

14.03 APREPITANT

Capsule 165 mg,

Aprepitant Apotex[®], Apotex Pty Ltd.

1 Purpose of Application

- 1.1 The submission requested Section 100 (Efficient Funding of Chemotherapy – Related Benefits) and General Schedule Authority Required (STREAMLINED) listings of a new brand of aprepitant (Aprepitant Apotex[®]) for the same indication as the currently listed brand, Emend[®] (PBS item codes: 2518M and 2550F)

2 Requested listing

- 2.1 The minor submission requested no changes to the existing listing.

3 Background

- 3.1 Aprepitant (Aprepitant Apotex, 165 mg capsule) was listed on the Australian Register of Therapeutic Goods (ARTG) on 11 June 2019. It is indicated for use in combination with other antiemetic agents for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of:

- Highly emetogenic cancer chemotherapy
- Moderately emetogenic cancer chemotherapy

Aprepitant is also indicated for the prevention of postoperative nausea and vomiting.

- 3.2 The TGA considered that Aprepitant Apotex, as a generic brand of aprepitant, can be considered bioequivalent to Emend[®], the existing brand of aprepitant on the PBS. Whilst the listing of a bioequivalent brand does not normally require PBAC consideration, by the time of listing of this brand on the PBS, there will be no equivalent pharmaceutical item listed on the PBS following the deletion of the originator brand, Emend, therefore PBAC recommendation is required.

4 Current situation

Estimated PBS usage & financial implications

- 4.1 The minor submission estimated a net saving to the PBS as the proposed AEMP (\$65.58) is significantly lower than the currently listed brand, Emend (\$87.44). No financial estimates were provided.

5 PBAC outcome

- 5.1 The PBAC recommended Section 100 (Efficient Funding of Chemotherapy – Related Benefits) listing and General Schedule Authority Required (STREAMLINED) listing of a new brand of aprepitant (Aprepitant Apotex) for the same indication as the currently listed brand, Emend® (PBS item codes: 2518M and 2550F).
- 5.2 The PBAC noted that the requested listing would be unlikely to result in a cost to the PBS as the sponsor has requested an AEMP lower than the currently listed brand of aprepitant, Emend®.
- 5.3 The PBAC noted the sponsor requested that the Aprepitant Apotex brand be ‘a’ flagged against the reference product, Emend, across all item codes. The PBAC considered that ‘a’ flagging would not be possible if the two brands were not available on the PBS at the same time.
- 5.4 The PBAC reiterated its previous advice that aprepitant is suitable for prescribing by nurse practitioners on the General Schedule.
- 5.5 The PBAC reiterated its previous advice that that it is not appropriate to apply the Early Supply Rule to aprepitant.
- 5.6 The PBAC recalled its March 2016, it advice that aprepitant should not be treated as interchangeable with any other drugs.
- 5.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

- 6.1 Add new item with identical restriction wording to the originator brand, Emend.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor’s Comment

The sponsor had no comment.