

**6.11 FINGOLIMOD,
Capsule 250 micrograms (as hydrochloride)
Capsule 500 micrograms (as hydrochloride),
Gilenya[®],
OFATUMUMAB,
Solution for injection 20 mg in 0.4 mL pre-filled pen,
Kesimpta[®]
SIPONIMOD,
Tablet 250 micrograms (as hemifumarate),
Tablet 2 mg (as hemifumarate),
Mayzent[®]
NOVARTIS PHARMACEUTICALS AUSTRALIA PTY
LIMITED**

1 Purpose of Submission

- 1.1 The Category 4 submission requested an amendment to the Pharmaceutical Benefits Scheme (PBS) listings of fingolimod (Gilenya[®]), ofatumumab (Kesimpta[®]) and siponimod (Mayzent[®]) to allow nurse practitioners (NPs) to initiate and continue treatment of the abovementioned medicines, in consultation with a specialist physician for the treatment of multiple sclerosis (MS).

2 Background

- 2.1 Fingolimod and ofatumumab are currently listed on the PBS as Authority Required (STREAMLINED) listings for the treatment of relapsing-remitting MS (RRMS).
- 2.2 Siponimod is listed on the PBS as Authority Required (STREAMLINED) listings for the treatment of secondary progressive MS (SPMS).
- 2.3 Medical Practitioners are currently the only eligible prescribers for the listings of fingolimod, ofatumumab and siponimod.

Registration status

- 2.4 Fingolimod is Therapeutic Goods Administration (TGA) registered for the treatment of adult and paediatric patients of 10 years of age and above with relapsing forms of multiple sclerosis (RMS) to reduce the frequency of relapses and to delay the progression of disability.

- 2.5 Ofatumumab is TGA registered for the treatment of adult patients with RMS to delay the progression of physical disability and reduce the frequency of relapse.
- 2.6 Siponimod is TGA registered for the treatment of adult patients with SPMS.

Previous PBAC consideration

- 2.7 There were no previous PBAC considerations of this type of request in relation to fingolimod, ofatumumab and siponimod.
- 2.8 Following a deferred decision at the March 2011 PBAC meeting, the PBAC recommended listing of fingolimod 500 microgram (mcg) capsule for the initial and continuing treatment of clinically RRMS in patients who meet certain criteria on the basis of an acceptable cost-effectiveness ratio compared with interferon beta-1a (fingolimod (Gilenya), Public Summary Document (PSD), March 2011 PBAC meeting).
- 2.9 At its July 2019 meeting, the PBAC recommended the listing of fingolimod 250 mcg capsules for the treatment of RRMS in patients weighing 40kg or less. The PBAC advised that, consistent with the existing listing of fingolimod 500 mcg, fingolimod 250 mcg is not suitable for prescribing by NPs (paragraph 6.1 and 6.8, fingolimod (Gilenya) PSD, July 2019 PBAC meeting).
- 2.10 At its March 2021 meeting, the PBAC recommended the listing of ofatumumab for the treatment of RRMS. The PBAC advised that ofatumumab is not suitable for prescribing by NPs, consistent with other RRMS disease modifying therapy (DMT) listings (paragraph 7.14, ofatumumab (Kesimpta) PSD, March 2021 PBAC meeting).
- 2.11 At its July 2020 meeting, the PBAC recommended the listing of siponimod for SPMS. The PBAC advised that siponimod was not suitable for prescribing by NPs (paragraph 7.1 and 7.18, siponimod (Mayzent) PSD, July 2020 PBAC meeting). At its March 2024 meeting, the PBAC recommended listing a new strength of siponimod (1 mg tablet) on the basis of cost-minimisation to siponimod 250 mcg tablet (paragraph 6.1, Siponimod (Mayzent) PSD, March 2024 PBAC meeting).

Nurse practitioner prescribing on the PBS

- 2.12 NP prescribing under the PBS is currently restricted by the NP's scope of practice, adherence to professional practice standards as set by the Nursing and Midwifery Board of Australia (NMBA), and state or territory prescribing rights. Prescribing of PBS medicines is also contingent on a prescriber being an authorised NP as required by the *National Health Act 1953*. From 1 November 2024, the legislated requirement for NPs to be in a specified collaborative arrangement with a medical practitioner to provide MBS services or prescribe PBS medicines was removed.
- 2.13 The submission noted the Department is currently undertaking a review of PBS medicines that may be suitable for prescribing by NPs and endorsed midwives (the Review), for consideration by the PBAC. In May 2023, the Nurse Practitioner Workforce Plan was released and included a recommended action to 'review NP prescribing of medicines on the PBS with the aim to 'align the medicines authorised

NPs can prescribe through the PBS and the Repatriation PBS (RPBS) with their full scope of practice'. The Department is working with stakeholders to understand gaps within the PBS that may prevent NPs and midwives from prescribing subsidised medicines within their scope of practice. The sponsor was advised by the Department that DMTs may be included in the Review but confirmed its preference was for this submission to proceed separately.

Committee-In-Confidence information

2.14



End Committee-In-Confidence information

3 Requested listing

- 3.1 The submission requested NPs to be included as eligible prescribers for the initiation and continuation treatment of fingolimod, ofatumumab and siponimod, in consultation with a specialist physician for the treatment of MS.
- 3.2 As the submission did not request any other changes to the restriction/clinical criteria, an abridged version of the relevant listings is presented below. Suggested additions are in italics and deletions are in strikethrough.

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|---|---------------------|----------------------|----------------------|----------------|------------------|
| FINGOLIMOD | | | | | |
| fingolimod 250 microgram capsule, 28 | 11818B | 1 | 28 | 5 | Gilenya |
| fingolimod 500 microgram capsule, 28 | 5262Y | 1 | 28 | 5 | All brands |
| OFATUMUMAB | | | | | |
| ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device | 12641H | 1 | 1 | 5 | Kesimpta |
| ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device | 12642J | 3 | 3 | 0 | Kesimpta |
| SIPONIMOD | | | | | |
| siponimod 2 mg tablet, 28 | 12158X | 1 | 28 | 5 | Mayzent |
| siponimod 250 microgram tablet, 120 | 12160B | 1 | 120 | 5 | Mayzent |
| siponimod 250 microgram tablet, 12 | 12172P | 1 | 12 | 0 | Mayzent |
| Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE) | | | | | |
| Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners | | | | | |
| Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [new/existing code] | | | | | |
| 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. | | | | | |
| Indication: Multiple sclerosis | | | | | |

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| <p>Treatment Phase: Initial treatment</p> |
| <p>Treatment criteria: <i>Must be treated by a medical practitioner; or Must be treated by a nurse practitioner in consultation with a specialist physician</i></p> |
| <p>Indication: Multiple sclerosis</p> |
| <p>Treatment Phase: Continuing treatment</p> |
| <p>Treatment criteria: <i>Must be treated by a medical practitioner; or Must be treated by a nurse practitioner in consultation with a specialist physician</i></p> |

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted and welcomed the input from six health care professionals and two organisations via the Consumer Comments facility on the PBS website. The comments from health care professionals stated that many patients with MS live in rural, regional and remote settings and these patients may experience difficulties in securing an appointment with a GP or neurologist. Therefore allowing NPs to prescribe medicines for MS in consultation with a specialist physician would reduce delays in commencing treatment, reduce impact on general practitioners and reduce cost to patients for seeking medical consultations. Inputs also stated that NP prescribing would improve continuity of care, improve safety and improve patient relationships.

4.3 The Multiple Sclerosis Nurses Australasia organisation provided support for NP prescribing of MS treatments, noting this would improve the quality, accessibility and continuity of care for patients living with MS, allowing for more efficient healthcare delivery and reducing delays to treatment. MS Australia also provided support for NP prescribing of MS treatments, noting that it would enable people with MS to receive timely adjustments to their treatment plans, enhancing adherence and ultimately leading to better health outcomes.

Basis of the request

4.4 The submission stated the proposed amendment to allow NPs to initiate and continue treatment of fingolimod, ofatumumab and siponimod, in consultation with a specialist physician for the treatment of MS would streamline the patient’s journey with MS, free up specialist/clinician capacity, and reduce burden on the healthcare system.

4.5 The submission stated patients experiencing the onset of MS symptoms are usually referred from their GP to a specialist neurologist for testing and diagnosis of MS. Following a confirmed MS diagnosis, the neurologist discusses treatment options with

the patient, and in specialty MS clinics, the neurologist would consult with the specialist neurology NP regarding a shared care plan for the patient.

- 4.6 The submission noted NPs in specialty MS clinics assess the appropriateness of MS treatments at the initial appointment and can prescribe medicines for conditions associated with MS such as antidepressants and anti-epileptic medicines; however, PBS restrictions prevent them from prescribing DMTs. At follow-up appointments, the NP performs and interprets tests to determine the patient's response to treatment and if there is a requirement to switch therapies. These recommendations are discussed with a neurologist under shared care arrangements, but NPs are restricted from prescribing DMTs on the PBS. The submission contended this process is inefficient and creates duplication of work as NPs must seek a medical practitioner to re-review the patient's chart and issue the DMT prescription. In some cases, if another clinic doctor is unavailable, patients are referred back to their GP to obtain the continuation prescription creating duplication of healthcare resources and causing delay to treatment. The submission therefore claimed the requested change would enable NPs to prescribe DMTs in a timely manner to prevent patient's delay to treatment which may lead to irreversible disease progression.
- 4.7 The pre-PBAC response reiterated that NPs play a vital role in the healthcare of patients with MS and the requested change to allow NPs to initiate and continue treatment of fingolimod, ofatumumab and siponimod in consultation with a specialist physician supports the Nurse Practitioner Workforce Plan and the Department's review to enable NPs to utilise their specialist knowledge to prescribe to their full scope of practice.

Estimated PBS usage and financial implications

- 4.8 The submission stated there will be no change to the diagnostic pathway or criteria for MS where diagnosis of MS patients will remain with the neurologist. The submission stated that patients stable on MS medicines will not be switched unless there is a clinical need, thus it is not anticipated that the proposed prescriber change will increase prescribing of fingolimod, ofatumumab and siponimod. The submission anticipated there to be no change to the utilisation of fingolimod, ofatumumab and siponimod and therefore estimated a nil financial impact to the PBS and RPBS.

5 PBAC Outcome

- 5.1 The PBAC recommended the amendment to the PBS listings of fingolimod, ofatumumab and siponimod to allow nurse practitioners (NPs) to initiate and continue treatment in consultation with a specialist physician for the treatment of multiple sclerosis (MS).
- 5.2 The PBAC noted the submission did not propose any changes to the diagnostic pathway or criteria for MS and that the patient's diagnosis would remain with the neurologist. The PBAC also noted the submission stated patients stable on MS

medicines will not be switched unless there is a clinical need and thus it is not anticipated that the proposed prescriber change will increase the prescribing of fingolimod, ofatumumab and siponimod. The PBAC considered adding NPs as eligible prescribers to the PBS listings could potentially lead to an increase in the treated population initially due to improved access. However, it considered that the increase in utilisation would be expected to align with the intended population estimates when fingolimod, ofatumumab and siponimod were first listed for MS. The PBAC therefore considered a nil financial impact to the PBS and RPBS to be reasonable.

- 5.3 The PBAC noted that the submission's proposed amendments to the listing of fingolimod, ofatumumab and siponimod would streamline the patient's journey with MS, free up specialist/clinician capacity, and reduce burden on the healthcare system.
- 5.4 The PBAC recommended that the restriction changes to NP prescribing arrangements flow-on to other disease modifying treatments (DMTs) listed on the PBS which include ozanimod, cladribine, teriflunomide, peginterferon beta 1a, interferon beta 1b, glatiramer acetate, dimethyl fumarate and diroximel fumarate.
- 5.5 The PBAC noted that flow-on recommendations to alemtuzumab, natalizumab and ocrelizumab would not be feasible as these medicines are listed under Section 100 Highly Specialised Drugs (HSD) arrangements which currently exclude NPs from prescribing these benefits. Legislative changes would be required to allow NPs to prescribe these medicines as HSD legislation currently restricts the initial prescribing of such benefits to medical practitioner specialists affiliated with a hospital, and prescribing continuing therapy by medical practitioner specialists affiliated with a hospital or medical practitioners with the agreement of medical practitioner specialists who are affiliated with a hospital under specific conditions. The PBAC noted the Section 100 HSD medicines may be considered more broadly as part of the Review of items for NP and Endorsed Midwife (EM) prescribing on the PBS.
- 5.6 The PBAC found that the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met. Specifically, the PBAC found that in the circumstances of its recommendation for amendment to the NP prescribing arrangements of fingolimod, ofatumumab and siponimod for the treatment of MS, the amendment is not expected to address a high and urgent unmet clinical need.
- 5.7 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

- 6.1 Amend Nurse Practitioner prescribing arrangements (abridged restrictions):

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| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|--|---------------------|----------------------|----------------------|----------------|------------------|
| FINGOLIMOD | | | | | |
| fingolimod 250 microgram capsule, 28 | 11818B | 1 | 28 | 5 | Gilenya |
| fingolimod 500 microgram capsule, 28 | 5262Y | 1 | 28 | 5 | All brands |
| OFATUMUMAB | | | | | |
| ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device | 12641H | 1 | 1 | 5 | Kesimpta |
| ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device | 12642J | 3 | 3 | 0 | Kesimpta |
| SIPONIMOD | | | | | |
| siponimod 2 mg tablet, 28 | 12158X | 1 | 28 | 5 | Mayzent |
| siponimod 250 microgram tablet, 120 | 12160B | 1 | 120 | 5 | Mayzent |
| siponimod 250 microgram tablet, 12 | 12172P | 1 | 12 | 0 | Mayzent |
| Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE) | | | | | |
| Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners | | | | | |
| Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [new/existing code] | | | | | |
| 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. | | | | | |
| Indication: Multiple sclerosis | | | | | |
| Treatment Phase: Initial treatment | | | | | |
| Treatment criteria: <i>Must be treated by a medical practitioner; or Must be treated by a nurse practitioner in consultation with a specialist physician</i> | | | | | |
| Indication: Multiple sclerosis | | | | | |
| Treatment Phase: Continuing treatment | | | | | |
| Treatment criteria: <i>Must be treated by a medical practitioner; or Must be treated by a nurse practitioner in consultation with a specialist physician</i> | | | | | |

6.2 Flow on changes to the NP prescribing arrangements for the following items indicated for MS:

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|--|---------------|----------------------|----------------------|----------------|------------------|
| OZANIMOD | | | | | |
| ozanimod 920 microgram capsule, 28 | 12271W | 1 | 28 | 5 | Zeposia |
| ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7 | 12278F | 1 | 1 | 0 | |

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| CLADRIBINE | | | | | |
|---|--------|---|-----|---|--|
| cladribine 10 mg tablet, 1 | 11603Q | 1 | 1 | 1 | Mavenclad |
| cladribine 10 mg tablet, 4 | 11604R | 2 | 8 | 1 | |
| cladribine 10 mg tablet, 6 | 11611D | 1 | 6 | 1 | |
| TERIFLUNOMIDE | | | | | |
| teriflunomide 14 mg tablet, 28 | 2898M | 1 | 28 | 5 | APO-TERIFLUNOMIDE Pharmacor Teriflunomide TERIFLAGIO Teriflunomide Dr.Reddy's Teriflunomide GH Teriflunomide Sandoz Terimide |
| PEGINTERFERON BETA-1A | | | | | |
| peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices | 10212L | 1 | 2 | 4 | Plegridy |
| | 10220X | 1 | 2 | 5 | |
| peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL pen device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL pen device], 1 pack | 10218T | 1 | 1 | 0 | |
| INTERFERON BETA-1B | | | | | |
| interferon beta-1b 8 million units (250 microgram) injection [15 vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack | 8101J | 1 | 15 | 5 | Betaferon |
| GLATIRAMER ACETATE | | | | | |
| glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes | 10416F | 1 | 12 | 5 | Copaxone GLATIRAMER ACETATE-TEVA Glatira |
| glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices | 13110B | 1 | 12 | 5 | Copaxone |
| DIMETHYL FUMARATE | | | | | |
| dimethyl fumarate 120 mg enteric capsule, 14 | 2896K | 2 | 28 | 0 | APO-DIMETHYL FUMARATE Dimethyl Fumarate MSN Dimethyl Fumarate Sandoz Pharmacor Dimethyl Fumarate Tecfidera |
| | 2943X | 2 | 28 | 0 | |
| dimethyl fumarate 240 mg enteric capsule, 56 | 2966D | 1 | 56 | 5 | APO-DIMETHYL FUMARATE Dimethyl Fumarate MSN Dimethyl Fumarate Sandoz Pharmacor Dimethyl Fumarate Tecfidera Trazent |
| DIROXIMEL FUMARATE | | | | | |
| diroximel fumarate 231 mg enteric capsule, 120 | 13059H | 1 | 120 | 5 | Vumerity |

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 Context for Decision

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

8 Sponsor's Comment

The sponsor had no comment.