

6.10 ENOXAPARIN

Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe

Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe

Clexane[®], Sanofi-Aventis Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought to increase the maximum number of repeats of the General Schedule listings of enoxaparin injections 20 mg (item number 8558K) and 40 mg (item number 8510X), from zero to one.

2 Requested listing

- 2.1 The submission requested the following changes to the existing listing:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
ENOXAPARIN				
enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	2	01	\$82.63	Clexane and Sanofi-aventis Australia Pty Ltd
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	2	01	\$85.65	Enoxaparin Winthrop

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction Level / Method:	<input checked="" type="checkbox"/> Unrestricted benefit

Source: Enoxaparin (Clexane) minor submission, p13

3 Background

- 3.1 Enoxaparin is a low molecular weight heparin (LMWH) which is TGA registered for a number of conditions including prophylaxis or treatment of deep vein thrombosis (DVT) and venous thromboembolism (VTE) prophylaxis.
- 3.2 Enoxaparin has a restricted PBS listing for use in haemodialysis and an unrestricted benefit listing. Only the unrestricted benefit listing was relevant to this application.

- 3.3 The 40 mg injections were PBS listed in 2001 and the 20 mg injections since 2002.
- 3.4 Based on dosing recommendations in the TGA approved Product Information, a patient receiving enoxaparin injections for VTE prophylaxis should receive a 40 mg injection once daily for a minimum of 6 days and up to 20 days. In the case of patients who have a risk of developing VTE, the duration can be longer than the 20 days, such as in the case for hip replacement surgery patients who have received a hip replacement where the recommended dosing is 40 mg daily for 30 post-operative days.
- 3.5 Under the current PBS listing, surgical patients requiring enoxaparin injections for VTE prophylaxis can be dispensed a maximum of 2 packs of 10 syringes (20 mg or 40 mg enoxaparin sodium) which provides sufficient therapy for 20 days under a standard prescription.
- 3.6 The minor submission refers to clinical guidance¹ from the Australian New Zealand Working Party on the Management and Prevention of Venous Thromboembolism which identifies the types of circumstances in which a patient may require extended VTE prophylaxis with enoxaparin as presented in the table below:

Table 1. Duration of prophylaxis of VTE with LMWH recommended by ANZ working party

Type of surgery / patient circumstances	Duration of prophylaxis with LMWH
Total hip replacement surgery	28-35 days
Hip fracture surgery	28-35 days
Total knee replacement	At least 10 days
Any surgery and prior VTE	5-10 days or until hospital discharge
Major surgery ² : intra-abdominal surgery or surgery >45 mins and age >40 years	28-35 days
Surgical cancer patients	28-35 days for major cancer surgery

Abbreviation: ANZ, Australia and New Zealand; LMWH, low molecular weight heparin; VTE, venous thromboembolism.

Source: Enoxaparin (Clexane) minor submission, Table E.2.

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

4 Current Situation

- 4.1 Patients at high risk of developing VTE and requiring sufficient supply of enoxaparin for VTE prophylaxis for a period greater than 20 days have the following options:
- Obtain an Authority script with approval for increased maximum quantity that enables the dispensing of additional packs; or
 - Obtain two standard prescriptions on two separate doctor's visits.

¹ The Australia and New Zealand Working Party on the Management and Prevention of Venous Thromboembolism, 5th Edition. Published by Health Education and Management Innovations (2010).

- 4.2 The submission has presented an analysis of a 10% sample of the PBS authority prescription data for enoxaparin indicating that patients requiring extended prophylaxis comprise 2.8% of the total number of prescriptions for enoxaparin 20 mg strength and 8.3% for enoxaparin 40 mg strength.
- 4.3 An additional analysis of a 10% sample of PBS prescription data involving patients filling scripts of the same strength less than 20 days apart indicates this occurs in 15.1% of patients for the 20mg strength and 14.6% of patients for the 40 mg strength.
- 4.4 Based on the two analyses conducted by the minor submission, it has concluded that approximately 5% of enoxaparin prescriptions involve Authority approved requests for increased maximum quantities and an additional 15% of prescriptions involve patients having two scripts dispensed within 20 days of each other that indicates two doctor's visits were required. The submission noted that a minority of prescriptions may be used for other purposes such as DVT prophylaxis and that the change to listing is not expected to have a notable budget impact or alter prescribing practice.
- 4.5 The DUSC Secretariat undertook an analysis of scripts dispensed for enoxaparin 20 mg (item 8558K) and 40 mg (item 8510X) for a full PBS sample in 2018, based on the date of supply. This found that:
- 6.8% of scripts for both the 20 mg and 40 mg strengths were dispensed with a quantity of more than 20 units. Separately, the proportion of dispensed scripts with a quantity above 20 units was 3.1% and 7.6% for the 20 mg and 40 mg strengths, respectively.
 - 14.2% of scripts dispensed in 2018 for enoxaparin 20 mg were for a second script dispensed within 20 days of a prior script. The proportion of second scripts dispensed within 20 days for the 40 mg strength was 12.5%.

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

5 PBAC 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 and welcomed the input from individuals (1) via the Consumer Comments facility on the PBS website. The comments noted the improved affordability of extended treatment with enoxaparin that will result from fewer GP visits for repeat prescriptions.

Clinical trials

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

Economic analysis

5.4 As a minor submission, an economic comparison was not relevant.

Estimated PBS usage & financial implications

5.5 The minor submission estimated a net save to the PBS and RPBS of less than \$10 million in Year 5 of listing. The submission also estimated net savings to the MBS as a result of fewer GP visits for the sole purpose of prescribing enoxaparin as it was assumed that 50% of patients currently filling a second prescription require a second GP visit, however as these MBS savings would not be realised, they have not been included in Table 2.

Table 2. Overall net cost to Commonwealth Government

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
	2019	2020	2021	2022	2023	2024
Net cost to the PBS (DPMQ-copay)	-\$██████	-\$██████	-\$██████	-\$██████	-\$██████	-\$██████
Net cost to the RPBS (DPMQ-copay)	\$██████	\$██████	\$██████	\$██████	\$██████	\$██████
Net cost to the PBS/ RPBS (DPMQ-copay)	-\$██████	-\$██████	-\$██████	-\$██████	-\$██████	-\$██████

Abbreviation: DPMQ, dispensed price for maximum quantity; MBS, Medicare benefits Schedule; PBS, Pharmaceutical Benefits Schedule; RPBS, Repatriation Pharmaceutical Benefits Scheme.

[Source: Enoxaparin (Clexane) minor submission, p9]

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

6 PBAC Outcome

6.1 The PBAC recommended an increase to the maximum number of repeats for the unrestricted benefit listings of enoxaparin injections 20 mg (PBS item code 8558K) and 40 mg (PBS item code 8510X), from zero to one.

6.2 The PBAC noted the recent clinical guidance published by the Australian New Zealand Working Party on the Management and Prevention of Venous Thromboembolism that establishes a need for broader availability of low molecular weight heparin for extended VTE prophylaxis in high-risk patients after discharge from hospital. The PBAC considered that repeat prescriptions for enoxaparin injections would help fulfil this need.

6.3 The PBAC considered that the estimated saving to the PBS were uncertain, but accepted that the requested increase in the number of repeats will not result in any additional cost to Government.

6.4 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Amend maximum number of repeats as follows:

Amend items **8558K and 8510X**

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
ENOXAPARIN enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	2	1	Clexane and Enoxaparin Winthrop
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	2	1	Sanofi-aventis Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
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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

Sanofi welcomes the PBAC's decision to recommend the requested increase to the maximum number of repeats for Clexane, in recognition of the need for broader availability of low molecular weight heparin for extended VTE prophylaxis in high-risk patients after discharge from hospital.