5.21 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, Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe, Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe, Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe, Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe, Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe, Enoxaject®, Pharmacor Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested a new enoxaparin biosimilar (Enoxaject®) under the same circumstances (on the General Schedule [Section 85] for the same indications and level of restrictions) as the existing PBS-listed brands of enoxaparin (Clexane® and Exarane®).

1.2 The submission requested listing on a cost-minimisation basis to Clexane and Exarane.

2 Background

2.1 Enoxaject was TGA registered on 17 February 2025 as a biosimilar to the reference brand (Clexane) and with the same indications:

- prevention of thrombo-embolic disorders of venous origin in patients undergoing orthopaedic and general surgery;
- prophylaxis of venous thromboembolism in medical patients bedridden due to acute illness;

- prevention of thrombosis in extra-corporeal circulation during haemodialysis;
- treatment of established deep vein thrombosis;
- treatment of unstable angina and non-Q-wave myocardial infarction, administered concurrently with aspirin; and
- treatment of acute ST-segment Elevation Myocardial Infarction as an adjunctive to thrombolytic treatment, including patients to be managed medically or with subsequent Percutaneous Coronary Intervention.

3 Requested listing

3.1 The submission requested listing Enoxaject under the same circumstances as the existing PBS-listed brands of enoxaparin (Clexane and Exarane).

3.2 Add brand to existing items:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ENOXAPARIN enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	8558K	2	20	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	8510X	2	20	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	8262W	1	10	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	8263X	1	10	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	8264Y	1	10	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes	13710N	1	10	1	Clexane Forte Safety-Lock[a] (originator) Exarane Forte[a] Exarane Forte Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes	13729N	1	10	1	Clexane Forte Safety-Lock[a] (originator) Exarane Forte[a] Exarane Forte Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)

Category / Program: GENERAL – General Schedule (Code GE)		
Prescriber type: ☒Medical Practitioners ☒Nurse practitioners ☒*Midwives*		
Benefit Type: ☒ ~~Unrestricted benefit~~ ☒*Restricted benefit*		
Pr es		**Administrative Advice:** **Biosimilar prescribing policy**

		Prescribing of the biosimilar brand~~s~~ where available ~~Exarano / Exarano Forte or Enoxaject~~ is encouraged for treatment naive patients.
		Administrative Advice Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).
Restriction Summary 16261 / ToC: 16261		
		For prescribing by certain health practitioners
		Treatment criteria:
		Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ENOXAPARIN enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	8716R	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	8639Q	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	8640R	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	5434B	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	5435C	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes	13688K	1	10	3	Exarane Forte[a] Exarane Forte Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)
enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes	13717Y	1	10	3	Exarane Forte[a] Exarane Forte Safety-Lock[a] Enoxaject Safety-Lock[a] (proposed biosimilar)

Category / Program: GENERAL – General Schedule (Code GE)		
Prescriber type: ☒Medical Practitioners ☒Nurse practitioners		
Benefit Type: ☒Restricted benefit		
Prescribing rule		**Administrative Advice:** **Biosimilar prescribing policy** Prescribing of the biosimilar brands where available ~~Exarane / Exarane Forte or Enoxaject~~ is encouraged for treatment naive patients.
		Administrative Advice Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).
Restriction Summary 4910 / ToC: 4910		
		Indication: Haemodialysis

3.3 The submission requested that Enoxaject be considered equivalent ('a' flagged) to Clexane and Exarane for the purpose of substitution.

3.4 From 1 February 2025, unrestricted enoxaparin listings were restricted to include a treatment criteria for prescribing by certain health practitioners including midwives (as a result of September 2024 PBAC recommendations: https://www.pbs.gov.au/info/reviews/review-pbs-items-prescribing-nurse-practitioners-endorsed-midwives). The Secretariat has amended the proposed restrictions for Enoxaject in line with the current PBS Schedule. (Section 3.2).

3.5 Enoxaject will have the same drug, form and manner of administration as the existing enoxaparin brands and, as such, will be required to have the same approved ex-manufacturer price (AEMP) as the existing enoxaparin brands as per Section 85C of the National Health Act 1953.

3.6 The submission requested the addition of administrative advice reflecting the biosimilar update policy (i.e. encouraging uptake of biosimilar prescribing for treatment-naïve patients). At its July 2023 meeting, the PBAC advised that the addition of administrative advice to encourage the uptake of biosimilar prescribing for treatment naïve patients would be appropriate for another biosimilar brand of enoxaparin, in accordance with the Government's policy to encourage the use of biosimilar medicines (paragraph 6.7, enoxaparin Public Summary Document, July 2023 PBAC Meeting). The Secretariat noted that the existing Administrative Advice for those items is "Prescribing of a biosimilar brand where available is encouraged for treatment naive patients."

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted that no consumer comments were received for this item.

Clinical evidence

4.3 As per the Product Information, the TGA has confirmed that "Enoxaject is a biosimilar medicine to Clexane. The evidence for comparability supports the use of Enoxaject for the listed indications."

4.4 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Estimated PBS usage and financial implications

4.5 Listing of biosimilar brands does not change overall utilisation of the drug.

4.6 The submission stated that Enoxaject is expected to substitute for the other brands of enoxaparin and, as such, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

5 PBAC Outcome

5.1 The PBAC recommended General Schedule (Restricted Benefit) listings of a new enoxaparin biosimilar (Enoxaject®) on a cost-minimisation basis and under the same circumstances as the existing PBS-listed biosimilar brands of enoxaparin (Clexane® and Exarane®), for the same indications.

5.2 The PBAC noted that the TGA has confirmed that Enoxaject is a biosimilar medicine to Clexane.

5.3 The PBAC noted that the submission requested the addition of administrative advice reflecting the biosimilar update policy (i.e. encouraging uptake of biosimilar prescribing for treatment-naïve patients). As is the case for Exarane, the PBAC also considered that this administrative advice is clinically appropriate for Enoxaject.

5.4 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, Enoxaject, Clexane and Exarane should be considered equivalent for the purpose of substitution at the pharmacy level (i.e., 'a' flagged in the Schedule of Pharmaceutical Benefits).

5.5 The PBAC considered that the listing of Enoxaject would not result in a net cost to the PBS as it would likely substitute for the other brands of enoxaparin and not increase the overall market utilisation.

5.6 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Enoxaject is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over the other brands of enoxaparin, and is not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health*

(Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022 for Pricing Pathway A were not met.

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

Outcome:
Recommended

6 Recommended listing

6.1 Add Enoxaject biosimilar listings, with schedule equivalence ('a' flag) for the same indications as Clexane and Exarane.

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ENOXAPARIN enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	8558K	2	20	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	8510X	2	20	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	8262W	1	10	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	8263X	1	10	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	8264Y	1	10	1	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes	13710N	1	10	1	Clexane Forte Safety-Lock[a] (originator) Exarane Forte[a] Exarane Forte Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes	13729N	1	10	1	Clexane Forte Safety-Lock[a] (originator) Exarane Forte[a] Exarane Forte Safety-Lock[a] Enoxaject Safety-Lock[a]

Category / Program: GENERAL – General Schedule (Code GE)		
Prescriber type: ☒Medical Practitioners ☒Nurse practitioners ☒Midwives		
Benefit Type: ☒Restricted benefit		
Prescribing rule		**Administrative Advice:** **Biosimilar prescribing policy** Prescribing of the biosimilar brand where available is encouraged for treatment naive patients.
		Administrative Advice Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Restriction Summary 16261 / ToC: 16261	
	For prescribing by certain health practitioners
	Treatment criteria:
	Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner

Name, Restriction, Manner of administration and form	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
ENOXAPARIN enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	8716R	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	8639Q	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	8640R	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	5434B	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	5435C	2	20	3	Clexane Safety-Lock[a] (originator) Exarane[a] Exarane Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes	13688K	1	10	3	Exarane Forte[a] Exarane Forte Safety-Lock[a] Enoxaject Safety-Lock[a]
enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes	13717Y	1	10	3	Exarane Forte[a] Exarane Forte Safety-Lock[a] Enoxaject Safety-Lock[a]

Category / Program: GENERAL – General Schedule (Code GE)		
Prescriber type: ☒Medical Practitioners ☒Nurse practitioners		
Benefit Type: ☒Restricted benefit		
Prescribing rule		**Administrative Advice:** **Biosimilar prescribing policy** Prescribing of the biosimilar brand where available is encouraged for treatment naive patients.
		Administrative Advice Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).
Restriction Summary 4910 / ToC: 4910		
		Indication: Haemodialysis

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

The sponsor had no comment.