Ontario

Ministry of Health

Drugs and Devices Division

Drug Submission Status

Generic Name: ENOXAPARIN SODIUM

Brand Name: Noromby AND Noromby HP

Strength: 30 mg/0.3 mL, 40 mg/ 0.4 mL, 60 mg/.06 mL, 80 mg/ 0.8 mL, 100 mg/ML, 120 mg/mL and 150 mg/mL

Manufacturer: Juno Pharmaceutical Corp.

Indications:

NOROMBY (enoxaparin sodium) is indicated for:

- The prophylaxis of thromboembolic disorders (deep vein thrombosis) in patients undergoing:
  - orthopedic surgery of the hip or knee. In addition, NOROMBY is indicated in hospital or after hospital discharge for long-term prevention of venous thromboembolic diseases following hip replacement surgery.
  - high risk abdominal, gynecological, or urological surgeries;
  - colorectal surgery.

- The prophylaxis of deep vein thrombosis (DVT) in medical patients who are at moderate risk of DVT and who are bedridden due to moderate to severe acute cardiac insufficiency (NYHA Class III or IV heart failure), acute respiratory failure revealing or complicating chronic respiratory insufficiency not requiring ventilatory support and acute respiratory infections (excluding septic shock), who require short-term prophylaxis of deep vein thrombosis.
- The prevention of thrombus formation in the extra-corporeal circulation during hemodialysis.

- The treatment of deep vein thrombosis, with or without pulmonary embolism.
- The treatment of unstable angina or non-Q-wave myocardial infarction, concurrently with ASA.
- Treatment of acute ST-segment Elevation Myocardial Infarction (STEMI), including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI).

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	04/12/2020	21/01/2021	EO decision rendered	Listed on the Formulary as Limited Use Benefit

Review Status:

- Screening - Ministry is screening the manufacturer's submission to ensure all regulatory and policy requirements have been met in order to proceed with the drug review.
- Submission incomplete - Manufacturer did not meet the necessary requirements to allow review to proceed.
- Submission complete & under review - Manufacturer met all requirements to proceed with the drug review, and evaluation of the drug submission is underway.
- Committee to Evaluate Drugs* (CED) review completed, manufacturer requesting reconsideration – A recommendation was made by the CED, however the manufacturer has submitted or will be submitting additional information.
- Committee to Evaluate Drugs (CED) review completed - A recommendation was made by the CED.
- Ontario Steering Committee for Cancer Drugs** (OSCCD) review completed - A recommendation was made by the OSCCD.
- Executive Officer (EO) decision rendered.

Funding Status:

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision, if available, can be found at:

The CED recommendation and the EO decision

* The Committee to Evaluate Drugs (CED) is the Ministry's independent expert advisory committee on drug-related issues. The committee is comprised of practicing physicians, pharmacists, health economists, and patient representatives. In conducting its review, the CED considers data contained in the drug manufacturer's submission, input provided by patient groups, findings from the national Common Drug Review and the pan-Canadian Oncology Drug Review, and other scientific information as necessary.

** The Ontario Steering Committee for Cancer Drugs (OSCCD) was created to enhance and support the administration of Ontario's cancer drug programs. The committee advises the Ministry of Health and Long-Term Care's Ontario Public Drug Programs and Cancer Care Ontario's Provincial Drug Reimbursement Programs.

Updated: June 30, 2021