

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Drug Submission Status

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|----------------------|---|
| Generic Name: | tinzaparin sodium |
| Brand Name: | Innohep |
| Strength: | 2,500 IU/0.25mL prefilled syringe injection (New dosage strength) |
| Manufacturer: | Leo Pharma Inc. |
| Indication: | <ul style="list-style-type: none">- Prevention of postoperative venous thromboembolism in patients undergoing orthopaedic surgery and in patients undergoing general surgery- Treatment of deep vein thrombosis and/or pulmonary embolism- Prevention of clotting in indwelling intravenous lines for haemodialysis |
| Rapid Review: | Not requested |

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Decision: |
|--------------------------------------|---------------------------|----------------------------------|----------------------|--|
| First Review (Initial Submission) | 26/08/2009 | 25/01/2010 | EO decision rendered | Funding available through the Exception Access Program (EAP) |

Rapid Review:

Details of the Rapid Review process can be found at:

www.health.gov.on.ca/english/providers/program/drugs/drug_submissions/rapid_review_process.html

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.
- Executive Officer (EO) decision rendered.

Funding Decision:

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision can be found at: www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html

Updated: August 20, 2010