300 mL	11349H	1	1	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures
	Treatment Phase: Initial treatment
	Treatment criteria
8656	Must be treated by a neurologist
	Clinical criteria:
8658	The treatment must be in combination with two or more ~~anti-epileptic drugs~~ *antiseizure medications* which includes one second-line adjunctive agent
	AND
	Clinical criteria:
8660	The condition must have failed to be controlled satisfactorily by ~~anti-epileptic drugs~~ *antiseizure medications*, which includes at least one first-line ~~anti-epileptic~~ *antiseizure* agent and at least two second-line adjunctive ~~anti-epileptic~~ *antiseizure* agents
	AND
	Clinical criteria:
21574	The treatment must not be given concomitantly with levetiracetam, except for cross titration
	AND
	***Clinical criteria:**
*18849	* Patient must be unable to take a solid dose form of this drug,

*Note: Criteria denoted with an * (asterix) refer to the oral liquid formation only.*

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
BRIVARACETAM					
brivaracetam 25 mg tablet, 56	11327E	1	56	5	Briviact
brivaracetam 50 mg tablet, 56	11338R	1	56	5	
brivaracetam 75 mg tablet, 56	11350J	1	56	5	
brivaracetam 100 mg tablet, 56	11357R	1	56	5	

*brivaracetam 10 mg/mL oral liquid, 300 mL	11358T	1	1	5	
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (STREAMLINED)				
Restriction Summary New / Treatment of Concept: New					
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures				
	Treatment Phase: Continuing treatment				
	Clinical criteria:				
21572	Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition				
	AND				
	Clinical criteria:				
21472	The treatment must not be given concomitantly with levetiracetam				
	AND				
	***Clinical criteria:**				
*18849	* Patient must be unable to take a solid dose form of this drug,				

*Note: Criteria denoted with an * (asterix) refer to the oral liquid formation only.*

Perampanel

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PERAMPANEL					
perampanel 2 mg tablet, 7	10157N	2	14	1	Fycompa
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (STREAMLINED)				
Restriction Summary New / Treatment of Concept: New					
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures				
	Treatment Phase: Initial treatment				
	Clinical criteria:				
8658	The treatment must be in combination with two or more ~~anti-epileptic drugs~~ *antiseizure medications* which includes one second-line adjunctive agent				
	AND				
	Clinical criteria:				
8660	The condition must have failed to be controlled satisfactorily by ~~anti-epileptic drugs~~ *antiseizure medications*, which includes at least one first-line ~~anti-epileptic~~ *antiseizure* agent and at least two second-line adjunctive ~~anti-epileptic~~ *antiseizure* agents				
	AND				
	Treatment criteria				
8656	Must be treated by a neurologist				

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PERAMPANEL					
perampanel 4 mg tablet, 28	10162W	1	28	5	Fycompa
perampanel 6 mg tablet, 28	10163X	1	28	5	
perampanel 8 mg tablet, 28	10160R	1	28	5	
perampanel 10 mg tablet, 28	10151G	1	28	5	
perampanel 12 mg tablet, 28	10159Q	1	28	5	
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners				

Concept ID (for internal Dept. use)	**Restriction type:** ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures
	Treatment Phase: Continuing
	Clinical criteria:
8658	Patient must have previously been issued with an authority prescription for this drug

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PERAMPANEL					
perampanel 2 mg tablet, 7	11436X	2	14	1	Fycompa

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
14229	**Indication:** Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures
	Treatment Phase: Initial treatment
	Clinical criteria:
21911	The condition must have failed to be controlled satisfactorily by at least two ~~anti-epileptic drugs~~ *antiseizure medications*
	AND
	Clinical criteria:
21913	The treatment must be in combination with at least one PBS-subsidised ~~anti-epileptic drugs~~ *antiseizure medications*
	~~**AND**~~
	~~**Clinical criteria:**~~
~~8662~~	~~The treatment must be for dose titration purposes~~
	Treatment criteria
8656	Must be treated by a neurologist
	Population criteria:
9083	Patient must be aged 12 years or older
13615	**Administrative Advice:** No applications for increased maximum quantities will be authorised.

Perampanel – 60-day listing

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PERAMPANEL					
perampanel 4 mg tablet, 28	13948D	2	56	5	Fycompa
perampanel 6 mg tablet, 28	14010J	2	56	5	
perampanel 8 mg tablet, 28	13970G	2	56	5	
perampanel 10 mg tablet, 28	13914H	2	56	5	
perampanel 12 mg tablet, 28	13865R	2	56	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures

	Treatment Phase: Continuing
	Clinical criteria:
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	Clinical criteria:
8658	Patient must have previously been issued with an authority prescription for this drug

Lacosamide

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LACOSAMIDE					
lacosamide 50 mg tablet, 14	9333F	1	14	5	Vimpat (Various other brands)
lacosamide 100 mg tablet, 14	9334G	1	14	5	
lacosamide 150 mg tablet, 14	9336J	1	14	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures
	Treatment Phase: Initial treatment
	Clinical criteria:
8658	The treatment must be in combination with two or more ~~anti-epileptic drugs~~ *antiseizure medications* which includes one second-line adjunctive agent
	AND
	Clinical criteria:
8660	The condition must have failed to be controlled satisfactorily by ~~anti-epileptic drugs~~ *antiseizure medications*, which includes at least one first-line ~~anti-epileptic~~ *antiseizure* agent and at least two second-line adjunctive ~~anti-epileptic~~ *antiseizure* agents
	AND
	Treatment criteria
8656	Must be treated by a neurologist
	AND
	Clinical criteria:
8662	The treatment must be for dose titration purposes

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LACOSAMIDE					
lacosamide 50 mg tablet, 14	10293R	4	56	5	Vimpat (Various other brands)

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures
	Treatment Phase: Continuing treatment
	Clinical criteria:

11364	Patient must have previously received PBS-subsidised treatment with this drug for this condition

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LACOSAMIDE					
lacosamide 100 mg tablet, 14	9335H	1	56	5	Vimpat (Various other brands)
lacosamide 150 mg tablet, 14	9337K	1	56	5	
lacosamide 200 mg tablet, 56	9338L	1	56	5	
lacosamide 10 mg/mL oral liquid, 200 mL	11694L	6	6	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures
	Treatment Phase: Initial treatment
	Clinical criteria:
8658	The treatment must be in combination with two or more ~~anti-epileptic drugs~~ *antiseizure medications* which includes one second-line adjunctive agent
	AND
	Clinical criteria:
8660	The condition must have failed to be controlled satisfactorily by ~~anti-epileptic drugs~~ *antiseizure medications*, which includes at least one first-line ~~anti-epileptic~~ *antiseizure* agent and at least two second-line adjunctive ~~anti-epileptic~~ *antiseizure* agents
	AND
	Treatment criteria
8656	Must be treated by a neurologist
Restriction Summary New / Treatment of Concept: New	
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures
	Treatment Phase: Continuing treatment
	Clinical criteria:
11364	Patient must have previously received PBS-subsidised treatment with this drug for this condition

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LACOSAMIDE					
lacosamide 50 mg tablet, 14	12626M	4	56	5	Fycompa
lacosamide 100 mg tablet, 56	12634Y	1	56	5	
lacosamide 150 mg tablet, 56	12627N	1	56	5	
lacosamide 200 mg tablet, 56	12658F	1	56	5	
lacosamide 10 mg/mL oral liquid, 200 mL	12628P	2	2	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
14229	**Indication:** Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures
	Clinical criteria:
27524	The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised ~~anti-epileptic drugs~~ *antiseizure medications* at the time the drug is/was first commenced

	AND
	Clinical criteria:
27524	The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised ~~anti-epileptic drugs~~ *antiseizure medications* at the time the drug is/was first commenced
	Treatment criteria
8656	Must be treated by a neurologist; or
10064	Must be treated by a paediatrician; or
27534	Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion
	Population criteria:
9083	Patient must be aged 12 years or older
13615	**Administrative Advice:** No applications for increased maximum quantities will be authorised.

Lacosamide – 60-day listing

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
LACOSAMIDE					
lacosamide 50 mg tablet, 14	14011K	8	112	5	Vimpat (Various other brands)
lacosamide 100 mg tablet, 56	13867W	2	112	5	
lacosamide 150 mg tablet, 56	14053P	2	112	5	
lacosamide 200 mg tablet, 56	13951G	2	112	5	
lacosamide 10 mg/mL oral liquid, 200 mL	14048J	12	12	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
8655	**Indication:** Intractable ~~partial epileptic~~ *focal onset* seizures
	Treatment Phase: Continuing
	Clinical criteria:
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	AND
	Clinical criteria:
11364	Patient must have previously received PBS-subsidised treatment with this drug for this condition

Everolimus

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EVEROLIMUS					
everolimus 2 mg dispersible tablet, 30	11591C	1	30	5	Diacomit
everolimus 3 mg dispersible tablet, 30	11599L	1	30	5	
everolimus 5 mg dispersible tablet, 30	11592D	1	30	5	

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Telephone/Online)
Restriction Summary New / Treatment of Concept: New	
23005	**Indication:** Refractory seizures associated with tuberous sclerosis complex
	Treatment Phase: Initial treatment

	Clinical criteria:
22987	Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC)
	AND
	Clinical criteria:
22988	Patient must be experiencing a minimum of two partial-onset seizures per week
	AND
	Clinical criteria:
22989	The condition must have failed to be controlled satisfactorily at stable doses of at least two ~~anti-epileptic drugs~~ *antiseizure medication*
	AND
	Clinical criteria:
22991	The treatment must be in combination with at least one ~~anti-epileptic drugs~~ *antiseizure medication*
	AND
	Clinical criteria:
22992	Patient must not be a candidate for curative surgery
22995	**Population criteria:**
22994	Patient must be at least 2 years of age

Cannabidiol

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
CANNABIDIOL					
cannabidiol 100 mg/mL oral liquid, 100 mL	12467E	1	1	5	Epidyolex

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Telephone/Online)
Restriction Summary New / Treatment of Concept: New	
26155	**Indication:** Severe myoclonic epilepsy in infancy (Dravet syndrome)
	Clinical criteria:
27181	Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two ~~anti-epileptic drugs~~ *antiseizure medications*
	AND
	Clinical criteria:
27182	The treatment must be as adjunctive therapy to at least two other ~~anti-epileptic drugs~~ *antiseizure medication*
	Treatment criteria:
26160	Must be treated by a neurologist if treatment is being initiated; or
26161	Must be treated by a neurologist if treatment is being continued or re-initiated; or
26162	Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; or
26163	Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued
30425	**Prescribing Instructions:** Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness.
29712	**Prescribing Instructions:** Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CANNABIDIOL						
cannabidiol 100 mg/mL oral liquid, 100 mL		13277T	1	1	5	Epidyolex
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)					
	Prescriber type: ☒Medical Practitioners					
	Restriction type: ☒Authority Required (Telephone/Online)					
Restriction Summary New / Treatment of Concept: New						
8655	**Indication:** Seizures of the Lennox-Gastaut syndrome					
	Clinical criteria:					
30419	Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible)					
	AND					
	Clinical criteria:					
30421	Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures					
	AND					
	Clinical criteria:					
30423	Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other ~~anti-epileptic drugs~~ *antiseizure medications* prior to initiating treatment with this medicine					
	AND					
	Clinical criteria:					
27182	The treatment must be as adjunctive therapy to at least two other ~~anti-epileptic drugs~~ *antiseizure medication*					
	Treatment criteria:					
26160	Must be treated by a neurologist if treatment is being initiated; or					
26161	Must be treated by a neurologist if treatment is being continued or re-initiated; or					
26162	Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; or					
26163	Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued					
30425	**Prescribing Instructions:** Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness.					
29712	**Prescribing Instructions:** Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.					

Stiripentol

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
STIRIPENTOL						
stiripentol 250 mg capsule, 60		12103B	2	120	3	Diacomit
stiripentol 250 mg powder for oral liquid, 60 sachets		12106E	2	120	3	
stiripentol 500 mg capsule, 60		12107F	2	120	3	
stiripentol 500 mg powder for oral liquid, 60 sachets		12088F	2	120	3	
	Category / Program: ☒ GENERAL - General Schedule (Code GE)					
	Prescriber type: ☒Medical Practitioners					

Concept ID (for internal Dept. use)	Restriction type: ☒Authority Required (STREAMLINED)
Restriction Summary New / Treatment of Concept: New	
26155	**Indication:** Severe myoclonic epilepsy in infancy (Dravet syndrome)
	Clinical criteria:
27181	Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two ~~anti-epileptic drugs~~ *antiseizure medications*
	AND
	Clinical criteria:
27182	The treatment must be as adjunctive therapy to at least two other ~~anti-epileptic drugs~~ *antiseizure medication*
	Treatment criteria:
26160	Must be treated by a neurologist if treatment is being initiated; or
26161	Must be treated by a neurologist if treatment is being continued or re-initiated; or
26162	Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; or
26163	Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued

Fenfluramine

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
FENFLURAMINE					
fenfluramine hydrochloride 2.2 mg/mL oral liquid, 360 mL	14833Q	1	1	5	Diacomit

Concept ID (for internal Dept. use)	
	Category / Program: ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Telephone/Online)
Restriction Summary New / Treatment of Concept: New	
26155	**Indication:** Severe myoclonic epilepsy in infancy (Dravet syndrome)
	Clinical criteria:
33269	Patient must have (if initiating) generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other ~~anti-epileptic drugs~~ *antiseizure medications*; or
33270	Patient must have had (if continuing) generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other ~~anti-epileptic drugs~~ *antiseizure medications*
	AND
	Clinical criteria:
27182	The treatment must be as adjunctive therapy to at least two other ~~anti-epileptic drugs~~ *antiseizure medication*
	Treatment criteria:
26160	Must be treated by a neurologist if treatment is being initiated; or
26161	Must be treated by a neurologist if treatment is being continued or re-initiated; or
26162	Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; or
26163	Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued

Migalastat

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
MIGALASTAT					

migalastat 123 mg capsule, 14	14573B	1	14	5	Galafold

Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (Written)
Restriction Summary 15808 / Treatment of Concept: 15808	
26155	**Indication:** Fabry disease
	Treatment Phase: Initial treatment
	Clinical criteria:
32549	Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity
	AND
	Clinical criteria:
32551	Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant
	AND
	Clinical criteria:
32553	Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m2
	AND
	Clinical criteria:
32555	Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; or
32557	Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; or
32558	Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; or
32559	Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; or
32560	Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and ~~antiepileptic~~ *antiseizure* medications for peripheral neuropathy; or
32561	Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies
	Treatment criteria:
32562	Must be treated by a physician with expertise in the management of Fabry disease
	Population criteria:
30140	Patient must be at least 12 years of age
32564	**Prescribing Instructions:** If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.
32569	**Prescribing Instructions:** Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.
32530	**Prescribing Instructions:** The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

28584	**Administrative Advice:** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001