

5.26 GLATIRAMER

Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled pen, Copaxone[®], Teva Pharma Australia Pty Ltd

1 Purpose of Submission

- 1.1 The submission requested listing a new form of 40 mg glatiramer acetate pre-filled pen (herein referred to as GA PFP) under the same circumstances as the PBS-listed 40 mg glatiramer pre-filled syringe (herein referred to as GA PFS) for the treatment of multiple sclerosis (MS).

2 Background

- 2.1 GA PFS is currently PBS-listed as an Authority Required (STREAMLINED) listing. There are currently three brands listed on the Pharmaceutical Benefits Scheme (PBS) which are considered equivalent for the purposes of substitution (i.e. 'a'-flagged).
- 2.2 The dosage and frequency of administration is the same between the GA PFS and GA PFP.

Registration status

- 2.3 GA PFP was registered on the Australian Register of Therapeutic Goods (ARTG) on 17 April 2019 under the same indications as GA PFS.

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

3 Requested listing

- 3.1 The submission requested listing GA PFP under the same circumstances as the existing glatiramer acetate PFS PBS listing:

Add new medicinal product pack as follows:

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MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
GLATIRAMER ACETATE glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes	10416F	1	12	5	Copaxone GLATIRAMER ACETATE-TEVA Glatira
GLATIRAMER ACETATE glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices	NEW	1	12	5	Copaxone

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

4 Comparator

4.1 The sponsor nominated GA PFS as the comparator. This was appropriate.

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

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted and welcomed input from an individual (1) and an organisation (1) via the Consumer Comments facility on the PBS website. The PBAC noted that both the individual and MS Australia's comments described a range of benefits of treatment with GA PFP, including easier administration, reduced adverse effects, improved adherence, and an option for patients with reduced dexterity.

Clinical claim

- 5.3 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of the GA PFP compared with the GA PFS.
- 5.4 The Therapeutic Goods Administration (TGA) confirmed that GA PFP and GA PFS are the same, noting that GA PFS is integrated into a GA PFP.
- 5.5 As a Committee Secretariat submission, no evaluation of the clinical evidence was undertaken.
- 5.6 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.
- 5.7 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

Pricing considerations

- 5.8 The requested approved ex-manufacturer price (AEMP) (\$791.54) was based on the 1 October 2021 AEMP of GA PFS. GA PFS has been subject to a First New Brand price reduction following the PBS-listing of two generic brands on 1 February 2022. It is appropriate to use the current AEMP (\$584.71) for GA PFS, if recommended.
- 5.9 The submission presented a cost-minimisation analysis (CMA) of the GA PFP compared with the GA PFS. The CMA presented was a comparison of drug costs only as the submission assumed no differences in the utilisation of other healthcare resources relating to the administration of the drugs and management of adverse effects. The submission estimated the equi-effective doses to be: GA PFS 40 mg = GA PFP 40 mg.

Estimated PBS utilisation and financial implications

- 5.10 The submission used a market share approach to estimate the financial impact of listing the GA PFP on the PBS. The sponsor stated the GA PFP was expected to substitute directly for the GA PFS and that the listing of the GA PFP was not expected to impact the growth or size of the glatiramer acetate market. The submission claimed that the proposed listing of the GA PFP is estimated to have no net impact on the PBS/RPBS. This is appropriate as the listing of GA PFP is expected to be cost neutral.
- 5.11 As a Committee Secretariat submission, the financial estimates analysis has not been independently evaluated.

Quality Use of Medicines

- 5.12 The sponsor claimed that GA PFP reduces the risk of needle stick injury, improves administration options for some patients with reduced dexterity and may improve patient adherence.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of a new form of 40 mg glatiramer acetate pre-filled pen (GA PFP) under the same circumstances as the PBS-listed 40 mg glatiramer pre-filled syringe (GA PFS) for the treatment of multiple sclerosis.
- 6.2 The PBAC recommended listing GA PFP on a cost-minimisation basis to the PBS-listed GA PFS. The PBAC noted the listing of GA PFP is expected to have no net cost to the PBS.
- 6.3 The PBAC noted the TGA considered the GA PFP and GA PFS to be the same, and that GA PFS is integrated into a GA PFP. The PBAC accepted GA PFS as comparator. The PBAC advised the equi-effective doses were: GA PFS 40 mg = GA PFP 40 mg.

- 6.4 The PBAC advised that, under section 101(4AACD) of the Act, in the Schedule of Pharmaceutical Benefits, Copaxone[®], Glatiramer Acetate-Teva[®] and Glatira[®] PFS, and Copaxone[®] PFP, should be treated as equivalent to each other for the purpose of substitution (i.e. ‘a’-flagged in the Schedule). The PBAC advised that the pharmacist can provide counselling to patients on the correct use of the device at the point of dispensing.
- 6.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because 40 mg glatiramer acetate pre-filled pen is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed 40 mg glatiramer acetate, 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.
- 6.6 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item:

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GLATIRAMER ACETATE glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices	NEW	1	12	5	^a Copaxone

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 had no comment.