5.14 EFGARTIGIMOD ALFA, Injection 1000 mg in 5.0 mL pre-filled syringe, Vyvgart®, Argenx Australia Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission requested to add an efgartigimod alfa (EFG) 1000 mg / 5.0 mL pre-filled syringe (PFS), alongside the already PBAC-recommended intravenous (IV) and subcutaneous (SC) formulations of EFG for the treatment of adult patients with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

1.2 Listing was requested on the basis of cost-minimisation versus EFG SC. The cost-minimisation was based on a proposed published price for EFG SC, as an effective price was not available.

2 Background

2.1 March 2025 PBAC meeting: EFG IV was recommended as a Section 100 Highly Specialised Drug (s100 HSD) listing, along with 3 other therapies for the treatment of gMG: ravulizumab, rozanolixizumab and zilucoplan. All 4 submissions were recommended on the basis of a cost-comparison versus intravenous immunoglobulin (IVIg), supported by a cost-per-responder analysis versus placebo. The PBAC considered that all 4 therapies were non-inferior in effectiveness and safety compared to IVIg. The PBAC advised that these 4 therapies should be listed for 3 settings: acute severe, bridging therapy and treatment refractory. The PBAC advised that a single Risk Sharing Arrangement (RSA) including all four therapies would be required to mitigate the risk of use outside intended restrictions, and for the FcRn blockers (efgartigimod alfa and rozanolixizumab) the RSA would need to mitigate the risk of an increase in the frequency of cycles received over time.

2.2 November 2025 PBAC meeting: EFG SC was recommended under the same circumstances as the IV formulation (based on a cost comparison to IVIg). The PBAC advised that the requested general schedule (s85) listing would be inappropriate and recommended a s100 HSD listing, consistent with the IV formulation, ravulizumab, rozanolixizumab and zilucoplan. The PBAC noted that the proposed cost-minimisation approach (CMA) of IV versus SC was not reasonable. In particular, the PBAC did not accept the reduced use of MBS items as an acceptable cost offset as part of the CMA, as it was unclear that the savings would be realised in practice. For EFG SC, noting the submission's proposed equivalence of 1 SC vial to 2.4 vials of EFG IV, the PBAC advised

that the cost comparison should incorporate an annual dose EFG SC of 18,880 mg per year (or simply put, the 1 vial EFC SC should be priced equivalent to 2.4 vials of EFG IV). The PBAC provided additional advice in November 2025 with respect to the price premium for these therapies over the cost of IVIg and also the reimbursement rates for expenditure over the RSA caps. The outcomes of the November 2025 PBAC meeting were not available to the sponsor at the time of submission for the March 2026 PBAC meeting.

2.3 As of March 2026, listing arrangements for zilucoplan have been agreed and ravulizumab is now available on the PBS. The sponsor for EFG lodged a post-PBAC listing proposal for EFG IV on 23 July 2025, however it had not progressed.

Registration status

2.4 EFG (Vyvgart) PFS was approved by the Therapeutic Goods Administration (TGA) on 16 February 2026.

2.5 EFG (Vyvgart) IV and SC were TGA registered on 24 February 2025 for the treatment of adult patients with gMG who are AChR antibody positive.

3 Requested listing

3.1 The submission requested a new form of EFG, a PFS. The sponsor requested a listing that would include the same restriction wording, administrative advice and prescribing instructions as the IV and SC. However, the submission proposed a different category/program of general schedule (s85) and a lower authority level of Telephone/Online, instead of the previously PBAC recommended s100 HSD and Written/Online authority. For brevity, the full recommended restrictions have not been reproduced. Secretariat additions are in *italics* and deletions are in strikethrough below.

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EFGARTIGIMOD ALFA					
~~Injection 1000mg in 5.0mL pre-filled syringe~~ *efgartigimod alfa 1 g/5 mL injection, 5 mL syringe*	NEW	4	4	1 (acute severe)	Vyvgart
efgartigimod alfa 1 g/5 mL injection, 5 mL syringe	NEW	4	4	3 (bridging therapy)	Vyvgart
efgartigimod alfa 1 g/5 mL injection, 5 mL syringe	NEW	4	4	3 (treatment refractory)	Vyvgart

Concept ID	**Category / Program:** ☒ ~~GENERAL - General Schedule (Code GE)~~ *Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)*
	Prescriber type: ☒ Medical Practitioners
	Restriction type: ☒ Authority Required (~~telephone~~ *Written*/online PBS Authorities system)

3.2 The sponsor requested a general schedule (s85) listing for EFG PFS, claiming that subcutaneous delivery is appropriate for community administration, and a s85 listing would allow dispensing from community pharmacies, supporting equitable access for patients in rural and regional areas.

3.3 The submission did not propose an effective price as pricing for EFG SC on the PBS has not been agreed. It requested a Special Pricing Arrangement with a published AEMP of $[redacted] for the EFG PFS (this was also requested to apply to EFG SC, and was reduced from the November 2025 requested published price of $[redacted]).

4 Comparator

4.1 The submission proposed a PFS formulation of EFG, and compared this to the previously recommended SC and IV formulations of the same drug. The submission did not consider other near-market comparators.

4.2 The PBAC could only recommend listing efgartigimod alfa PFS at a higher price than the alternative therapy or therapies if it is satisfied that it provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies *(National Health Act 1953, Section 101(3B)).* The alternative therapies in this case could include the EFG IV and SC, ravulizumab, rozanolixizumab and zilucoplan, or IVIg. Since there are no data to establish superiority over the comparators, there is no justification for the price of EFG PFS to be higher than any of EFG IV, EFC SC, ravulizumab, rozanolixizumab or zilucoplan.

4.3 This submission was made prior to outcomes of the November 2025 PBAC meeting being available to the sponsor. In its consideration of the SC formulation, the PBAC had agreed that EFG IV was a relevant comparator, but considered that EFG SC could also be used in place of IVIg, zilucoplan, ravulizumab or rozanolixizumab. The PBAC had considered that there was insufficient evidence to support superior efficacy or safety of any of these newly recommended agents (including EFG SC) over IVIg, hence PBAC advised that the subcutaneous form be priced as per the other gMG medicines recommended at the March 2025 PBAC meeting.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer inputs

5.2 The PBAC noted and welcomed input from one health care professional and one organisation, Myasthenia Alliance Australia via the Office of Health Technology Assessment Consultation Hub. Their inputs described a range of benefits of treatment with EFG PFS including a reduction in medicine burden and improved access for regional and rural patients, as subcutaneous forms allow self-administration at home. The inputs also noted the need for new treatment pathways and administration forms to provide more options for people with gMG, especially treatments that can be provided outside of the hospital environment.

Clinical trials

5.3 At the March 2025 PBAC meeting, the PBAC advised that the clinical effectiveness and safety of EFG IV, ravulizumab, rozanolixizumab and zilucoplan should be considered as non-inferior with each other and with IVIg.

5.4 At the November 2025 PBAC meeting, the PBAC considered that the clinical claim of non-inferior effectiveness and non-inferior safety of EFG SC versus IV was reasonable, noting the clinical data provided, along with the opinion of the TGA and European Medicines Agency (EMA) that the SC and IV forms are therapeutically equivalent.

5.5 The submission provided a phase 1, open-label, randomised, single-dose, 2-period crossover bioequivalence study (ARGX-113-2312). This study was considered by the EMA in its EFG PFS assessment report.

Table 1: Study presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
ARGX-113-2312	A Phase 1, Open-Label, Randomized, Single-Dose, 2-Period Cross-Over, Bioequivalence Study of Efgartigimod PH20 SC Administered via a Prefilled Syringe Versus a Vial + Syringe Presentation in Healthy Participants	Not published

Source: p7 of the submission.

5.6 The study recruited 72 healthy adult participants, half of whom were randomised to receive the SC injection followed by the PFS. The other half received the PFS followed by the SC injection.

Comparative bioequivalence

5.7 The claim of comparative bioequivalence between EFG SC and PFS is supported with a statistical analysis which resulted in a 90% confidence interval (CI) around the geometric least-squares mean ratios (GMR) of C_{max} and of $AUC_{0\text{-}inf}$ between the predefined bioequivalence criteria of 80% to 125%. Based on the GMRs, C_{max} for the PFS was 9.70% higher than that for the SC, and $AUC_{[0\text{-}inf]}$ for the PFS was 7.89% higher than that for the SC, after a single injection, but the upper bounds of the 90% CIs were less than 125%.

5.8 The EMA assessment report states "Vyvgart formulated for and presented in a prefilled syringe is considered bioequivalent to the currently marketed formulation presented in a vial in terms of key pharmacokinetic parameters Cmax, Tmax, AUC0-t and AUCinf."

Comparative harms

5.9 The study claimed that frequency of adverse events (AEs) and treatment-related AEs was similar between participants who received SC vs PFS. One grade ≥3 AE was reported for a participant receiving SC, all other AEs were reported as grade 1 or 2. No serious AEs were reported, and no AEs lead to discontinuation from the study.

5.10 The EMA assessment report states "the clinical safety of SC efgartigimod administration via prefilled syringe is similar to SC administration via vial + syringe

(short-term). The long-term safety profile of efgartigimod administered via prefilled syringe can be extrapolated from the known long-term safety profile of efgartigimod administered via vial + syringe given that bioequivalence is also shown."

Clinical claim

5.11 Clinical effectiveness and safety non-inferiority has previously been established between EFG IV/SC, other FcRn and complement-based therapies and chronic IVIg.

5.12 The submission claimed bioequivalence between EFG SC and PFS. The TGA evaluation leveraged the EMA assessment report via the TGA Comparable Overseas Regulator (COR-B) pathway, as such, the TGA have accepted the EMA conclusion that EFG PFS is bioequivalent to EFG SC.

5.13 The PBAC considered that a claim of non-inferior effectiveness was reasonable.

5.14 The PBAC considered that a claim of non-inferior comparative safety was reasonable.

Economic analysis

5.15 The submission presented a CMA of EFG PFS compared to SC, assuming a 1:1 substitution and requesting the same price per unit. The sponsor stated that as a simplifying assumption, it was assumed that EFG is the only treatment listed for gMG on the PBS and therefore that all potential patients would use EFG to the exclusion of all other therapies.

5.16 The proposed equi-effective dose is 1x1000 mg/5.6 mL SC = 1x1000 mg/5.0 mL PFS.

- At the March 2025 meeting, the PBAC recommended 4.72 cycles of treatment per year in a pattern of 4 weeks of treatment followed by 4 weeks of no treatment. This equates to an annual dose of 18,880 mg of EFG per patient per year.

5.17 At the November 2025 meeting, the PBAC advised that the equi-effective dose of 2.4 vials of 400 mg/20 mL for IV (960 mg) was equivalent to 1x1000 mg/5.6 mL SC (1000 mg).

5.18 The TGA has determined EFG PFS to be bioequivalent to EFG SC, as such the listing of the PFS – provided that the SC is already listed at that time—would trigger a first brand statutory price reduction of 25% under the *National Health Act 1953* (the Act).

- The sponsor has submitted a 'New Presentation' request whereby if the Minster recognises the PFS as a new presentation under *99ACB(3A)* of the Act, then its listing will not trigger a statutory price reduction at the time of listing.

Drug cost/patient/year: $[redacted]

5.19 The estimated drug cost of EFG PFS per patient per year would be $[redacted], based on 18.88 required injections of 1000 mg to reach the recommended 18,880 mg per year. This cost is based on the sponsor's proposed effective AEMP for the EFG SC from its submission to the November 2025 PBAC meeting ($[redacted]), on the understanding that the

annual drug cost for the PFS will equate with that for the SC, and noting that the proposed effective price is not an agreed price for listing.

Estimated PBS usage and financial implications

5.20 This submission included usage and financial estimates that were previously assessed by the PBAC in November 2025. Noting that the sponsor made this submission prior to receiving outcomes from the November 2025 PBAC meeting, the following section will only provide a brief overview.

5.21 Refer to Table 2 which presents the estimated extent of use, cost of EFG PFS to the PBS/RPBS and net financial implications to the PBS/RPBS, and MBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process. The following assumptions have been included in these calculations:

- Market share has been displayed for both EFG SC and EFG PFS in Table 2, as the sponsor has stated that "for the purposes of the submission, it is assumed that PFS is listed [redacted] after the SC vial and [redacted]. The rate of uptake is based on the assumption that patients will rapidly preferentially adopt the PFS based on ease of use versus the SC vial. Should both subcutaneous presentations be listed, it is anticipated that the SC vial will be [redacted]".

5.22 The number of scripts was calculated based on a pack quantity of 4, which would cover the previously recommended 18,880 mg annual dosage of EFG.

5.23 The number of patients treated is based on an assumption that all gMG patients eligible for other therapies to treat gMG are using EFG SC or PFS and the other medicines hold no market share.

5.24 The submission estimated that 20,000 to < 30,000 scripts would be supplied between EFG SC and PFS over the first six years of listing (500 to < 5,000 in Year 1 to 500 to < 5,000 in Year 6).

- The submission stated that there is expected to be no net cost to the PBS/RPBS or MBS over the forecast horizon from introduction of the PFS form, as the PFS and SC vial are at price parity and require the same healthcare resources (and introduction of the PFS is not expected to grow the market).

- The submission stated that the estimated financial impact to the PBS/RPBS for the listing of EFG PFS is > $1 billion over six years (Year 1 $80 million to < $90 million to Year 6 $400 million to < $500 million), based estimated PFS script volume and on the published PFS price. This is offset by the estimated displacement of SC scripts.

Table 2: Estimated use and financial implications of EFG SC & PFS

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of patients treated (SC & PFS)	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Number of scripts dispensed (SC & PFS)	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Number of scripts dispensed (PFS)[a]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
SC market share	[redacted]%	[redacted]%	[redacted]%	[redacted]%	[redacted]%	[redacted]%
PFS market share	[redacted]%	[redacted]%	[redacted]%	[redacted]%	[redacted]%	[redacted]%
Estimated financial implications of incremental changes to PBS/RPBS due to proposed listing						
Increased net cost (PFS)	$[redacted][2]	$[redacted][3]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Decreased net cost (SC)	$[redacted][2]	$[redacted][3]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Net financial implications						
Overall net cost to PBS/RPBS (PFS)	$0	$0	$0	$0	$0	$0

[a] Assuming 4.72 scripts per patient per year (18,880 mg EFG annually) as estimated by the submission.
Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; SC = EFG subcutaneous injection; PFS = EFG pre-filled syringe
Source (pages 14-16 of the submission): Table 4-3: Projected efgartigimod script volume, Table 4-4: PFS market penetration, Table 4-7: Expected PFS PBS/RPBS cost at published pricing, Table 4-12: Incremental changes to PBS/RPBS due to proposed listing
The redacted values correspond to the following ranges:
[1] *500 to < 5,000*
[2] *$80 million to < $90 million*
[3] *$200 million to < $300 million*
[4] *$300 million to < $400 million*

Quality use of medicines

5.25 The submission stated that a patient support program (PSP) will be available nationally for all patients on EFG. The PSP will provide education about treatment objectives, administration requirements, and potential AEs. The program will include injection training and support to ensure that patients can safely and confidently self-administer EFG. The PSP will also support treatment reminders and monitoring.

Risk-sharing arrangements

5.26 At the November 2025 PBAC meeting, the committee advised that EFG SC should also join the RSA for the gMG medicines as recommended in March 2025, to mitigate the same risks in terms of use outside the intended restriction and the increase in frequency of cycles over time.

6 PBAC Outcome

6.1 The PBAC recommended the listing of efgartigimod alfa pre-filled syringe for the treatment of generalised myasthenia gravis (gMG), on the basis that it should be available only under special arrangements under the section 100 Highly Specialised Drug program (s100 HSD) as an Authority Required (Written/Online) listing. The PBAC advised that the requested section 85 general schedule listing would be inappropriate

and recommended a s100 HSD listing, consistent with its recommendations in March and November 2025 for other novel gMG medicines.

6.2 The PBAC considered that a claim of non-inferior effectiveness and non-inferior comparative safety of EFG PFS versus EFG SC and EFG IV was reasonable, noting the study provided in the submission along with the opinion of the TGA and EMA that the PFS form is therapeutically equivalent to the SC and IV forms.

6.3 The submission presented a cost minimisation approach (CMA) of EFG PFS compared to EFG SC, assuming a 1:1 substitution and requesting the same price per unit. The PBAC agreed that EFG SC was a relevant comparator, however, alternative therapies in this case could also include EFG IV, ravulizumab, rozanolixizumab and zilucoplan, or IVIg (and the PBAC noted that ravulizumab was PBS-listed for gMG on 1 March 2026). Since there are no data to establish superiority over the alternative comparators, there is no justification for the price of EFG PFS to be higher than any of EFG IV, EFG SC, ravulizumab, rozanolixizumab or zilucoplan. The PBAC advised that the PFS should be priced as per the other gMG medicines recommended at the March 2025 and November 2025 PBAC meetings. This comprised a cost-comparison to IVIg (average annual dose per year of 541.1 g) with a price premium for the administration benefits over IVIg (refer to para 8.24, efgartigimod alfa Public Summary Document [PSD], March 2025 PBAC meeting and subsequent advice provided at the November 2025 meeting). For EFG PFS, noting the submission's proposed equivalence of 1 PFS vial and 1 SC vial, the PBAC advised the cost comparison should incorporate an annual dose of EFG PFS of 18,880 mg per year (or simply put, 1 vial EFG PFS should be priced equivalent to 1 vial EFG SC or 2.4 vials of EFG IV).

6.4 The PBAC recalled its consideration of the EFG SC where it did not accept a reduced use of MBS items as an acceptable cost offset as part of the CMA to the IV formulation (para 6.3, efgartigimod alfa PSD, November 2025 PBAC meeting). The PBAC reiterated that such savings would unlikely be realised in practice.

6.5 The PBAC noted that the submission's financial estimates were based solely on substitution with EFG SC, which is not PBS listed. The PBAC recalled that it had previously considered that the financial estimates associated with listing EFG SC were uncertain as no gMG medicines were PBS-listed at that time and the estimates did not account for zilucoplan, ravulizumab and rozanolixizumab (para 6.4, efgartigimod alfa PSD, November 2026 PBAC meeting).

6.6 Nonetheless, the PBAC advised that it was reasonable to expect that the listing of efgartigimod alfa would be cost-neutral to the PBS/RPBS, given the recommended pricing equivalence between the different gMG agents (and noting that ravulizumab listed on 1 March 2026).

6.7 The PBAC advised that EFG PFS should join the Risk Sharing Arrangement that the PBAC had previously recommended for EFG SC and IV, ravulizumab, rozanolixizumab, and zilucoplan at the March 2025 and November 2025 PBAC meetings.

6.8 The PBAC advised that EFG PFS is suitable for prescribing by medical practitioners only, consistent with previous PBAC recommendations for EFG SC and IV.

6.9 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because EFG PFS is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over EFG IV, EFG SC, ravulizumab, rozanolixizumab and zilucoplan, or IVIg, or not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

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

Outcome:
Recommended

7 Recommended Listing

Add new PFS form (shown in italics) as follows:

Acute severe patients

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
EFGARTIGIMOD ALFA					
efgartigimod alfa 1 g/5 mL injection, 5 mL syringe	*NEW (HSD Public) NEW (HSD Private)*	*4*	*4*	*1*	*Vyvgart PFS*
efgartigimod alfa 1000 mg in 5.6 mL vial	NEW (HSD Public) NEW (HSD Private)	4	4	1	Vyvgart SC
efgartigimod alfa 400mg/20mL vial	NEW (HSD Public) NEW (HSD Private)	12	12	1	Vyvgart

Concept ID (for internal Dept. use)		**Category / Program:** ☒Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
		Prescriber type: ☒ Medical Practitioners
		Restriction type: ☒ Authority Required (Written/Online - Immediate assessment)
		Authority type: ☒ Complex Authority Required (CAR)
Prescribing rule level		**Administrative Advice:** Definitions for the purposes of administering this restriction. Where the term **'gMG biological agent'** is referenced in this restriction, it refers to efgartigimod alfa, ravulizumab, rozanolixizumab, and zilucoplan. The following are settings and time limits where a gMG biological agent are PBS subsidised: (1) three months of acute treatment - 'acute severe gMG' (2) six months of bridging therapy - 'bridging therapy for gMG' (3) Continuous therapy - 'treatment refractory gMG'

		A patient may transition sequentially from one setting to another where all criteria are met e.g. (1) to (2) to (3), but cannot return to an earlier treatment setting. **Definitions:** A non-steroidal immunosuppressant (NS-IST) is one of the following: (i) azathioprine, (ii) ciclosporin, (iii) cyclophosphamide, (iv) methotrexate, (v) mycophenolate (vi) tacrolimus The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/ The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/
		Administrative Advice: **Treatment switching:** Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)]. In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment phase will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic. In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either: a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment. Mark any remaining unused repeat prescriptions as "cancelled".
		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 authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively, 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

		Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
		Administrative Advice: No increase in the maximum number of repeats may be authorised.
		Administrative Advice: Special Pricing Arrangements apply.
		Indication: Acute severe generalised myasthenia gravis (gMG)
		Treatment Phase: [Blank]
		Clinical criteria:
		Patient must have a diagnosis of MGFA Disease Class II to IV
		AND
		Clinical criteria:
		Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies
		AND
		Clinical criteria:
		Patient must not be experiencing a myasthenic crisis
		AND
		Clinical criteria:
		Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent
		AND
		Clinical criteria:
		Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition.
		AND
		Clinical criteria:
		Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); or
		Patient must be commencing treatment with an NS-IST within 2 weeks; or
		Patient must have had a thymectomy
		AND
		Clinical criteria:
		Patient must be receiving concomitant treatment with an oral corticosteroid
		AND
		Clinical criteria:
		Patient must not receive more than 3 months total of treatment with gMG biological agents under this PBS indication (e.g. for 'acute severe gMG')
		AND
		Clinical criteria:
		Patient must not have accessed a prior PBS-subsidised gMG biological agent; or
		Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment
		Treatment criteria:
		Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; or
		Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion

	Prescribing Instructions: The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include the following: (1) details of the proposed prescription (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)

Bridging therapy

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
EFGARTIGIMOD ALFA					
efgartigimod alfa 1 g/5 mL injection, 5 mL syringe	*NEW (HSD Public)* *NEW (HSD Private)*	*4*	*4*	*3*	*Vyvgart PFS*
efgartigimod alfa 1000 mg in 5.6 mL vial	NEW (HSD Public) NEW (HSD Private)	4	4	3	Vyvgart SC
efgartigimod alfa 400mg/20mL vial	NEW (HSD Public) NEW (HSD Private)	12	12	3	Vyvgart

Concept ID (for internal Dept. use)		**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
		Prescriber type: ☒ Medical Practitioners
		Restriction type: ☒ Authority Required (Written/Online - Immediate assessment)
		Authority type: ☒ Complex Authority Required (CAR)
Prescribing rule level		**Administrative Advice:** Definitions for the purposes of administering this restriction. Where the term **'gMG biological agent'** is referenced in this restriction, it refers to efgartigimod alfa, ravulizumab, rozanolixizumab, and zilucoplan. The following are settings where a gMG biological agent are PBS subsidised: (1) three months of acute treatment - 'acute severe gMG' (2) six months of bridging therapy - 'bridging therapy for gMG' (3) Continuous therapy - 'treatment refractory gMG' A patient may transition sequentially from one setting to another where all criteria are met e.g. (1) to (2) to (3), but cannot return to an earlier treatment setting. **Definitions:** A non-steroidal immunosuppressant (NS-IST) is one of the following: (i) azathioprine, (ii) ciclosporin, (iii) cyclophosphamide, (iv) methotrexate, (v) mycophenolate (vi) tacrolimus The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/ The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

		The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/
		Administrative Advice: **Treatment switching:** Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)]. In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment phase will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic. In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either: a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment. Mark any remaining unused repeat prescriptions as "cancelled".
		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 authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively, 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
		Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
		Administrative Advice: No increase in the maximum number of repeats may be authorised.
		Administrative Advice: Special Pricing Arrangements apply.
		Indication: Bridging therapy for generalised myasthenia gravis (gMG)
		Treatment Phase: [Blank]
		Clinical criteria:
		Patient must have a diagnosis of MGFA Disease Class II to IV
		AND
		Clinical criteria:
		Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies
		AND
		Clinical criteria:
		Patient must not be experiencing a myasthenic crisis
		AND

	Clinical criteria:
	Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); or
	Patient must have had a thymectomy
	AND
	Clinical criteria:
	Patient must be receiving concomitant treatment with an oral corticosteroid
	AND
	Clinical criteria:
	Patient must have a MG-ADL score of ≥ 6 and a MGC score of ≥ 10, despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy
	AND
	Clinical criteria:
	Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition
	AND
	Clinical criteria:
	Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication
	Treatment criteria:
	Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; or
	Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion
	Prescribing Instructions: The authority application must be via the Online PBS Authorities System or in writing and must include: (a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted) (b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy] If the application is submitted through HPOS form upload or mail, it must include the following: (1) details of the proposed prescription (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)
	Prescribing Instruction: A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Treatment Refractory patients

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
EFGARTIGIMOD ALFA					
efgartigimod alfa 1 g/5 mL injection, 5 mL syringe	*NEW (HSD Public) NEW (HSD Private)*	*4*	*4*	*3*	*Vyvgart PFS*
efgartigimod alfa 1000 mg in 5.6 mL vial	NEW (HSD Public) NEW (HSD Private)	4	4	3	Vyvgart SC
efgartigimod alfa 400mg/20mL vial	NEW (HSD Public) NEW (HSD Private)	12	12	3	Vyvgart

Concept ID (for internal Dept. use)		**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
		Prescriber type: ☒ Medical Practitioners
		Restriction type: ☒ Authority Required (Written/Online - Immediate assessment)
		Authority type: ☒ Complex Authority Required (CAR)
Prescribing rule level		**Administrative Advice:** Definitions for the purposes of administering this restriction. Where the term **'gMG biological agent'** is referenced in this restriction, it refers to efgartigimod alfa, ravulizumab, rozanolixizumab, and zilucoplan. The following are settings where a gMG biological agent are PBS subsidised: (1) three months of acute treatment - 'acute severe gMG' (2) six months of bridging therapy - 'bridging therapy for gMG' (3) Continuous therapy - 'treatment refractory gMG' A patient may transition sequentially from one setting to another where all criteria are met e.g. (1) to (2) to (3), but cannot return to an earlier treatment setting. **Definitions:** A non-steroidal immunosuppressant (NS-IST) is one of the following: (i) azathioprine, (ii) ciclosporin, (iii) cyclophosphamide, (iv) methotrexate, (v) mycophenolate (vi) tacrolimus The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/ The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/
		Administrative Advice: **Treatment switching:** Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

		In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment phase will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic. In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either: a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment. Mark any remaining unused repeat prescriptions as "cancelled".
		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 authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively, 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
		Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
		Administrative Advice: No increase in the maximum number of repeats may be authorised.
		Administrative Advice: Special Pricing Arrangements apply.

	Indication: Treatment refractory generalised myasthenia gravis (gMG)
	Treatment Phase: Initial treatment – Treatment refractory gMG patients
	Clinical criteria:
	Patient must have a diagnosis of MGFA Disease Class II to IV
	AND
	Clinical criteria:
	Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies
	AND
	Clinical criteria:
	Patient must not be experiencing a myasthenic crisis
	AND
	Clinical criteria:
	Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); or
	Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent;
	AND
	Clinical criteria:

	Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition.
	AND
	Clinical criteria:
	Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); or
	Patient must have had a thymectomy
	AND
	Clinical criteria:
	Patient must have a MG-ADL score of ≥ 6 and a MGC score of ≥ 10, despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months; (iii) a thymectomy.
	AND
	Clinical criteria:
	The treatment must provide no more than 6 months of therapy per initial authority application
	Treatment criteria:
	Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis, or
	Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion
	Prescribing Instruction: Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months)
	Prescribing Instructions: The authority application must be via the Online PBS Authorities System, or in writing and must include: (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy] (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted) If the application is submitted through HPOS form upload or mail, it must include: (1) details of the proposed prescription; (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);
	Indication: Treatment refractory generalised myasthenia gravis (gMG)
	Treatment Phase: Continuing treatment – Treatment refractory gMG patients
	Clinical criteria:
	Patient must have previously received PBS subsidised treatment with a gMG biological agent for this PBS indication.
	AND
	Clinical criteria:
	Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline
	AND
	Clinical criteria:

	Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline
	AND
	Clinical criteria:
	Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition.
	AND
	Clinical criteria:
	Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); or
	Patient must have had a thymectomy
	AND
	Clinical criteria:
	The treatment must provide no more than 6 months of therapy per continuing authority application
	AND
	Treatment criteria:
	Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; or
	Must be treated by a medical practitioner who has consulted at least one of the above-mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.
	Prescribing Instructions: The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment. If the application is submitted through HPOS form upload or mail, it must include: (1) details of the proposed prescription; (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);
	Indication: Treatment refractory generalised myasthenia gravis (gMG)
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment
	Clinical criteria:
	Patient must have received non-PBS subsidised treatment with this drug for this PBS indication prior to [PBS listing date].
	AND
	Clinical criteria:
	Patient must have a diagnosis of MGFA Disease Class II to IV
	AND
	Clinical criteria:
	Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies
	AND
	Clinical criteria:
	Patient must not be experiencing a myasthenic crisis
	AND
	Clinical criteria:

	Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition.
	AND
	Clinical criteria:
	Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); or
	Patient must have had a thymectomy
	AND
	Clinical criteria:
	Patient must have had a MG-ADL score of ≥ 6 and a MGC score of ≥ 10, despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months; (iii) a thymectomy.
	AND
	Clinical criteria:
	Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline
	AND
	Clinical criteria:
	Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline
	AND
	Clinical criteria:
	The treatment must provide no more than 6 months of therapy under this restriction
	Treatment criteria:
	Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis, or
	Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion
	Prescribing Instructions: The authority application must be via the Online PBS Authorities System, or in writing and must include: (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy] (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments was conducted) (c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessments were conducted) If the application is submitted through HPOS form upload or mail, it must include: (1) details of the proposed prescription; (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);
	Prescribing Instruction: A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS subsidised treatment for this indication.

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	Administrative Advice: Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.
	Administrative Advice: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

These restrictions 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 had no comment.

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