**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

# Purpose of Application

* 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.

# Requested Listing:

* 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.

# Background

* 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.
	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.

# Pricing considerations

* 1. The temporary listing will likely result in net saving to the Government, as the sponsor proposed an AEMP of $'''''''''''''' 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).

# PBAC Outcome

* 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.
	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
	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

1. **Recommended listing**

Add new item: same restrictions for item 9653C (S100 HSD Public) and 6371H (S100 HSD Private)

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| **Name, Restriction,****Manner of administration and form** | **Max.****Qty** | **№.of****Rpts** |  | **Proprietary Name and Manufacturer** |
| ZOLEDRONIC ACIDInjection 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:** | [ ] Dental [x] Medical Practitioners [ ] Nurse practitioners [ ] Optometrists[ ] Midwives |
| **Episodicity:** |  |
| **Condition:** | Multiple myeloma |
| **PBS Indication:** | Multiple myeloma |
| **Treatment phase:** |  |
| **Restriction Level / Method:** | [ ] Restricted benefit[x] Authority Required - In Writing (Private)[x] Authority Required – Telephone (Private)[ ] Authority Required – Emergency[x] Authority Required – Electronic (Private)[ ] Streamlined (Public) |
| **Clinical criteria:** |  |

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

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

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| **Category / Program** | Section 100 – Highly Specialised Drugs Program – Public and Private |
| **Prescriber type:** | [ ] Dental [x] Medical Practitioners [ ] Nurse practitioners [ ] Optometrists[ ] Midwives |
| **Episodicity:** |  |
| **Condition:** | Hypercalcaemia of malignancy |
| **PBS Indication:** | Hypercalcaemia of malignancy |
| **Treatment phase:** |  |
| **Restriction Level / Method:** | [ ] Restricted benefit[x] Authority Required - In Writing (Private)[x] Authority Required – Telephone (Private)[ ] Authority Required – Emergency[x] Authority Required – Electronic (Private)[ ] Streamlined (Public) |
| **Clinical criteria:** | Patient must have a malignancy refractory to anti-neoplastic therapy. |

# 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.

# Sponsor’s Comment

The sponsor had no comment.