

6.09 NADROPARIN

**injection containing nadroparin calcium,
(1,900 I.U. anti-Xa) in 0.2 mL
(2,850 I.U. anti-Xa) in 0.3 mL
(3,800 I.U. anti-Xa) in 0.4 mL
(5,700 I.U. anti-Xa) in 0.6 mL
(7,600 I.U. anti-Xa) in 0.8 mL
(9,500 I.U. anti-Xa) in 1 mL
(11,400 I.U. anti-Xa) in 0.6 mL
(15,200 I.U. anti-Xa) in 0.8 mL
(19,000 I.U. anti-Xa) in 1 mL,
Fraxiparine[®] and Fraxiparine Forte[®],
Aspen Pharmacare Australia Pty Ltd.**

1 Purpose of Application

- 1.1 The minor submission requested an increase in maximum quantities (MQ) and changes in the number of repeats for the listed formulations to be consistent with the proposed comparator enoxaparin.

2 Requested listing

- 2.1 The submission requested an increase in the MQ for all listed strengths of nadroparin calcium, as outlined in table 1.

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Table 1. Summary of requested change to Max Qty

Item Code	Legal Instrument Form	Current						Proposed					
		Pack Qty	Pricing Qty	Maximum Qty	Maximum Repeats	AEMP	DPMQ	Pack Qty	Pricing Qty	Maximum Qty	Maximum Repeats	AEMP (No change)	DPMQ
10687L	Injection containing nadroparin calcium (1,900 I.U. anti-Xa) in 0.2 mL pre-filled syringe	2	2	4	3	\$3.33	\$17.72	2	2	20	3	\$3.33	\$
10735B	Injection containing nadroparin calcium (1,900 I.U. anti-Xa) in 0.2 mL pre-filled syringe	2	2	4	0	\$3.33	\$17.72	2	2	20	0	\$3.33	\$
10706L	Injection containing nadroparin calcium (11,400 I.U. anti-Xa) in 0.6 mL pre-filled syringe	2	2	2	1	\$19.95	\$32.01	2	2	10	1	\$19.95	\$
10725L	Injection containing nadroparin calcium (15,200 I.U. anti-Xa) in 0.8 mL pre-filled syringe	2	2	2	1	\$26.60	\$39.16	2	2	10	1	\$26.60	\$
10707M	Injection containing nadroparin calcium (19,000 I.U. anti-Xa) in 1 mL pre-filled syringe	2	2	2	1	\$33.25	\$46.31	2	2	10	1	\$33.25	\$
10686K	Injection containing nadroparin calcium (2,850 I.U. anti-Xa) in 0.3 mL pre-filled syringe	2	2	4	0	\$4.99	\$21.30	2	2	20	0	\$4.99	\$
10701F	Injection containing nadroparin calcium (2,850 I.U. anti-Xa) in 0.3 mL pre-filled syringe	2	2	4	3	\$4.99	\$21.30	2	2	20	3	\$4.99	\$
10685J	Injection containing nadroparin calcium (3,800 I.U. anti-Xa) in 0.4 mL pre-filled syringe	2	2	4	0	\$6.65	\$24.86	2	2	20	0	\$6.65	\$
10717C	Injection containing nadroparin calcium (3,800 I.U. anti-Xa) in 0.4 mL pre-filled syringe	2	2	4	3	\$6.65	\$24.86	2	2	20	3	\$6.65	\$

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Item Code	Legal Instrument Form	Current						Proposed					
		Pack Qty	Pricing Qty	Maximum Qty	Maximum Repeats	AEMP	DPMQ	Pack Qty	Pricing Qty	Maximum Qty	Maximum Repeats	AEMP (No change)	DPMQ
10716B	Injection containing nadroparin calcium (5,700 I.U. anti-Xa) in 0.6 mL pre-filled syringe	2	2	4	0	\$9.98	\$32.02	2	2	20	0	\$9.98	\$
10718D	Injection containing nadroparin calcium (5,700 I.U. anti-Xa) in 0.6 mL pre-filled syringe	2	2	4	3	\$9.98	\$32.02	2	2	20	3	\$9.98	\$
10734Y	Injection containing nadroparin calcium (7,600 I.U. anti-Xa) in 0.8 mL pre-filled syringe	2	2	2	1	\$13.30	\$24.86	2	2	10	1	\$13.30	\$
10740G	Injection containing nadroparin calcium (7,600 I.U. anti-Xa) in 0.8 mL pre-filled syringe	2	2	4	3	\$13.30	\$39.16	2	2	20	3	\$13.30	\$
10702G	Injection containing nadroparin calcium (9,500 I.U. anti-Xa) in 1 mL pre-filled syringe	2	2	2	1	\$16.63	\$28.44	2	2	10	1	\$16.63	\$
10733X	Injection containing nadroparin calcium (9,500 I.U. anti-Xa) in 1 mL pre-filled syringe	2	2	4	3	\$16.63	\$46.32	2	2	20	3	\$16.63	\$

Source: compiled from tables 2 and 3 of the submission, and updated based on table 1 of the pre-PBAC response.

For more detail on PBAC’s view, see section 6 “PBAC outcome”

3 Background

- 3.1 The TGA-approved indications for the lower concentration formulation of nadroparin (Fraxiparine®) are prophylaxis against deep vein thrombosis (DVT) associated with general or orthopaedic surgery, treatment of DVT and prevention of clotting during haemodialysis. The higher concentration formulation of nadroparin (Fraxiparine Forte®) is TGA-approved for the treatment of DVT.
- 3.2 At the July 2015 PBAC meeting, the sponsor requested an Unrestricted listing for nadroparin (Fraxiparine® and Fraxiparine Forte®) and Restricted Benefit listing for nadroparin (Fraxiparine®) for haemodialysis on a cost-minimisation basis against its comparator, enoxaparin. However, the PBAC considered that there was potential for more wastage with the presentation and requested MQ, and recommended the listing on the basis of the smaller pack size and lower MQ, which the current listings are set at (nadroparin PSD, July 2015 PBAC meeting, pg 21).
- 3.3 In this current submission, the sponsor is requesting the same number of syringes per script as the comparator enoxaparin for both the restricted and unrestricted indications, as summarised in table 2 below.

Table 2. Number of syringes in one prescription under each indication

Indication / Use	Comparator Clexane (enoxaparin sodium)	nadroparin calcium currently listed MQ	nadroparin calcium proposed MQ
Unrestricted benefit (DVT prophylaxis/treatment)	20mg, 40mg Maximum 2 packs or 20 syringes. No repeats i.e. total = 20 syringes per script and per dispense.	1900, 2850, 3800, 5700 IU anti-Xa Maximum 2 packs or 4 syringes. No repeats i.e. total = 4 syringes per script and per dispense.	1900, 2850, 3800, 5700 IU anti-Xa Maximum 20 syringes with no repeat i.e. total = 20 syringes per script, 20 per dispense.
	60mg, 80mg, 100mg Maximum 1 pack or 10 syringes with One repeat i.e. total = 20 syringes per script and 10 per dispense.	7600, 9500, 11,400, 15,200, 19,000 IU anti-Xa, Maximum 1 pack or 2 syringes. 1 repeat; total = 4 syringes per script and 2 per dispense.	7600, 9500, 11,400, 15,200, 19,000 IU anti-Xa, Maximum 10 syringes with one repeat i.e. total = 20 syringes per script and 10 per dispense.
Haemodialysis	All strengths Maximum 2 packs or 20 syringes with Three repeats i.e. Total = 80 syringes per script, 20 per dispense.	All strengths Maximum 2 packs or 4 syringes. Three repeats i.e. Total = 16 syringes per script, 4 syringes per dispense.	All strengths Maximum 20 syringes with Three repeats i.e. Total = 80 syringes per script, 20 per dispense.

Source: submission pg 2 and 3, pre-PBAC response pg 3.

- 3.4 The sponsor claimed that the current practice and guidelines for prophylaxis

recommend treatment for durations of more than four days in some cases, which cannot be met through one script with the current MQ for nadroparin.

- 3.5 The sponsor also claimed that the wastage issue was previously addressed by the change of pack size, and that “patients receiving too many syringes should be of concern, as wastage is an inevitable result of the large pack size of Clexane® which does not apply to Fraxiparine®/Fraxiparine Forte® injections” (submission pg 3).
- 3.6 The PBAC considered that making the same number of syringes available per script for nadroparin as its comparator, enoxaparin was reasonable.

For more detail on PBAC’s view, see section 6 “PBAC outcome”

4 Comparator

- 4.1 The minor submission nominated enoxaparin. At the July 2015 meeting, the PBAC agreed that this was the appropriate comparator.

5 Consideration of 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 that no consumer comments were received for this item.

Economic analysis

- 5.3 The submission presented an analysis of savings based on market share and the model presented in July 2015 submission. However, the evaluation of an economic model is out of scope for a minor submission.

Estimated PBS usage & financial implications

- 5.4 The minor submission estimated the financial implications by analysing the net difference between the model presented in the July 2015 submission and this submission. However, as identified in the pre-PBAC response, current utilisation does not reflect the estimates in the July 2015 submission, as there have been no scripts dispensed for nadroparin since its listing, and as such the estimated financial impact was highly uncertain. As the submission is requesting a change such that they have the same MQ and repeats as their comparator, the PBAC considered that it was likely that nadroparin would substitute for the comparator enoxaparin. The PBAC recommended that the Department should negotiate further with the sponsor such that the proposed change will result in nil financial impact to the PBS.

6 PBAC Outcome

- 6.1 The PBAC recommended a change to the PBS listing for nadroparin to increase its MQ and repeats across all strengths, such that the same number of syringes can be dispensed per script as the comparator enoxaparin for both the restricted and unrestricted listings.
- 6.2 The PBAC noted that the current practice and guidelines for prophylaxis recommend treatment for durations of more than four days in some cases, which cannot be met through one script with the current MQ for nadroparin.
- 6.3 The PBAC considered that the estimated financial implications presented in the submission were highly uncertain, but that as the nadroparin listing would have the same MQ and repeats as the comparator enoxaparin, utilisation was likely to be as a result of substitution, and as nadroparin was listed on a cost-minimisation basis to enoxaparin, should be cost neutral to the PBS.
- 6.4 The PBAC considered that the requested MQ and repeats were appropriate.
- 6.5 The PBAC advised that nadroparin should remain suitable for prescribing by nurse practitioners.
- 6.6 The PBAC noted that this submission is not eligible for an Independent Review as it is a request a request to modify an existing listing, and has received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Amend maximum quantity and number of repeats as follows:

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
NADROPARIN CALCIUM injection 1,900 IU anti-Xa in 0.2 mL, 2 x 0.2 mL single use pre-filled syringe	20	0	
injection 2,850 IU anti-Xa in 0.3 mL, 2 x 0.3 mL single use pre-filled syringe	20	0	
injection 3,800 IU anti-Xa in 0.4 mL, 2 x 0.4 mL single use pre-filled syringe	20	0	Fraxiparine®
injection 5,700 IU anti-Xa in 0.6mL, 2 x 0.6 mL single use pre-filled syringe	20	0	
injection 7,600 IU anti-Xa in 0.8 mL, 2 x 0.8 mL single use pre-filled syringe	10	1	Aspen
injection 9,500 IU anti-Xa in 1mL, 2 x 1 mL single use pre-filled syringe	10	1	
NADROPARIN CALCIUM injection 11,400 IU anti-Xa in 0.6mL, 2 x 0.6 mL single use pre-filled syringe	10	1	
injection 15,200 IU anti-Xa in 0.8mL, 2 x 0.8 mL single use pre-filled syringe	10	1	Fraxiparine Forte
injection 19,000 IU anti-Xa in 1 mL, 2 x 1 mL single use pre-filled syringe	10	1	

Category / Program	General Benefit
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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
NADROPARIN CALCIUM				
injection 1,900 IU anti-Xa in 0.2 mL, 2 x 0.2 mL single use pre-filled syringe	20	3		
injection 2,850 IU anti-Xa in 0.3 mL, 2 x 0.3 mL single use pre-filled syringe	20	3		
injection 3,800 IU anti-Xa in 0.4 mL, 2 x 0.4 mL single use pre-filled syringe	20	3	Fraxiparine®	Aspen
injection 5,700 IU anti-Xa in 0.6mL, 2 x 0.6 mL single use pre-filled syringe	20	3		
injection 7,600 IU anti-Xa in 0.8 mL, 2 x 0.8 mL single use pre-filled syringe	20	3		
injection 9,500 IU anti-Xa in 1mL, 2 x 1 mL single use pre-filled syringe	20	3		

Category / Program	General Benefit
PBS Indication:	Haemodialysis
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit

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

The sponsor had no comment.