Clinical Policy: Blood Formation, Coagulation, and Thrombosis Agents: Heparin-Related Preparations

Reference Number: OH.PHAR.PPA.27
Effective Date: 01/01/2020
Last Review Date: N/A
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description

FDA Approved Indication(s): Varies by drug product, please see package insert; clinical pharmacology or other appropriate clinical reference.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation®, that are **medically necessary** when the following criteria are met:

BLOOD AGENTS: HEPARIN-RELATED PREPARATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ENOXAPARIN (generic of Lovenox®)	FONDAPARINUX (generic of Arixtra®) FRAGMIN® (dalteparin)

I. Initial Approval Criteria

A. Non-Preferred Fondaparinux(Arixtra); D**alteparin(Fragmin)**

1. FDA-Approved Indications: FDA-approved or supported by standard pharmacopeias
2. Member must meet labeled age requirements for the medication;
3. Has the member failed therapeutic trials of **two weeks** with medications not requiring prior approval unless one of the following (a,b, or c)
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to all medications not requiring prior approval
    c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval duration: Initial approval 35 days.

B. Requests for Non-Preferred Fondaparinux(Arixtra); D**alteparin(Fragmin) for greater than 35 days of therapy**

1. Member is unable to be changed to oral anticoagulant due to at least one of the following. (a,b, or c)
    a. Member has diagnosis of cancer **OR**
    b. Member is pregnant **(approved up to 280 days)** OR
    c. Member has contraindication, is unable to tolerate, or has experienced treatment failure with oral anticoagulant.

Approval duration: **Cancer diagnosis = 180 days**
Member is pregnant = 280 days
Member is unable to take warfarin = 180 days

II. Diagnoses/Indications for which coverage is NOT authorized:
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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
enoxaparin (Lovenox®) - Adults	-DVT prophylaxis in abdominal surgery 40 mg SC once daily -DVT prophylaxis in knee replacement surgery 30 mg SC every 12 hours -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)	Dose as specified; duration may vary.

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- *See package insert; clinical pharmacology or other appropriate clinical reference.*

IV. Dosage and Administration

Drug name	Indication	Dosing Regimen	Maximum Dose
Dalteparin (Fragmin)	Unstable angina and non-Q-wave MI	120 IU/kg SC every 12 hours (with aspirin)	Varies
Dalteparin (Fragmin)	DVT prophylaxis in abdominal surgery	2,500 IU SC once daily or 5,000 IU SC once daily or 2,500 IU SC followed by 2,500 IU SC 12 hours later and then 5,000 IU SC once daily	Varies
Dalteparin (Fragmin)	DVT prophylaxis in hip replacement surgery	Postoperative start – 2,500 IU SC 4 to 8 hours after surgery, then 5,000 IU SC once daily or Preoperative start – day of surgery 2,500 IU SC 2 hours before surgery followed by 2,500 IU SC 4 to 8 hours after surgery, then 5,000 IU SC once daily Preoperative start – evening before surgery 5,000 IU SC followed by 5,000 IU SC 4 to 8 hours after surgery	Varies
Dalteparin (Fragmin)	DVT prophylaxis in medical patients	5,000 IU SC once daily	Varies
Dalteparin (Fragmin)	Extended treatment of VTE in patients	Month 1: 200 IU/kg SC once daily Months 2 – 6: 150 IU/kg SC once daily	Varies
Dalteparin (Fragmin)	Treatment of VTE in pediatric patients	Starting dose by age: 4 weeks to less than 2 years: 150 IU/kg SC BID 2 years to less than 8 years: 125 IU/kg SC BID 8 years to less than 17 years: 100 IU/kg SC BID Whenever possible, administer benzyl alcohol-free formulations (prefilled syringes) in pediatric patients.	Varies
Fondaparinux (Arixtra)	DVT prophylaxis following hip fracture, hip replacement, and knee	2.5 mg SC per day	2.5 mg per day

Drug name	Indication	Dosing Regimen	Maximum Dose
	replacement surgery and abdominal surgery		
Fondaparinux (Arixtra)	Acute DVT/PE treatment	SC based on body weight: < 50 kg: 5 mg per day 50 to 100 kg: 7.5 mg per day > 100 kg: 10 mg per day	10 mg per day

V. Product Availability

Drug Name	Availability
Dalteparin (Fragmin)	Single-dose prefilled syringe: 2,500 IU/ 0.2 mL, 5,000 IU/ 0.2 mL. 7,500 IU/ 0.3 mL, 12,500 IU/ 0.5 mL, 15,000 IU/ 0.6 mL, 18,000 IU/ 0.72 mL
Dalteparin (Fragmin)	Single-dose graduated syringe: 10,000 IU/ mL
Dalteparin (Fragmin)	Multiple dose vial: 95,000 IU/3.8 mL
Fondaparinux (Arixtra)	Single-dose, prefilled syringes: 2.5 mg, 5 mg, 7.5 mg, or 10 mg

I. References.

Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.