**14.3 MINOR LISTINGS AND CHANGES TO LISTINGS PROCESSED BY THE SECRETARIAT**

**APOMORPHINE HYDROCHLORIDE**

**Injection, 10 mg in 1 mL,**

**Apomine®, Hospira Pty Ltd**

1. **Purpose of application**

* 1. The submission requested a Section 100 (Highly Specialised Drugs Program) Authority Required listing of a lower strength presentation (10 mg in 1 mL) for the management of advanced Parkinson disease.

1. **PBAC** **Outcome**
   1. The PBAC recommended listing of the 10 mg in 1 mL presentation of apomorphine at the same price per mg as the 20 mg in 2 mL presentation currently listed on the PBS.
   2. The PBAC recommended listing under the same conditions as the existing listing for the 20 mg in 2 mL presentation.
   3. Consistent with the existing arrangements for the current strengths, the PBAC advised that the new apomorphine strength is not suitable for prescribing by nurse practitioners.
   4. As a Section 100 item, the PBAC noted that the Safety Net 20 Day Rule should not apply.

**Outcome:**

Recommended

1. **Recommended listing**

Add new item:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name, Restriction,  Manner of administration and form | | Max.  Qty (Packs) | Max.  Qty (Units) | No. of  Rpts | Proprietary Name and Manufacturer | |
| APOMORPHINE  apomorphine hydrochloride 10 mg/1 mL injection, 5 x 1 mL ampoules | | 72 | 360 | 5 | Apomine | HH |
|  | | | | | | |
| **Category / Program** | Section 100 – Highly Specialised Drugs Program – Public Hospitals | | | | | |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives | | | | | |
| **Episodicity:** | - | | | | | |
| **Severity:** | - | | | | | |
| **Condition:** | Parkinson disease | | | | | |
| **PBS Indication:** | Parkinson disease | | | | | |
| **Treatment phase:** | - | | | | | |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined | | | | | |
| **Clinical criteria:** | Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy | | | | | |

|  |  |
| --- | --- |
| **Category / Program** | Section 100 – Highly Specialised Drugs Program – Private Hospitals |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **Episodicity:** | - |
| **Severity:** | - |
| **Condition:** | Parkinson disease |
| **PBS Indication:** | Parkinson disease |
| **Treatment phase:** | - |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy |

1. **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.

1. **Sponsor’s Comment**

The sponsor had no comment.