Clinical Policy: Dalteparin (Fragmin)
Reference Number: ERX.SPMN.232
Effective Date: 01/17
Last Review Date:

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that dalteparin (Fragmin®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Venous Thrombosis, Unstable Angina, Myocardial Infarction (must meet all):
      1. Dalteparin 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) Abdominal surgery and member is at risk for thromboembolic complications;
            ii. Thromboembolic complications due to severely restricted mobility during acute illness;
            iii. Thromboembolic complications due to acute thromboembolic stroke with impaired mobility;
            iv. Ischemic complications in unstable angina and non-Q-wave myocardial infarction (MI);
            v. Venous thromboembolism (VTE) in the presence of cancer;
         b. Treatment of one of the following:
            i. Symptomatic VTE (proximal DVT and/or pulmonary embolism (PE)), no contraindication or failure of enoxaparin required;
               a) For DVT without PE, meets both of the following:
                  1) Unless contraindicated, concomitant warfarin sodium therapy is initiated when appropriate, usually within 72 hours of Fragmin initiation;
                  2) Fragmin 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. To reduce the recurrence of VTE in the presence of cancer, no contraindication or failure of enoxaparin required;
            iii. Noncatheter-related superficial vein thrombus in close proximity to the deep venous system in the presence of cancer;
               iv. Splanchnic vein thrombosis in the presence of cancer;
      2. Member has a contraindication to or has failed a trial of enoxaparin for the requested use.

Approval duration: 3 months
B. Anticoagulation in Pregnancy: Ante- and Postpartum (must meet all):
   1. Member is pregnant or < 6 months postpartum and Fragmin 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 (request is for the postpartum period) and
      both of the following:
         i. At least one additional risk factor for VTE is present including but not limited
            to any other indication listed in Section B, as well as prolonged immobility,
            postpartum hemorrhage, preeclampsia, systemic lupus erythematosus, heart
            disease, sickle cell disease, blood transfusion, postpartum infection, BMI > 30
            kg/m², multiple pregnancy, smoking > 10 cigarettes/day, fetal growth
            restriction;
         ii. Unless contraindicated, if anticoagulation therapy is required for greater than
             6 weeks, Fragmin therapy will be bridged to warfarin therapy;
   2. Member has a contraindication to or has failed a trial of enoxaparin for the requested
      use.

   Approval duration: Antepartum: to estimated delivery date (EDD)
   Postpartum: to 6 months postpartum (3 month approvals)

C. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
A. VTE 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.

   Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently, receiving medication via health plan benefit and documentation supports
      positive response to therapy; or
   2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Fragmin Injection (dalteparin sodium injection) is a sterile, low molecular weight heparin. It is
available in single-dose, prefilled syringes preassembled with a needle guard device, and
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Multiple-dose vials. Dalteparin is a low molecular weight heparin with antithrombotic properties. It acts by enhancing the inhibition of Factor Xa and thrombin by antithrombin. In humans, dalteparin potentiates preferentially the inhibition of coagulation Factor Xa, while only slightly affecting the activated partial thromboplastin time (APTT).

FDA Approved Indications:
Fragmin (dalteparin sodium) Injection is a low molecular weight heparin for subcutaneous injection indicated for:
- Prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin therapy;
- Prophylaxis of DVT, which may lead to PE:
  - In patients undergoing hip replacement surgery;
  - In patients undergoing abdominal surgery who are at risk for thromboembolic complications;
  - In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness;
- Extended treatment of symptomatic VTE (proximal DVT and/or PE), to reduce the recurrence of VTE in patients with cancer. In these patients, the Fragmin therapy begins with the initial VTE treatment and continues for six months.

Limitations of use:
- Fragmin is not indicated for the acute treatment of VTE.

Appendices
Appendix A: Abbreviation Key
APTT: activated partial thromboplastin time
DVT: deep vein thrombosis
EDD: estimated delivery date
MI: myocardial infarction
PE: pulmonary embolism
VTE: venous thromboembolism

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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1645</td>
<td>Injection, dalteparin sodium, per 2500 IU</td>
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Reviews, Revisions, and Approvals
Policy created.  
Date: 12/16  Approval Date: 01/17
References

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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CLINICAL POLICY
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