

Why did we do this review?

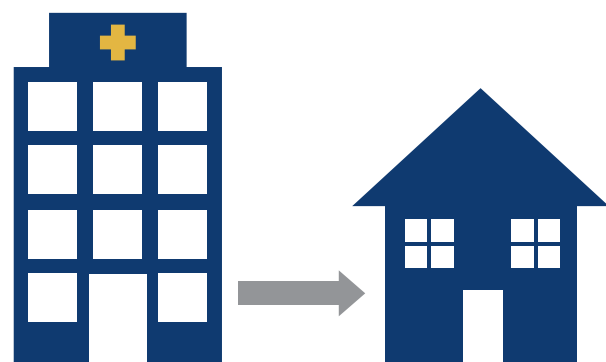
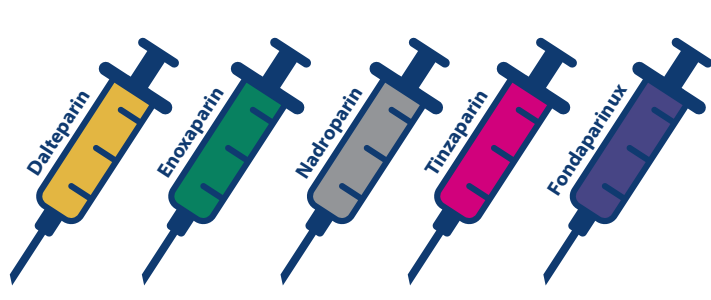
The Ontario Drug Policy Research Network (ODPRN) conducted multiple studies on the recommended use and accessibility of low-molecular-weight heparins (LMWHs) using various research methods as part of an initiative to modernize the public drug formulary in Ontario.

What are low-molecular-weight heparins (LMWHs)?

They are blood thinners, also known as anticoagulants, used for the prevention and treatment of blood clots which can be life-threatening.

In our review of 28 guidelines, we found that LMWHs are recommended for the use in a broad range of patients, from those undergoing surgery, to cancer patients, to pregnant women; in general, all LMWHs have very similar efficacy.

Availability



In Canada, there are four LMWHs commercially available: **dalteparin**, **enoxaparin**, **nadroparin**, and **tinzaparin**. **Fondaparinux**, a synthetic heparin-like compound, is also available.

Many patients begin treatment in the hospital and then need to continue the treatment at home.

Current listing

- LMWHs are covered under a series of different codes and criteria for various indications; they are listed under Limited Use and available through the Exceptional Access Program telephone request service.
- Interviews with prescribers found that the presence of both multiple Limited Use Codes and separate EAP criteria is confusing and not inclusive.

- Dalteparin
- Enoxaparin
- Nadroparin
- Tinzaparin
- Fondaparinux

Limited Use*

<p>Treatment of deep vein thrombosis (DVT) in non-cancer patients</p> <p>Most frequently used code - 186 (48.9%)</p>	<p>Post-operative prophylaxis of venous thromboembolism (VTE) for lower limb surgery</p>	<p>Treatment of pulmonary embolism</p>
<p>DVT in patients in whom treatment with warfarin is not tolerated or is contraindicated</p> <p>Second most used code - 188 (29.2%)</p>	<p>Treatment of DVT in patients who failed on warfarin</p>	<p>Treatment of DVT in pregnant/lactating females</p>

*LU codes used are used inappropriately to gain access for different indications

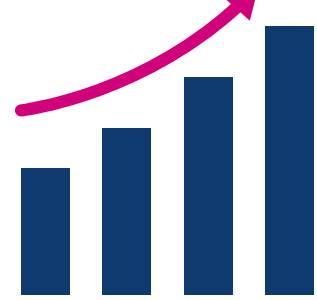
Exceptional Access Program

<p>Treatment (extended) of VTE in patients with cancer</p>	<p>Prophylaxis for peri-operative bridging in patients who require long-term warfarin and must temporarily discontinue it before and after surgery</p>	<p>Prophylaxis for DVT for patients who had hip or knee surgery, and cannot use warfarin</p>
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Not listed

<p>Prevention of VTE in non-orthopedic surgical patients</p>	<p>Prevention of VTE in cancer patients with additional risk factors for VTE</p>
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Utilization & Cost

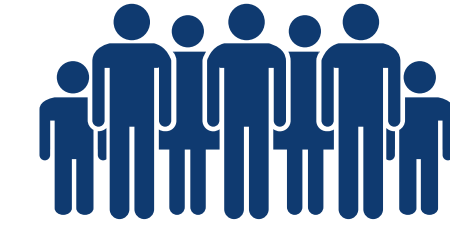


Ontario has seen a 143% increase in the number of publicly-funded users over 10 years.

from



10,121 users in 2004



to 24,584 users in 2014



Dalteparin has the most users but has seen a decrease in its market share from 62% (6,300 users) in 2004 to 44% (10,791 users) in 2014.



Enoxaparin is the second most commonly used (41%, 10,140 users).

\$33,660,440



The overall cost for LMWHs obtained through the OPDP program in 2014

Recommendation

Based on clinical guidelines for the use of LMWHs and increased accessibility for indications currently not funded (e.g., post-operative prophylaxis in non-orthopaedic surgery) or currently funded through EAP (e.g., extended treatment of VTE in cancer patients), the following reimbursement option is recommended. It should be noted that a slight increase in utilization and cost is anticipated with this recommendation.

Limited Use for LMWHs and fondaparinux (streamlined codes)

This option combines the current Limited Use codes and EAP criteria into six streamlined codes based on patient population.

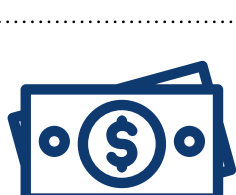
- 1** Acute treatment of VTE in non-cancer patients
- 2** Acute treatment and secondary prophylaxis for VTE in patients with cancer
- 3** Treatment and prophylaxis in pregnant or lactating females
- 4** Post-operative prophylaxis of VTE for patients undergoing surgery of lower limbs
- 5** Post-operative prophylaxis of VTE for patients undergoing non-orthopaedic surgery and who are at high risk of thromboembolic complications
- 6** Peri-operative bridging for patients who require long-term warfarin therapy

Other considerations



LMWH use in pediatrics:

The pediatric population is unique, and an additional review of LMWHs in pediatrics is warranted.



Price negotiations:

LMWHs were not shown to be cost-effective at currently listed prices for extended treatment of VTE in patients with cancer.

91%



EAP

EAP for fondaparinux for patients with cancer-associated thrombosis and heparin-induced thrombocytopenia (HIT) or in pregnant females with history of HIT:

Although fondaparinux has not been studied in patients with cancer-associated thrombosis, guidelines suggest that fondaparinux is an option for patients with a history of HIT in this population. Additionally, fondaparinux has been used during pregnancy in patients with history of HIT.