Clinical Policy: Dalteparin (Fragmin)

Reference Number: PA.CP.PHAR.225
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for dalteparin (Fragmin®).

FDA Approved Indication(s)
Fragmin is indicated:

- For prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin therapy;
- For prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (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;
- For extended treatment of symptomatic venous thromboembolism (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.

Limitation(s) of use: Fragmin is not indicated for the acute treatment of VTE.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that dalteparin is **medically necessary** when the following criteria are met:

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 and 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;
2. Failure of a trial of enoxaparin unless (a, b or c):
   a. Enoxaparin is contraindicated;
   b. History of clinically significant adverse effects to enoxaparin;
   c. The requested use is FDA labeled for dalteparin but not for enoxaparin (i.e., VTE treatment in patients with cancer).

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**Includes off-label use for adults and pediatrics.*

Approval duration: 6 months

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 (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;
3. Failure of a trial of enoxaparin unless contraindicated or clinically significant adverse effects are experienced.

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

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Thrombosis/Thromboembolism (must meet all):
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria, and documentation supports positive response to therapy 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

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria, and documentation supports positive response to therapy 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 (1 or 2)**:**

1. Currently, receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy 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

Background

Description/Mechanism of Action:

Fragmin Injection (dalteparin sodium injection) is a sterile, LMHW. It is available in single-dose, prefilled syringes preassembled with a needle guard device, and multiple-dose vials. Dalteparin is a LMHW 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.

Formulations:

Solution, Subcutaneous:

- Fragmin: 25,000 units/mL (95,000 units/3.8 mL (3.8 mL) [contains benzyl alcohol]

Solution, Subcutaneous [preservative free]:

- Fragmin: 10,000 units/mL (1 mL); 2500 units/0.2 mL (0.2 mL); 5000 units/0.2 mL (0.2 mL); 7500 units/0.3 mL (0.3 mL); 12,500 units/0.5 mL (0.5 mL); 15,000 units/0.6 mL (0.6 mL); 18,000 units/0.72 mL (0.72 mL)

Appendices

Appendix A: Abbreviation Key

DVT: deep vein thrombosis
LMWH: low molecular weight heparin
PE: pulmonary embolism
VTE: venous thromboembolism (typically refers to DVT or PE)

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
J1645	Injection, dalteparin sodium, per 2500 IU

Reviews, Revisions, and Approvals	Date	Approval Date
Venous Thrombosis, is changed to "Thrombosis and Thromboembolism" so as not to restrict to venous thrombi. Section I.A criteria are edited to encompass CHEST guidelines for neonates and children (seen primarily under implantable devices), and the criteria is collapsed to maximize consistency across the LMWH policies. Per specialist recommendation an additional indication is added for short-term prophylaxis to or from oral anticoagulation. Continuation criteria added for pregnancy. References reviewed and updated.		

References

1. Fragmin Prescribing Information. New York, NY: Pfizer, Inc.; June 2017. Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=2293. Accessed October 2017.
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 2017. *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. 123. American College of Obstetrics and Gynecologists. *Obstet Gynecol.* 2011; 118: 718-729.
4. Dalteparin. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed October 2017.
5. Cancer-associated venous thromboembolic disease (Version 1.2017). In: National Comprehensive Cancer Network Clinical Practice Guidelines. Available at nccn.org. Accessed October 2017.