

4.01 FREMANEZUMAB,

Injection 225 mg in 1.5 mL pre-filled syringe,

Ajovy[®],

Teva Pharma Australia Pty Ltd

1 Purpose of Application

- 1.1 At its November 2019 meeting, the PBAC deferred making a recommendation for fremanezumab for the treatment of chronic migraine in patients who have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications.
- 1.2 The PBAC considered fremanezumab was an alternative treatment to botulinum toxin type A (herein referred to as Botox) (currently listed) and galcanezumab (recommended for listing in July 2019) for patients with chronic migraine and provided a similar reduction in monthly migraine days. The PBAC was of a mind to recommend fremanezumab for listing on the basis of cost-minimisation to Botox or galcanezumab but deferred making a recommendation to address the uncertainties regarding the number of patients who would be treated and the net financial cost of listing fremanezumab on the PBS (paragraph 7.1, fremanezumab public summary document (PSD), November 2019 PBAC meeting).
- 1.3 The Sponsor provided the following information to address the PBAC’s concerns (paragraph 7.11 fremanezumab PSD, November 2019 PBAC meeting):
- A revised cost-minimisation analysis (CMA) versus Botox with equi-effective doses of fremanezumab 225 mg every month and 164U of Botox every 12 weeks;
 - A revised estimate of patient numbers;
 - A revised estimate of the net financial cost of listing fremanezumab; and
 - Details regarding a risk share arrangement (RSA) to manage the uncertainty regarding the size of the patient population.

2 Requested listing

Name, restriction, manner of administration, form	Maximum quantity (packs)	Maximum quantity (units)	No. of repeats	Dispensed price for maximum quantity	Proprietary name and manufacturer
FREMANEZUMAB 225 mg/1.5 mL injection, 1.5 mL syringe.	1	1	2	Published: \$ [REDACTED] Effective: \$ [REDACTED]	Ajovy [®] , TEVA
PBS Indication:	Chronic migraine				

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Treatment phase:	Initial treatment
Restriction:	<input checked="" type="checkbox"/> Streamlined
Treatment criteria:	Must be treated by a neurologist
Clinical criteria:	<p>Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition</p> <p>AND</p> <p>Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with medicine for this condition</p> <p>AND</p> <p>Patient must be appropriately managed for medication overuse headache, prior to initiation of treatment with this medicine for this condition</p> <p>AND</p> <p>The treatment must not be in combination with PBS-subsidised botulinum toxin type A</p> <p>AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition</p>
Population criteria:	Patient must be aged 18 years or older
Prescriber instructions:	<p>Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate</p> <p>Patient must have a baseline measurement of the number of migraine days per month documented in their medical records</p>
Administrative Advice	<p>No increase in the maximum quantity or number of units may be authorised</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>Special Pricing Arrangement apply</p>

Name, restriction, manner of administration, form	Maximum quantity (packs)	Maximum quantity (units)	No. of repeats	Dispensed price for maximum quantity	Proprietary name and manufacturer
FREMANEZUMAB 225 mg/1.5 mL injection, 1.5 mL syringe.	1	1	5	Published: \$ [REDACTED] Effective: \$ [REDACTED]	Ajovy®, TEVA

PBS Indication:	Chronic migraine
Treatment phase:	First continuing treatment
Restriction:	<input checked="" type="checkbox"/> Streamlined
Treatment criteria:	Must be treated by a neurologist

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Clinical criteria:	Patient must have previously received PBS-subsidised treatment with this drug for this condition AND Patient must have achieved a 50% or greater reduction from baseline in the number of migraine days per month AND Patient must continue to be appropriately managed for medication overuse headache AND The treatment must not be in combination with PBS-subsidised botulinum toxin type A
Prescriber instructions:	Patient must have the number of migraine days per month documented in their medical records
Administrative Advice	No increase in the maximum quantity or number of units may be authorised No increase in the maximum number of repeats may be authorised. Special Pricing Arrangement apply

PBS Indication:	Chronic migraine
Treatment phase:	Second and subsequent continuing treatment
Restriction:	<input checked="" type="checkbox"/> Streamlined
Treatment criteria:	Must be treated by, or in consultation with, a neurologist
Clinical criteria:	Patient must have previously received PBS-subsidised treatment with this drug for this condition AND Patient must have achieved a 50% or greater reduction from baseline in the number of migraine days per month AND Patient must continue to be appropriately managed for medication overuse headache AND The treatment must not be in combination with PBS-subsidised botulinum toxin type A
Prescriber instructions:	Patient must have the number of migraine days per month documented in their medical records
Administrative Advice	No increase in the maximum quantity or number of units may be authorised No increase in the maximum number of repeats may be authorised. Special Pricing Arrangement apply

- 2.1 The proposed listing is an Authority Required (Streamlined) listing for the treatment of patients with chronic migraine who have had an inadequate response, intolerance or a contraindication to ≥ 3 prophylactic migraine medications.
- 2.2 The proposed maximum quantity and repeats will provide 3 months of initial treatment and 6 months of continuing treatment at the recommended dose of 225 mg every month.
- 2.3 The proposed listing required initial treatment and first continuing treatment be prescribed by a neurologist, with subsequent continuing treatment able to be prescribed by, or in conjunction with, a neurologist (which allows for prescribing by general practitioners). The PBAC previously advised the criteria for fremanezumab should allow for all continuing treatment to be prescribed by, or in conjunction with, a neurologist (paragraph 7.11, fremanezumab PSD, November 2019 PBAC meeting) for consistency with the recommended galcanezumab criteria.

- 2.4 The Sponsor requested grandfathering provisions for an estimated less than 10,000 patients who are currently being treated under product familiarisation programs for other calcitonin gene-related peptide (CGRP) inhibitors (mostly erenumab). However, the PBAC considered grandfathered patients should be eligible for PBS subsidised treatment under the proposed initial restriction criteria and therefore a separate grandfather restriction was not required.

For more detail on PBAC's view, see section 6 PBAC outcome.

3 Background

Registration status

- 3.1 Fremanezumab was approved by the TGA on 17 September 2019 for the “preventive treatment of migraine in adults”. The proposed restriction is narrower than the TGA indication, which does not restrict treatment based on migraine frequency (i.e. episodic or chronic) or prior therapies.

Previous PBAC consideration

- 3.2 The previous submission identified a number of different patient populations that would be appropriate for treatment with fremanezumab and identified two main comparators, depending on the patient population: best supportive care and Botox. The PBAC considered the methodology used to derive the different patient populations was arbitrary and highly uncertain and there was likely to be overlap in the populations and double counting of patients (paragraph 7.3, fremanezumab PSD, November 2019 PBAC meeting).
- 3.3 The previous submission presented a cost-effectiveness analysis versus best supportive care and a cost-minimisation analysis versus Botox with a single weighted price for fremanezumab calculated using a weight of █████% for the cost-effective price. The ESC considered the weighted price for fremanezumab was highly dependent on the proportion of use between the different populations which was uncertain (paragraph 6.73, fremanezumab PSD, November 2019 PBAC meeting).
- 3.4 The PBAC considered fremanezumab should be restricted to the same high need patient population as Botox and advised that the main comparator for fremanezumab should be Botox (paragraph 7.4, fremanezumab PSD, November 2019 PBAC meeting).
- 3.5 The previous submission also nominated two medicines with a similar mechanism of action, erenumab and galcanezumab, as supplementary comparators. Erenumab has been rejected by the PBAC twice¹ (July 2018, March 2019) and galcanezumab received a positive recommendation in July 2019 but is not currently listed on the PBS.

¹ A major resubmission was withdrawn prior to consideration at the November 2019 meeting

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3.6 The PBAC considered that, on balance, the claim of non-inferior comparative effectiveness and safety compared to Botox, galcanezumab and erenumab was uncertain but reasonably supported by the data (paragraph 6.54, fremanezumab PSD, November 2017 PBAC meeting).

3.7 The outstanding matters of concern from the November 2019 meeting are summarised in Table 1.

Table 1: PBAC matters of concern in previous consideration (November 2019)

Matters of concern	How the resubmission addresses it
<p>The PBAC considered were fremanezumab recommended for listing, it should be listed on a cost-minimisation basis versus Botox.the equi-effective doses are: fremanezumab 225 mg every month or 675 mg every three months and 164U of Botox every 12 weeks. The PBAC advised the CMA should be conducted over 2 years of treatment for both medicines (paragraph 7.7).</p>	<p>The Sponsor proposed an equi-effective dose of fremanezumab 225 mg per month and 164U of Botox every 12 weeks and conducted the CMA over 2 years.</p> <p>The Sponsor assumed that all patients would be treated with 225 mg per month (rather than 675 mg quarterly). Only listing the monthly dose addresses wastage and quality use of medicine issues previously raised by the Secretariat (paragraph 2.5, fremanezumab PSD, November 2019 PBAC meeting).</p>
<p>The PBAC noted the submission estimated 10,000 – 50,000 patients would be treated with fremanezumab in the first year, increasing to 10,000 – 50,000 patients in year 6 and considered these estimates were highly uncertain because the methodology used was not reliable (paragraph 7.9)</p>	<p>The Sponsor has estimated less than 10,000 patients would initiate treatment in April 2020. An estimated less than 10,000 grandfathered patients (mostly from the erenumab access program) would also commence treatment in April 2020.</p> <p>It has been estimated that in the first full year of listing, less than 10,000 of patients would initiate treatment, by the fifth year of listing there would be 10,000 – 50,000 patients treated.</p>
<p>The PBAC noted the financial estimates included an offset for up to 10,000 – 50,000 patients treated with Botox and considered this was based on assumptions that were not reasonable (paragraph 6.85).</p>	<p>The revised financial estimates include a cost offset for up to less than 10,000 patients treated with Botox.</p>
<p>The PBAC considered that a RSA with significant rebates above the caps will be required to manage the total financial impact of listing fremanezumab, noting highly uncertain and high financial estimates (paragraph 7.11).</p> <p>The PBAC considered that the proposed █% rebate did not adequately share the risk of use above the proposed expenditure cap (paragraph 6.89).</p>	<p>The Sponsor proposed an RSA with two expenditure caps with a █% rebate for expenditure between the Tier 1 and Tier 2 cap and an █% rebate for expenditure above the Tier 2 cap.</p> <p>The Tier 1 cap is set at the predicted cost of fremanezumab (net of co-payments) and the Tier 2 cap is set at █times the Tier 1 cap. No justification was provided for the Tier 2 cap.</p>
<p>The PBAC further considered that any RSA would likely need to take into account the use of Botox and be shared across any other novel agents for this condition, such as other CGRP ligand antagonists, or CGRP receptor antagonists that might be listed on the PBS in the future (paragraph 7.11).</p>	<p>The Sponsor has proposed the expenditure caps apply to █</p>
<p>The submission assumed that █% of patients would continue treatment beyond 12 weeks based on the continuation rate for Botox at 24 weeks reported in the 2017 DUSC Botox review. This continuation rate differed from the continuation rate in the economic model and observed in the clinical trials. This continuation rate differed from the continuation rate of █% assumed in the economic model... (paragraph 6.81) [and the rate observed in the clinical trials]. The submission assumed that an additional █% of patients treated with fremanezumab would discontinue treatment each</p>	<p>A continuation rate of █% at 12 weeks continues to be applied and the yearly discontinuation rate has been increased to █% (from █%).</p> <p>█% of patients treated with fremanezumab 225 mg monthly achieved a 50% reduction in migraine days at 12 weeks in the previous submission (paragraph 6.29, fremanezumab PSD, November 2019 PBAC meeting).</p>

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year. Given the lack of alternative treatments, and the convenience of fremanezumab administration compared to Botox, the discontinuation rate in subsequent years may be lower than estimated (paragraph 6.82).	
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CGRP calcitonin gene-related peptide; CMA cost minimisation analysis; DUSC drug utilisation sub-committee; PBAC Pharmaceutical Benefits Advisory Committee; PBS Pharmaceutical Benefits Scheme; RSA risk-sharing arrangement.

Source: Compiled during the evaluation. Paragraph references refer to the fremanezumab PSD, November 2019 PBAC meeting.

For more detail on PBAC's view, see section 6 PBAC outcome.

4 Comparator

4.1 The previous submission nominated Botox and best supportive care as the main comparators (paragraph 3.3); however, the PBAC advised that Botox should be the main comparator (paragraph 7.4, fremanezumab PSD, November 2017 PBAC meeting). Accordingly, the Sponsor provided a CMA versus Botox.

For more detail on PBAC's view, see section 6 PBAC outcome.

5 Consideration of the evidence

Economic analysis

- 5.1 The Sponsor proposed equi-effective doses of fremanezumab 225 mg per month and 164U of Botox every 12 weeks.
- 5.2 The results of the cost-minimisation analysis conducted over 2 years and based on the published price of Botox is provided in Table 2.

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Table 2: Results of the cost-minimisation analysis based on the published price for Botox

Component	Fremanezumab	Botox
Drug costs (AEMP)		
Pack	1 x 225 mg injection	1 x 100U vial
Cost per pack	\$264.39	\$337.49
Number of packs per dose	1.0	1.64
Cost per dose	\$264.39	\$553.48
Number of doses per 2 years	24.0	8.7
Total drug cost: 2 years	\$6,345.33	\$4,815.31
Administration costs		
Neurologist (MBS Item 116) per visit	\$77.90	\$77.90
Botox administration (MBS Item 18377) per visit	-	\$126.85
Number of visits per 2 years ¹	2.0	8.7
General practitioner MBS (Item 23)	\$38.20	\$38.20
Number of visits per 2 years ²	2.50	-
Total administration cost: 2 years	\$251.30	\$1,781.33
Total drug and administration cost: 2 years	\$6,596.63	\$6,596.63

AEMP approved ex-manufacturer price; MBS Medicare Benefits Schedule

1. Fremanezumab: neurologist visit at month 0 (initial script) and 3 (first continuing script); Botox: neurologist visits every 3 months (=364.25*2/84, rounded to 8.7)
2. Fremanezumab: GP visit at month 9 (second and subsequent continuing script), 15 and 21 = 3, reduced to 2.5 to account for 24 months of treatment.

Drug cost/patient/year: \$3,592.80.

5.3 Based on a dispensed price for maximum quantity (DPMQ) of \$299.40 per injection and assuming 12 injections per year, the drug cost per patient per year is \$3,592.80 (using the published price of Botox to determine the fremanezumab price).

Estimated PBS usage & financial implications

5.4 The key inputs into the financial estimates are summarised in Table 3.

Table 3: Key inputs for financial estimates

Parameter	Value applied and source	Comment
DPMQ per script	\$299.27	Calculated using the published price of Botox
Copayment	\$30.85	From November 2019 submission (based on Botox usage).
Initial patient numbers	April to June: less than 10,000	Prevalence of migraine: 1.305% adults, 37.24% have chronic migraine ¹ . Year 1: █% treated. Year 5: █% treated.
	Year 1: █	
	Year 2: █	
	Year 3: █	
	Year 4: █	
Continuing patient numbers	April to June: less than 10,000 (from CGRP inhibitor access programs)	The Sponsor estimated there are likely to be less than 10,000 patients on CGRP inhibitor access programs that will require transition (grandfathering) to PBS listed fremanezumab. The source of this estimate is unclear. Year 1 to Year 5 continuing patients calculated based on the number of initial patients and assumptions below.
	Year 1: █	
	Year 2: █	
	Year 3: █	
	Year 4: █	

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Parameter	Value applied and source	Comment
Continuation rate at 12 weeks	█% Based on the continuation rate for Botox reported in the 2017 DUSC Botox review (paragraph 6.81, fremanezumab PSD, November 2019 PBAC meeting).	Unchanged from previous submission.
Discontinuation rate in subsequent years	█%	The assumption that █% of continuing (responding) patients discontinue treatment each year is higher than the previous submission (which assumed █% of patients discontinued). It is also assumed that █% of the less than 10,000 grandfathered patients will discontinue treatment in the first full financial year of listing (i.e. year 1) which may not be reasonable. These patients may have been on CGRP inhibitor treatment for some time and may be less likely to discontinue treatment.
No. scripts	First 3 months: all initial and grandfathered patients receive 3 scripts ² For each full financial year: Initial patients: all receive 3 scripts, continuing receive 9 scripts Continuing patients: all receive 12 scripts	This is an overestimate as it assumes all patients receive a full 12 months of treatment.
Botox offsets	AEMP \$337.49 Patients: April to June: █ Year 1: █ Year 2: █ Year 3: █ Year 4: █ Year 5: █ 1.64 scripts per patient per dose 4.35 doses per patient per year	Assumptions consistent with the CMA. The offsets were calculated at the AEMP level which will underestimate the cost offsets.

AEMP approved ex-manufacturer price; CGRP calcitonin gene-related peptide; CMA cost-minimisation analysis; DPMQ dispensed price for maximum quantity; DUSC drug utilisation sub-committee; PBAC Pharmaceutical Benefits Advisory Committee; PBS Pharmaceutical Benefits Scheme; RSA risk-sharing arrangement

1. Based on epidemiology approach to estimate patient numbers included in November 2019 submission.
2. Proposal assumed all initial patients received 3 months plus continuing (responding) patients received 1 month treatment; all grandfathered patients received 4 months of treatment

The redacted table shows initial patient numbers to be less than 10,000 patients per year in Year 1 and 2 and 10,000 - 50,000 patients per year in Years 3-5. The continuing patient numbers is less than 10,000 patients in Year 1, and 10,000 – 50,000 per year in Year 2-5.

5.5 The net cost to the PBS in the fifth full financial year of listing is estimated to be \$30 - \$60 million, with a total net cost to the PBS of more than \$100 million over the first 5 full financial years of listing (based on published price of Botox) (Table 4).

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Table 4: Estimated use and financial implications

	April 2020 to June 2020	Year 1 July 2020 to June 2021	Year 2 July 2021 to June 2022	Year 3 July 2022 to June 2023	Year 4 July 2023 to June 2024	Year 5 July 2024 to June 2025
Estimated extent of use						
Number of patients treated						
Initial						
Continuing						
Number of scripts dispensed						
Estimated financial implications for fremanezumab						
Cost to PBS/RPBS less copayments	\$	\$	\$	\$	\$	\$
Estimated financial implications for Botox						
Cost to PBS/RPBS less copayments	-\$	-\$	-\$	-\$	-\$	-\$
Net financial implications						
Net cost to PBS/RPBS	\$	\$	\$	\$	\$	\$

a. The Sponsor assumed all initial patients would be treated for 3 months and % would receive 1 month of continuing treatment. This overestimated the number of months of treatment as April to June equates to 3 months. From April 2020 to June 2020, the Sponsor assumed all grandfathered patients would be treated for 4 months which also overestimated the treatment duration. The corrected numbers are presented in the table.

Risk share arrangement

5.6 The Sponsor proposed a RSA with expenditure caps to manage the cost of listing fremanezumab on the PBS. The expenditure caps proposed by the Sponsor (using a price for fremanezumab based on the published price of Botox) are provided in Table 5. Two expenditure caps were proposed with a % rebate of expenditure between Tier 1 and Tier 2 and % rebate above Tier 2. The Tier 1 cap is consistent with the cost of listing fremanezumab on the PBS/ RPBS in Table 4 and Tier 2 was set at times the Tier 1 expenditure cap. No justification was provided for the Tier 2 expenditure cap.



Table 5: Expenditure caps

	April 2020 to June 2020	Year 1 July 2020 to June 2021	Year 2 July 2021 to June 2022	Year 3 July 2022 to June 2023	Year 4 July 2023 to June 2024	Year 5 July 2024 to June 2025
Tier 1 % rebate	\$	\$	\$	\$	\$	\$
Tier 2 % rebate	\$	\$	\$	\$	\$	\$

For more detail on PBAC’s view, see section 6 PBAC outcome.

6 PBAC Outcome

6.1 The PBAC recommended the Authority Required (Streamlined) listing of fremanezumab for the treatment of chronic migraine in patients who have experienced an inadequate response, intolerance or a contraindication to at least

three prophylactic migraine medications. The PBAC considered fremanezumab was an alternative treatment to Botox for patients with chronic migraine and provided a similar reduction in migraine headache days. The PBAC considered the cost minimisation analysis should be based on equi-effective doses of 225 mg fremanezumab every month and 164U of Botox every 12 weeks over 2 years of treatment. Additionally, the PBAC considered it would be appropriate for the use, and associated expenditure, of fremanezumab to be restricted to the same high need patient population as for Botox.

- 6.2 The PBAC's recommendation for listing was based on, among other matters, its assessment, as described above, that the cost-effectiveness of fremanezumab would be acceptable if it were cost-minimised against Botox.
- 6.3 The PBAC considered the CMA methodology in paragraph 5.2 was appropriate (with the amendment outlined in paragraph 6.8) and should use the effective Botox price.
- 6.4 The PBAC recalled it had previously considered the number of patients with chronic migraine that would be treated with CGRP inhibitors to be highly uncertain (paragraph 7.3, fremanezumab PSD, November 2019 PBAC meeting; paragraph 7.4, galcanezumab PSD, July 2019 PBAC meeting; paragraph 7.12, erenumab PSD, March 2019 PBAC meeting). The PBAC noted the revised patient numbers included in the current fremanezumab proposal were significantly lower than those in the previous fremanezumab submission. However, the PBAC considered the methodology used to estimate the number of treated patients remained unclear and the number of patients likely to be treated continued to be uncertain.
- 6.5 The PBAC considered a 12 week continuation rate of ■% should be applied to the financial estimates to reflect the proportion of patients with a ≥50% reduction in monthly average number of migraine days observed in the clinical trial for the monthly dose (paragraph 6.29, fremanezumab PSD, November 2019 PBAC meeting).
- 6.6 The PBAC recalled it had previously considered the ■% discontinuation rate applied to the financial estimates to be high given the lack of alternative treatments and convenience of fremanezumab compared to Botox (paragraph 6.82, fremanezumab PSD, November 2019 PBAC meeting). The PBAC noted the proposal applied an even higher discontinuation rate to the financial estimates (■%) and advised a discontinuation rate of approximately ■% was likely to be a more reasonable assumption.
- 6.7 The PBAC considered it would be appropriate for the use, and associated expenditure, of fremanezumab to be restricted to the same high need patient population as for Botox. The PBAC did not consider that incremental expenditure beyond the current PBS spend on Botox was justified. The PBAC recommended that the Department work with the Sponsor on an appropriate RSA in this context.
- 6.8 The PBAC considered initial treatment with fremanezumab should be prescribed by neurologists and all continuing treatment could be prescribed by, or in conjunction

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with, a neurologist, consistent with its previous recommendation (paragraph 7.11, fremanezumab PSD, November 2019 PBAC meeting). The PBAC advised the CMA should be revised to reflect one neurologist visit and 3.5 GP visits for fremanezumab over 2 years.

- 6.9 The PBAC recalled it had previously considered fremanezumab non-inferior to galcanezumab in terms of effectiveness and safety and that the equi-effective doses were fremanezumab 225 mg every month and galcanezumab 240 mg initially followed by 120 mg every month (paragraph 7.6 and 7.8, fremanezumab PSD, November 2019 PBAC meeting).
- 6.10 The PBAC noted a number of flow on changes to the restriction criteria for Botox will be required as described in Section 7.
- 6.11 The PBAC recommended that fremanezumab should not be treated as interchangeable on an individual patient basis with Botox but could be treated as interchangeable on an individual patient basis with galcanezumab.
- 6.12 The PBAC advised that fremanezumab is not suitable for prescribing by nurse practitioners.
- 6.13 The PBAC noted that this submission is not eligible for an Independent Review.
- 6.14 The PBAC recommended that the Early Supply Rule should apply.
- 6.15 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because fremanezumab is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Botox, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009 for Pricing Pathway A were not met.

Outcome:

Recommended.

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary Manufacturer	Name and
FREMANEZUMAB fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe	NEW	1	1	2	Ajovy®	Teva Pty Ltd

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Chronic migraine
Treatment Phase: Initial treatment

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<p>Treatment criteria:</p> <ul style="list-style-type: none"> ▪ Must be treated by a neurologist <p>Clinical criteria:</p> <ul style="list-style-type: none"> ▪ Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition <p>AND</p> <ul style="list-style-type: none"> ▪ Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with medicine for this condition <p>AND</p> <ul style="list-style-type: none"> ▪ Patient must be appropriately managed for medication overuse headache, prior to initiation of treatment with this medicine for this condition <p>AND</p> <ul style="list-style-type: none"> ▪ The treatment must not be in combination with PBS-subsidised botulinum toxin type A <p>AND</p> <ul style="list-style-type: none"> ▪ Patient must not have previously received PBS-subsidised treatment with this drug for this condition <p>Population criteria:</p> <ul style="list-style-type: none"> ▪ Patient must be aged 18 years or older
<p>Prescribing Instructions: Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.</p> <p>Patient must have a baseline measurement of the number of migraine days per month documented in their medical records.</p>
<p>Administrative Advice: No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply</p>

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Proprietary Name and Manufacturer	
FREMANEZUMAB fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe	NEW	1	1	5	Ajovy®	Teva Pty Ltd

<p>Category / Program: GENERAL – General Schedule (Code GE)</p> <p>Prescriber type: <input type="checkbox"/>Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/>Nurse practitioners <input type="checkbox"/>Optometrists <input type="checkbox"/>Midwives</p> <p>Restriction Level / Method: <input checked="" type="checkbox"/> Authority Required - Streamlined</p> <p>Indication: Chronic migraine</p> <p>Treatment Phase: Continuing treatment</p> <p>Treatment criteria:</p> <ul style="list-style-type: none"> ▪ Must be treated by, or in consultation with, a neurologist <p>Clinical criteria:</p> <ul style="list-style-type: none"> ▪ Patient must have previously received PBS-subsidised treatment with this drug for this condition <p>AND</p> <ul style="list-style-type: none"> ▪ Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month <p>AND</p> <ul style="list-style-type: none"> ▪ Patient must continue to be appropriately managed for medication overuse headache <p>AND</p> <ul style="list-style-type: none"> ▪ The treatment must not be in combination with PBS-subsidised botulinum toxin type A <p>Prescribing Instructions: Patient must have the number of migraine days per month documented in their medical records.</p>
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Administrative Advice:

No increase in the maximum quantity or number of units may be authorised

No increase in the maximum number of repeats may be authorised

Special Pricing Arrangements apply

Flow-on changes to botulinum toxin type A's listing are as follows:

1) Delete the words 'by his or her practitioner' where they appear for consistency with fremanezumab;

2) Insert a new Clinical criterion to prevent simultaneous PBS-subsidy of Botox and fremanezumab;

Clinical criteria:

The treatment must not be in combination with PBS-subsidised calcitonin gene-related peptide (CGRP) inhibitors

3) Update the existing list of prophylactic migraine medications to be consistent with the list appearing in the prescribing instruction of the fremanezumab initial treatment listing above.

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

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

9 Sponsor's Comment

The Sponsor thanks the PBAC for its deliberations and will continue to work with the Department of Health and the PBAC Secretariat to make fremanezumab available to Australian chronic migraine patients.