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

**ENOXAPARIN**

**20 mg/0.2 mL injection, 10 x 0.2 mL pre-filled syringes,**

**40 mg/0.4 mL injection, 10 x 0.4 mL pre-filled syringes,**

**60 mg/0.6 mL injection, 10 x 0.6 mL pre-filled syringes,**

**80 mg/0.8 mL injection, 10 x 0.8 mL pre-filled syringes,**

**100 mg/1.0 mL injection, 10 x 1.0 mL pre-filled syringes,**

**Clexane Safety-Lock®, Sanofi-Aventis Australia Pty Ltd**

1. Purpose of application
   1. To request listing of a new presentation of safety-lock pre-filled syringes of enoxaparin on the PBS.
2. PBAC Outcome
   1. The PBAC considered enoxaparin (Clexane Safety-Lock®) as price equivalent to that of the currently PBS-listed enoxaparin (Clexane®) for all available strengths and indications.
   2. The PBAC recommended enoxaparin (Clexane Safety-Lock®) and enoxaparin (Clexane®) should be considered equivalent for the purposes of substitution.
   3. The PBAC recommend listing on the PBS under the conditions as outlined below.
3. Recommended listing

Unrestricted Benefit

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name, Restriction,  Manner of administration and form | Max.  Qty  (Packs) | Max.  Qty (Units) | No. of  Rpts | Proprietary Name and Manufacturer | |
| ENOXAPARIN SODIUM  enoxaparin sodium 20 mg/0.2 mL injection,  10 x 0.2 mL syringes | 2 | 20 | 0 | Clexane Safety-Lock® | SW |
| enoxaparin sodium 40 mg/0.4 mL injection,  10 x 0.4 mL syringes | 2 | 20 | 0 | Clexane Safety-Lock® | SW |
| enoxaparin sodium 60 mg/0.6 mL injection,  10 x 0.6 mL syringes | 1 | 10 | 1 | Clexane Safety-Lock® | SW |
| enoxaparin sodium 80 mg/0.8 mL injection,  10 x 0.8 mL syringes | 1 | 10 | 1 | Clexane Safety-Lock® | SW |
| enoxaparin sodium 100 mg/1 mL injection,  10 x 1 mL syringes | 1 | 10 | 1 | Clexane Safety-Lock® | SW |
| **Category / Program** | GENERAL – General Schedule (Code GE) | | | | |
| **Prescriber type:** | Medical Practitioners Nurse practitioners | | | | |

Restricted Benefit for patients undergoing haemodialysis.

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| --- | --- | --- | --- | --- | --- |
| Name, Restriction,  Manner of administration and form | Max.  Qty  (Packs) | Max.  Qty (Units) | No. of  Rpts | Proprietary Name and Manufacturer | |
| ENOXAPARIN SODIUM  enoxaparin sodium 20 mg/0.2 mL injection,  10 x 0.2 mL syringes | 2 | 20 | 3 | Clexane Safety-Lock® | SW |
| enoxaparin sodium 40 mg/0.4 mL injection,  10 x 0.4 mL syringes | 2 | 20 | 3 | Clexane Safety-Lock® | SW |
| enoxaparin sodium 60 mg/0.6 mL injection,  10 x 0.6 mL syringes | 2 | 20 | 3 | Clexane Safety-Lock® | SW |
| enoxaparin sodium 80 mg/0.8 mL injection,  10 x 0.8 mL syringes | 2 | 20 | 3 | Clexane Safety-Lock® | SW |
| enoxaparin sodium 100 mg/1 mL injection,  10 x 1 mL syringes | 2 | 20 | 3 | Clexane Safety-Lock® | SW |

|  |  |
| --- | --- |
| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Medical Practitioners Nurse practitioners |
| **Condition:** | Haemodialysis |
| **PBS Indication:** | Haemodialysis |
| **Restriction Level / Method:** | Restricted benefit |

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.