

### Clinical Pharmacy Program Guidelines for Exoxaparin

Program	Prior Authorization
Medication	Enoxaparin [Lovenox]
Pharmacy & Therapeutics Approval Date	12/18/2014, 11/2016
Effective Date	1/2017

**1. Background:**

**Indications:**

**DVT**

Indicated for: • Prophylaxis of DVT which may lead to PE in patients undergoing abdominal surgery who are at risk for thromboembolic complications, in patients undergoing hip replacement surgery during and following hospitalization, in patients undergoing knee replacement surgery, or medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness • Inpatient treatment of acute DVT with or without PE when administered in conjunction with warfarin • Outpatient treatment of acute DVT without PE when administered in conjunction with warfarin

**Prophylaxis of ischemic complications**

Indicated for the prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin therapy.

**STEMI**

Indicated for the treatment of acute ST-segment elevation myocardial infarction (STEMI) managed medically or with subsequent percutaneous coronary intervention (PCI)

**Off Label Uses:**

Prophylaxis or Treatment of VTE in Patients with Cancer [6, 12, 13]

Prophylaxis of VTE in Pregnancy [5, 10, 12]

Treatment of VTE in Pregnancy [5, 12]

**2. Coverage Criteria:**

<p><b><u>A. Continuation of Therapy Upon Hospital Discharge</u></b></p> <p>1. Will be approved as continuation of therapy upon hospital discharge</p> <p style="text-align: center;"><b>Authorization will be issued for 35 days.</b></p> <p><b><u>B. Prophylaxis of DVT - Orthopedic Surgery</u></b></p> <p>1. For deep vein thrombosis (DVT) prophylaxis</p> <p style="text-align: center;"><b>-AND-</b></p> <p>2. Patient is undergoing one of the following:</p>
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- a. Hip fracture surgery
- b. Hip replacement surgery
- c. Knee replacement surgery

**Authorization will be issued for 35 days.**

**C. Prophylaxis of DVT - Abdominal Surgery**

1. For deep vein thrombosis (DVT) prophylaxis following abdominal surgery

**-AND-**

2. Patient is at risk for thromboembolic complications

**Authorization will be issued for 4 weeks.**

**D. Prophylaxis of DVT - Restricted Mobility**

1. For deep vein thrombosis (DVT) prophylaxis in patients at risk for thromboembolic complications due to severely restricted mobility during acute illness

**Authorization will be issued for 2 weeks.**

**E. Prophylaxis of VTE in patients withholding warfarin**

1. For deep vein thrombosis (DVT) and/or pulmonary embolism (PE) prophylaxis in patients with one of the following:
  - a. Mechanical heart valve
  - b. Atrial fibrillation with history of thromboembolic stroke
  - c. Recent history (< 3 months) of venous thromboembolism
  - d. Atrial fibrillation with CHADs score of 5 or 6
  - e. Atrial fibrillation with Rheumatic valvular heart disease

**-AND-**

2. Patient needs to withhold Coumadin (warfarin) therapy due to surgery or other invasive procedures

**Authorization will be issued for 2 weeks.**

**F. DVT Treatment**

1. For the treatment of acute symptomatic deep vein thrombosis (DVT)

**Authorization will be issued for 2 weeks.**

**G. Prophylaxis or Treatment of VTE in Patients with Cancer**

1. One of the following:
  - a. For the treatment of symptomatic venous thromboembolism (VTE) in patients with cancer

**-OR-**

- b. For deep vein thrombosis (DVT) and/or pulmonary embolism (PE) prophylaxis in patients with cancer

**Authorization will be issued for the length of therapy**

**H. Prophylaxis of VTE in Pregnancy (Off-Label)**

1. For deep vein thrombosis (DVT) and/or pulmonary embolism (PE) prophylaxis in pregnant patients

**-AND-**

2. Patient has one of the following:
  - a. History of prior venous thromboembolism (VTE)
  - b. Mechanical heart valve
  - c. Antiphospholipid antibody (APLA) syndrome and history of pregnancy losses
  - d. Thrombophilia and one of the following:
    - (1) Homozygous for the factor V Leiden mutation
    - (2) Homozygous for the prothrombin G20210A mutation
    - (3) Antithrombin deficiency
  - e. Previously receiving long-term Coumadin (warfarin) anticoagulation treatment

**Authorization will be issued for duration of pregnancy**

**I. VTE Treatment in Pregnancy (off-label)**

1. For the treatment of symptomatic venous thromboembolism (VTE) during pregnancy

**Authorization will be issued for duration of pregnancy**

## **J. Prophylaxis of Ischemic Complications**

1. For prophylaxis of ischemic complications in one of the following:
  - a. Unstable angina
  - b. Non-Q-Wave myocardial infarction

**Authorization will be issued for 2 weeks**

## **3. References:**

1. Fragmin Prescribing Information. Eisai/Pfizer. March 2009.
2. Lovenox Prescribing Information. Sanofi-Aventis. October 2013.
3. Falck-Ytter Y, Francis CW, Johanson NA, et al. Prevention of VTE in Orthopedic Surgery Patients: Antithrombotic Therapy and Prevention of Thrombosis (9th edition). Chest. 2012;141(2)(suppl):e278S-e325S.
4. Gould MD, Garcia DA, Wren SM, et al. Prevention of VTE in Nonorthopedic Surgical Patients: Antithrombotic Therapy and Prevention of Thrombosis (9th edition). Chest. 2012; 141(2)(Suppl):e227S-e277S.
5. Bates SM, Greer IA, Middeldorp S, et al. VTE, Thrombophilia, Antithrombotic Therapy, and Pregnancy VTE, Thrombophilia, Antithrombotic Therapy, and Pregnancy: Antithrombotic Therapy and Prevention of Thrombosis (9th edition). Chest. 2012;141(2\_suppl):e691S-e736S
6. National Comprehensive Cancer Network. Venous thromboembolic disease. v.2.2013. Available at: [http://www.nccn.org/professionals/physician\\_gls/pdf/vte.pdf](http://www.nccn.org/professionals/physician_gls/pdf/vte.pdf). Accessed March 6, 2014.
7. ACCF/AHA/HRS 2013 Management of Patients With Atrial Fibrillation (Compilation of 2006 ACCF/AHA/ESC and 2011 ACCF/AHA/HRS Recommendations). Circulation. 2013; 127: 1916-1926. Available at: <http://circ.ahajournals.org/content/127/18/1916.full.pdf+html>. Accessed March 10, 2014.
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9. Dunn AS, Turpie AGG. Perioperative management of patients receiving oral anticoagulants. Arch Intern Med. 2003;163:901-8.
10. American College of Obstetricians and Gynecologists. Thromboembolism in pregnancy. 2011 Sep. 12 p. (ACOG practice bulletin; no. 123). Available at: <http://www.guideline.gov/content.aspx?id=34439>. Accessed March 13, 2014.
11. Per clinical consult with hematology/oncology consultant, December 19, 2008.
12. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed March 6, 2014.
13. Kearon C, Akl EA, Comerota AJ, et al. Antithrombotic Therapy for VTE Disease: Antithrombotic Therapy and Prevention of Thrombosis (9th edition). Chest 2012; 141(2 suppl):e419S-e494S.

14. Kahn SR, Lim W, Dunn AS, et al. Prevention of VTE in Nonsurgical Patients: Antithrombotic Therapy and Prevention of Thrombosis (9th edition). Chest 2012; 141(2)(Suppl):e195S–e226S.

**HISTORICAL CHANGE NOTES:**

<u>Date</u>	<u>Summary of Change</u>	<u>Reason for Change</u>
June 2009	Criteria taken from previously approved Unison policy, RX06 Low Molecular Weight Heparins. Policy was reformatted and renamed. Long term approval criteria clarified.	New policy template adopted. Criteria updated to reflect current guidelines.
Sept 2009	Long term approval periods adjusted based upon CHEST guidelines.	CPS recommendation
Dec 2010	Annual Review	No changes.
Dec 2011	Annual Review	No changes.
Dec 2012	Annual Review	No changes.
Dec 2014	Full review and clinical criteria updated to align across the UnitedHealthcare enterprise. Criteria sections changed to address each individual indication or off-label indication rather than sections based on length of therapy (acute, long term, or prevention).	UnitedHealthcare enterprise alignment of enoxaparin pharmacy criteria.
April 2015	Added two additional requirement options in the section “Prophylaxis of VTE in patients withholding warfarin”: <ul style="list-style-type: none"> <li>• Atrial fibrillation with CHADs score of 5 or 6</li> <li>• Atrial fibrillation with Rheumatic valvular heart disease</li> </ul>	Per PARP recommendation
Oct 2016	No changes. Policy template updated but no changes made to policy content.	Annual Review

**APPROVALS:**

<u>Date</u>	<u>Approved by</u>
6/17/2009	P&T Committee
8/24/2009	PARP
12/10/2009	P&T Committee
01/25/2010	PARP
12/09/2010	P&T Committee
1/31/2011	PARP
12/08/2011	P&T Committee
12/06/2012	P&T Committee
2/25/2013	PARP
12/18/2014	P&T Committee
4/27/2015	PARP