

MINOR LISTINGS AND CHANGES TO LISTINGS PROCESSED BY THE SECRETARIAT FOR CONSIDERATION BY THE COMMITTEE

14.02 ZOLEDRONIC ACID

Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL, 5 vials

Claris Lifesciences Zoledronic Acid[®],

Medsurge Healthcare Pty Ltd

1 Purpose of Application

- 1.1 The submission requested a temporary Section 100 Highly Specialised Drug Authority Required listing of zoledronic acid (Claris Lifesciences Zoledronic Acid[®]) on the Pharmaceutical Benefits Schedule (PBS) as an alternative to the currently listed zoledronic acid 4 mg/5 mL form (PBS items 6371H and 9653C), to address the current supply shortage issue.

2 Requested Listing:

- 2.1 As the pack size for Zoledronic Acid[®] is a pack of five vials, which is not equivalent supply duration provided by the currently listed 4 mg/5 mL form (1 vial). The PBAC supported the Secretariat's suggestion to increase the maximum quantity (MQ) to 5 vials (1 Pack) and no repeat for the temporary listing.

3 Background

- 3.1 The sponsors (Apotex Pty Ltd, Pfizer Australia Pty Ltd and Novartis Pharmaceuticals Australia Pty Limited) have been unable to guarantee supply of the currently listed zoledronic acid 4 mg/5 mL products (PBS items 6371HC and 9653C) due to issues with constrained supply. The 4 mg/100 mL forms of zoledronic acid are currently not available.
- 3.2 In order to minimise the clinical impact of this shortage, the Department received a request for an alternative supply from Medsurge Healthcare Pty Ltd. The alternative product, manufactured by Claris Lifesciences, has a current TGA Section 19A(1) approval. This equivalent stock is presented as a slightly different pack to the currently listed (a pack of five vials, rather than a single vial), necessitating a new listing on the PBS.

4 Pricing considerations

- 4.1 The temporary listing will likely result in net saving to the Government, as the sponsor proposed an AEMP of \$ [REDACTED] for a pack of five vials, which is a lower price than the currently listed zoledronic acid (AEMP \$173.89 for a pack of 1).

5 PBAC Outcome

- 5.1 The PBAC recommended the temporary listing of zoledronic acid (Claris Lifesciences Zoledronic Acid®) on the Pharmaceutical Benefits Scheme (PBS) to address the current supply shortage of zoledronic acid 4 mg/5mL form.
- 5.2 The PBAC considered that there is a clinical need for the supply of zoledronic acid to be maintained on the PBS. The PBAC considered that the listing should remain
- 5.3 The PBAC considered that listings should be the same authority conditions as Zoledronic Acid®, namely Authority Required (STREAMLINED) and suitable for inclusion for prescribing by nurse practitioners.

Outcome:

Recommended

6 Recommended listing

Add new item: same restrictions for item 9653C (\$100 HSD Public) and 6371H (\$100 HSD Private)

Name, Restriction, Manner of administration and form	Max. Qty	Nº. of Rpts	Proprietary Name and Manufacturer	
ZOLEDRONIC ACID Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL, 5 vials	1	0	Claris Lifesciences Zoledronic Acid®	Medsurge Healthcare Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program – Public and Private
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Episodicity:	
Condition:	Multiple myeloma
PBS Indication:	Multiple myeloma
Treatment phase:	

Public Summary Document – July 2018 PBAC Meeting

Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing (Private) <input checked="" type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required – Electronic (Private) <input type="checkbox"/> Streamlined (Public)
Clinical criteria:	

Category / Program	Section 100 – Highly Specialised Drugs Program – Public and Private
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Episodicity:	
Condition:	Bone metastases
PBS Indication:	Bone metastases
Treatment phase:	
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing (Private) <input checked="" type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required – Electronic (Private) <input type="checkbox"/> Streamlined (Public)
Clinical criteria:	The condition must be due to breast cancer.

Category / Program	Section 100 – Highly Specialised Drugs Program – Public and Private
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Episodicity:	
Condition:	Bone metastases
PBS Indication:	Bone metastases
Treatment phase:	
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing (Private) <input checked="" type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required – Electronic (Private) <input type="checkbox"/> Streamlined (Public)
Clinical criteria:	The condition must be due to castration-resistant prostate cancer.

Category / Program	Section 100 – Highly Specialised Drugs Program – Public and Private
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives

Episodicity:	
Condition:	Hypercalcaemia of malignancy
PBS Indication:	Hypercalcaemia of malignancy
Treatment phase:	
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing (Private) <input checked="" type="checkbox"/> Authority Required – Telephone (Private) <input type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required – Electronic (Private) <input type="checkbox"/> Streamlined (Public)
Clinical criteria:	Patient must have a malignancy refractory to anti-neoplastic therapy.

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.