

5.16 ALENDRONIC ACID

Tablet, effervescent, 70 mg (as alendronate sodium) Binosto[®], My Health 365 Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought to list an effervescent formulation of alendronate on the PBS.

2 Requested listing

- 2.1 The submission did not propose a restriction for the new formulation of alendronate. However, the estimated financial impact was based on use by patients with dysphagia or other swallowing difficulties. There is likely to be two potential populations that could be considered:
- a) any patients who meet the current bisphosphonate restriction; or
 - b) any patients who meet the current bisphosphonate restriction AND suffer from dysphagia or other swallowing conditions.

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

3 Background

- 3.1 Alendronate is TGA registered for the treatment of osteoporosis. Prior to treatment, osteoporosis must be confirmed by the finding of low bone mass of at least two standard deviations below the gender specific mean for young adults or by the presence of osteoporotic fracture.
- 3.2 Alendronate is currently PBS listed as the sole anti-resorptive agent for osteoporosis in patients aged 70 years and above with a BMD T-score of -2.5 or less; corticosteroid-induced osteoporosis in patients with a BMD T-score of -1.5 or less; and established osteoporosis in patients who have had a fracture due to minimal trauma.
- 3.3 Alendronate effervescent tablets have not been considered by the PBAC previously.

4 Clinical place for the proposed therapy

- 4.1 The submission proposed alendronate effervescent tablets as an alternative to alendronate tablets to improve compliance in patients with dysphagia or other swallowing conditions, claiming that the effervescent form has fewer oesophageal adverse effects.
- 4.2 The product information for both the tablet and effervescent forms of alendronate contains warnings about oesophageal and gastric adverse effects. The same dosage and administration applies for both forms of alendronate, where tablets should only

be taken in the morning 30 minutes before food and other medications, and patients are advised to not lie down for at least 30 minutes after administration and until after their first food of the day due to the risk of oesophageal adverse effects.

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 as it was a minor submission.

Consumer comments

5.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

5.3 As a minor submission, no clinical trials were presented.

Clinical claim

5.4 The submission claimed that alendronate effervescent tablets are superior to alendronate tablets. No clinical evidence was provided to support this claim.

5.5 The PBAC considered that the claim of superior comparative effectiveness and superior comparative safety was not adequately supported in the absence of any clinical data.

Economic analysis

5.6 The submission requested an approved ex-manufacturer price (AEMP) for alendronate effervescent tablets of \$[REDACTED]. The current AEMP for alendronate tablets is \$4.56.

5.7 The submission stated that the increased price of alendronate effervescent tablets compared with conventional tablets is justifiable as it is a superior product and will be used in a smaller subset of people. No evidence was provided to support this claim.

Estimated PBS usage & financial implications

5.8 The minor submission estimated that [REDACTED]% ([REDACTED] items) of the current alendronate tablets processed on the PBS may be replaced by alendronate effervescent tablets per annum. This was based on the prevalence of dysphagia as reported by the Australian and New Zealand Society for Geriatric Medicine (ANZSGM).

- 5.9 The minor submission estimated a net cost to the PBS of less than \$10 million per year which would result in a total cost to the PBS of less than \$10 million over the first five years of listing.
- 5.10 The estimated financial impact is considered to be an underestimate because:
- the submission had not accounted for patients currently receiving alternative bisphosphonates, such as risedronate, who may switch to alendronate effervescent tablets if they became available;
 - the estimate of ■% of the population experiencing dysphagia is at the lower limit reported by ANZSGM, with an upper estimate of ■%;
 - there is potential for leakage into other patient groups, such as those who experience gastrointestinal adverse effects with conventional bisphosphonate tablets; and
 - it is unclear how the rate of uptake of the alendronate effervescent tablets is affected by the usage of denosumab.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Restricted Benefit listing of alendronic acid in the form of 70 mg effervescent tablets (as alendronate sodium) for the treatment of osteoporosis, on the basis that it is bioequivalent to alendronate tablets.
- 6.2 The PBAC recommended that alendronate effervescent tablets have the same restriction as alendronate tablets on the basis the two forms are bioequivalent. The PBAC noted that there would be potential for leakage into the general osteoporosis patient population if alendronate effervescent tablets were restricted to patients with dysphagia or other swallowing difficulties.
- 6.3 The PBAC recommended that alendronate effervescent tablets should be priced equivalent to alendronate tablets in the absence of data to support superiority or improved compliance.
- 6.4 The PBAC considered that there was not a large clinical need for an effervescent form of alendronate, but agreed that some patients may prefer an effervescent formulation. The PBAC noted the listing would therefore likely be cost neutral.
- 6.5 The PBAC recommended under Section 101(3BA) of the *National Health Act, 1953* that alendronate and risedronate should be treated as interchangeable on an individual patient basis.
- 6.6 The PBAC recommended alendronate effervescent tablets and alendronate tablets should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule with a NOTE in the schedule stating that the forms are equivalent for the purposes of substitution). The product information noted that alendronate effervescent tablets were found to be bioequivalent to alendronate tablets.

- 6.7 The PBAC advised that alendronate effervescent tablets are suitable for prescribing by nurse practitioners.
- 6.8 The PBAC recommended that the Early Supply Rule should apply to align with the restriction for alendronate tablets.
- 6.9 The PBAC noted that this submission is not eligible for an Independent Review because the PBAC has made a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Amend existing listing as follows:

Add Binosto® brand to item code 8511Y.

8 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.

9 Sponsor's Comment

The sponsor did not agree with all the comments made by the PBAC and is considering the recommendation.