LOVENOX® (ENOXAPARIN)

Length of Authorization

<table>
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<tr>
<th>Initial Approval: 3 months</th>
<th>Continued Approval: 6 months</th>
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Approval duration for pregnancy:
Antepartum: up to estimated delivery date (EDD)
Postpartum: 6 months postpartum (3 month approvals)

FDA Indications

A. Prophylaxis of DVT, which may lead to PE:
   1. In patients undergoing:
      a. Abdominal surgery who are at risk for thromboembolic complications
      b. Hip replacement surgery, during and following hospitalization
      c. Knee replacement surgery
   2. In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness;
B. Treatment of acute DVT:
   1. Inpatient treatment of acute DVT with or without pulmonary embolism, when administered in conjunction with warfarin sodium;
   2. Outpatient treatment of acute DVT without pulmonary embolism when administered in conjunction with warfarin sodium
C. Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin;
D. Treatment of acute STEMI.*

*Dovenox, when administered concurrently with aspirin, has been shown to reduce the rate of the combined endpoint of recurrent myocardial infarction or death in patients with acute STEMI receiving thrombolysis and being managed medically or with percutaneous coronary intervention (PCI).

Clinical Criteria for Initial Approval

This medication will be covered with prior authorization when the following criteria are met:
A. Venous Thrombosis, Unstable Angina, Myocardial Infarction (must meet all):
   1. Enoxaparin is requested for one or more of the following outpatient indications:
      a. Prophylaxis of one of the following:
         i. Deep vein thrombosis (DVT) and member is undergoing one of the following:
            a) Hip replacement surgery
            b) Knee replacement surgery
            c) Abdominal surgery and member is at risk for thromboembolic complications
            d) Thromboembolic complications due to severely restricted mobility during acute illness
         ii. Thromboembolic complications due to acute thromboembolic stroke with impaired mobility
         iii. Ischemic complications of unstable angina and non-Q-wave myocardial infarction
         iv. Venous thromboembolism (VTE) in the presence of cancer
b. Treatment of one of the following:
   i. DVT without pulmonary embolism (PE), and both of the following:
      a) Concomitant warfarin sodium therapy is initiated when appropriate, usually within 72 hours of enoxaparin initiation.
      b) Enoxaparin should be continued for a minimum of 5 days and until a therapeutic oral anticoagulant effect has been achieved (International Normalization Ratio 2.0 to 3.0)
   ii. Noncatheter-related superficial vein thrombus in close proximity to the deep venous system in the presence of cancer
   iii. DVT or PE in the presence of cancer
   iv. Splanchnic vein thrombosis in the presence of cancer.

B. Anticoagulation in Pregnancy: Ante- and Postpartum (must meet all):
   1. Member is pregnant or < 6 months postpartum and enoxaparin is requested to address one or more of the following outpatient indications:
      a. Acute thromboembolism during current pregnancy
      b. Prior VTE
      c. Receiving long-term therapy with a vitamin K antagonist
      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 all of the following:
         i. Request is for the postpartum period
         ii. At least one additional risk factor for VTE is present (including, but not limited to, prior VTE, congestive heart or respiratory failure, age > 40)
         iii. If anticoagulation therapy is required for greater than 6 weeks, enoxaparin therapy will be bridged to warfarin therapy unless contraindicated.

Clinical Criteria for Continued Approval

This medication will have continued coverage with prior authorization when the following criteria are met:

A. Deep Vein Thrombosis or Pulmonary Embolism in the Presence of Cancer (must meet all):
   1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria, and documentation supports positive response to therapy.