Clinical Policy: Enoxaparin (Lovenox)

Reference Number: PA.CP.PHAR.224
Effective Date: 05.01.16
Last Review Date: 01.19

Coding Implications
Revision Log

Description
Enoxaparin (Lovenox®) is a low molecular weight heparin (LMWH).

FDA Approved Indication(s)
Lovenox is indicated:

- For prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism pulmonary embolism (PE):
  - In patients undergoing
    - Abdominal surgery who are at risk for thromboembolic complications;
    - Hip replacement surgery, during and following hospitalization;
    - Knee replacement surgery;
  - In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness.
- For treatment of acute DVT:
  - Inpatient treatment of acute DVT with or without PE, when administered in conjunction with warfarin sodium.
  - Outpatient treatment of acute DVT without pulmonary embolism when administered in conjunction with warfarin sodium.
- For prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin.
- For treatment of acute ST-elevation myocardial infarction (STEMI).

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness that Lovenox is **medically necessary** when the following criteria are met (please note a PA is not required for supplies <10 days):

I. Initial Approval Criteria

A. Thrombosis/Thromboembolism* (must meet all)**:**

1. Any of the following indications (a, b or c):
   a. Thrombosis or thromboembolism prevention associated with any of the following conditions:
      i. Cancer;
      ii. Unstable angina or myocardial infarction;
      iii. Atrial fibrillation or prosthetic heart valve;
      iv. Major surgery - orthopedic or non-orthopedic;
      v. Critical illness related to ICU admissions or events;

vi. Restricted mobility associated with acute illnesses or conditions;
vii. Implanted devices-vascular (e.g., central venous access device, umbilical venous catheter, devices/fistulas related to hemodialysis, ventricular assist devices);

b. Thrombosis or thromboembolism treatment;
c. Short-term prophylaxis for transition to or from oral anticoagulation.

Approval duration: 6 months

_____

**Includes off-label use for adults.*

B. Anticoagulation in Pregnancy: Ante- and Postpartum (off-label) (must meet all)**:**

1. Any of the following indications:
   a. Acute venous thrombosis during current pregnancy;
   b. Prior venous thrombosis;
   c. Receiving long-term therapy with a vitamin K antagonist (VKA) (e.g., warfarin);
   d. Prosthetic heart valve;
   e. Inherited thrombophilia;
   f. Antiphospholipid antibody syndrome;
   g. Development of severe ovarian hyperstimulation syndrome post assisted reproduction;
   h. Cesarean section – current pregnancy and request is for the postpartum period;
   i. Any other indication not listed here that is listed in section I.A.
2. Member is pregnant or < 6 months postpartum.

Approval duration: Antepartum (to estimated delivery date); postpartum (6 months)

C. Other diagnoses/indications

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. Thrombosis/Thromboembolism (must meet all)**:**

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Continued use is limited to any of the following indications (a, b or c):
   a. Venous thrombosis prophylaxis or treatment in the presence of cancer;
   b. Past history of failed anticoagulation therapy (clot development) on a non-LMWH* (e.g., failed therapy on heparin, fondaparinux, warfarin, apixaban, dabigatran, edoxaban, rivaroxaban);
   c. Any other indication in section I.A where bridging to warfarin is inappropriate or member has a contraindication to warfarin and extended (indefinite duration) anticoagulation therapy is required.

Approval duration: 6 months

_____

**LMWHs include enoxaparin and dalteparin.*

B. Anticoagulation in Pregnancy: Ante- and Postpartum (off-label) (must meet all)**:**
1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. See Section II.A for continued anticoagulation therapy beyond 6 months postpartum.

Approval duration: Antepartum (to estimated delivery date); postpartum (6 months)

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DVT: deep vein thrombosis
LMWH: low molecular weight heparin
PE: pulmonary embolism
STEMI: ST-elevation myocardial infarction

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Active major bleeding
  - History of immune-mediated heparin-induced thrombocytopenia (HIT) within the past 100 days or in the presence of circulating antibodies
  - Known hypersensitivity to enoxaparin sodium (e.g., pruritus, urticaria, anaphylactic/anaphylactoid reactions)
  - Known hypersensitivity to heparin or pork products
  - Known hypersensitivity to benzyl alcohol (which is in only the multidose formulation of Lovenox)
- Boxed warning(s): Spinal/epidural hematomas

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Adults		
DVT prophylaxis in abdominal surgery	40 mg SC once daily	Dose as specified;

Indication	Dosing Regimen	Maximum Dose
Adults		
DVT prophylaxis in knee replacement surgery	30 mg SC every 12 hours	duration may vary.
DVT prophylaxis in hip replacement surgery	30 mg SC every 12 hours or 40 mg SC once daily	
DVT prophylaxis in medical patients	40 mg SC once daily	
Inpatient treatment or acute DVT with or without PE	1 mg/kg SC every 12 hours or 1.5 mg/kg SC once daily	
Outpatient treatment of acute DVT without PI	1 mg/kg SC every 12 hours	
Unstable angina and non-Q wave MI	1 mg/kg SC every 12 hours (with aspirin)	
Acute STEMI in patient < 75 years of age	30 mg single IV bolus plus a 1 mg/kg SC dose followed by 1 mg/kg SC every 12 hours (with aspirin)	
Acute STEMI in patient ≥ 75 years of age	0.75 mg/kg SC every 12 hours (no bolus) (with aspirin)	

VI. Product Availability

- Prefilled syringes: 30 mg/0.3 mL, 40 mg/0.4 mL
- Graduated prefilled syringes: 60 mg/0.6 mL, 80 mg/0.8 mL,100 mg/1 mL, 120 mg/0.8 mL, 150 mg/1 mL
- Multiple-dose vial: 300 mg/3 mL

VII. References

1. Lovenox Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S., LLC; October, 2013. Available at http://products.sanofi.us/lovenox/lovenox.pdf. Accessed November 7, 2018.
2. Executive summary: Antithrombotic therapy and prevention of thrombosis: CHEST guidelines and expert panel reports. Available at http://www.chestnet.org/Guidelines-and-Resources/CHEST-Guideline-Topic-Areas/Pulmonary-Vascular. Accessed November 7, 2018. *The CHEST guideline series presents recommendations for the prevention, diagnosis, and treatment of thrombosis, addressing a comprehensive list of clinical conditions, including medical, surgery, orthopedic surgery, atrial fibrillation, stroke, cardiovascular disease, pregnancy, and neonates and children.*
3. Thromboembolism in pregnancy. Practice Bulletin No. 196. American College of Obstetrics and Gynecologists. *Obstet Gynecol.* July 2018; 132: e1-17.
4. Enoxaparin. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed November 7, 2018.
5. Cancer-associated venous thromboembolic disease (Version 2.2018). In: National Comprehensive Cancer Network Clinical Practice Guidelines. Available at nccn.org.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1650	Injection, enoxaparin sodium, 10 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 annual review; references reviewed and updated.	01/19	