Clinical Policy: Low Molecular Weight Heparins (LMWH)

Reference Number: CP.CPA.63
Effective Date: 11.16.16
Last Review Date: 11.17
Line of Business: Commercial

Revision Log

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

Description

The following are low molecular weight heparins (LMWH) requiring prior authorization: fondaparinux (Arixtra®), dalteparin (Fragmin®), enoxaparin (Lovenox®).

FDA approved indications

SUMMARY OF FDA APPROVED INDICATIONS			
Indication	Fragmin	Lovenox	Arixtra
Prophylaxis of DVT (deep vein thrombosis) that may lead to PE (pulmonary embolism)			
• *In abdominal surgery*	X	X	X
• *In hip replacement*	X	X	X
• *In knee replacement*	*	X	X
• *In patients with severely restricted mobility during acute illness*	X	X	
• *In moderate risk surgery patients*			
• *In high risk surgery patients*	*	*	
• *In orthopedic surgery*	*		*
• *In hip fracture surgery*	*	*	X
• *In neurosurgery*			
• *In major trauma*	*	*	
• *In acute spinal cord injury*	*	*	
• *In ischemic stroke with impaired mobility*	*	*	
• *In general medical patients at risk (congestive heart failure (CHF), cancer, severe lung disease, restricted to bed)*	*	*	*
• *In pregnancy related thromboembolism*	*	*	
Treatment of acute DVT		X	
Treatment of acute DVT with warfarin			X
Treatment of VTE (venous thromboembolism) with warfarin	*	*	
Treatment of acute PE with warfarin			X
Extended treatment of symptomatic VTE in patients with cancer	X		
Prophylaxis of ischemic complications in unstable angina and non-Q-wave MI (myocardial infarction)	X	X	*

Acute ST-segment elevation myocardial infarction (STEMI)		X	*
Percutaneous angioplasty, acute coronary syndrome	*	*	*
Anticoagulation for dialysis		*	

X FDA approved indication
* Sufficient data exist to support off-label use.

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 Centene Corporation® that the low molecular weight heparins (LMWH) Arixtra, Fragmin, and Lovenox are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Fragmin and Lovenox:

1. Prescribed for one of the following (a, b, c, d, or e):
   a. Prevention of venous thromboembolism in adults for any of the following:
      i. Hip surgery including replacement and hip fracture;
      ii. Knee replacement surgery;
      iii. Other major orthopedic procedures;
      iv. General, abdominal-pelvic, and thoracic surgery in patients at high risk for VTE (Caprini score ≥5);
      v. Members who are acutely ill and are hospitalized for severe respiratory infection or congestive heart failure or who are non-ambulatory and over 65 years of age, have a history of VTE, have active cancer, have severe respiratory disease, or congestive heart failure;
      vi. Acute multiple trauma;
      vii. Acute spinal cord injury;
      viii. Acute thromboembolic stroke with impaired mobility;
      ix. Active malignancy with recurrent VTE (venous thromboembolism) on oral anticoagulants with a therapeutic INR (international normalized ratio);
      x. Thrombophilia or congenital prethrombotic defects precluding use of oral anticoagulants or with recurrent VTE on oral anticoagulants with a therapeutic INR;
      xi. Acute ST-segment elevation myocardial infarction (STEMI) (Lovenox only – See Arixtra indications below);
      xii. Pregnancy under the following conditions:
         a) Single previous idiopathic VTE;
         b) Single previous VTE that was estrogen or pregnancy related;
         c) Anti-thrombin-deficient women (G20210A, factor V Leiden);
         d) Two or more previous VTE;
         e) Antiphospholipid antibodies and multiple previous miscarriages or a history of VTE;

f) Other congenital thrombophilic defects with recurrent miscarriages, second-trimester or later loss, severe or recurrent preeclampsia, or abruption;
g) Mechanical heart valve (DOSE MUST BE ADJUSTED TO ANTI-Xa LEVELS).

b. Prevention of thromboembolism in pediatric members 2 months of age and older for any of the following reasons:
   i. Short term prophylaxis in high-risk situations such as immobility, major surgery, or trauma;
   ii. Congenital prethrombotic states such as antithrombin deficiency or homozygous protein C and S deficiency;
c. Treatment of venous thrombosis and prophylaxis of extension of venous thrombosis when inpatient care can be diverted to an outpatient setting;
d. Use as short-term, preoperative therapy when a member on oral anticoagulation needs to be put on a drug with a shorter duration of action prior to surgery or as prophylaxis or treatment as a transition to oral anticoagulation;
e. Unstable angina, acute non-Q wave MI, acute coronary syndrome, or percutaneous angioplasty.

Approval duration: Length of Benefit

B. Arixtra:

1. Prescribed for one of the following (a, b, c, d, e, or f):
   a. Prevention of venous thromboembolism in adults for any of the following:
      i. Hip surgery including replacement and hip fracture;
      ii. Knee replacement surgery;
      iii. Abdominal surgery;
      iv. Other orthopedic surgery in patients at high-risk for thromboembolism;
      v. Members who are acutely ill and are hospitalized for severe respiratory infection or congestive heart failure or who are non-ambulatory and over 65 years of age, have a history of VTE, have active cancer, have severe respiratory disease, or congestive heart failure ;
   b. Treatment of venous thrombosis and prophylaxis of extension of venous thrombosis when inpatient care can be diverted to an outpatient setting;
   c. Unstable angina;
   d. Treatment of arterial thrombosis resulting in acute coronary syndrome;
   e. Acute ST-segment elevation myocardial infarction (STEMI);
   f. Treatment of heparin-induced thrombocytopenia (see general information).

Approval duration: Length of Benefit

C. Other diagnoses/indications

1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

B. Member is responding positively to therapy.
Approval duration: Length of Benefit

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – CP.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
LMWH: Low Molecular Weight Heparin(s)

Appendix B: General Information
- The approved indications include using in clinical settings in which LMWH products have been found to offer improved safety and efficacy over unfractionated heparins (UFHs) and is consistent with recommendations from the Ninth Edition of the American College of Chest Physicians Antithrombotic Therapy and Prevention of Thrombosis Evidence-Based Clinical Practice Guidelines.
- Each of these medicines has its own instructions for use.
- When transitioning patients to warfarin, a minimum of 4 to 5 days of overlapping therapy with a LMWH or fondaparinux is suggested. LMWH or fondaparinux should not be discontinued until a therapeutic INR has been achieved on two successive measurements.
- LMWH, with the exception of Arixtra should not be used in patients with heparin-induced thrombocytopenia as a cross-reaction occurs.
- Caprini Risk Assessment Score estimates VTE risk by adding points for various VTE risk factors. This scoring system was validated in a large retrospective study in a sample of general, vascular, and urological surgery patients and adapted by the CHEST guidelines committee to categorize VTE risk as being very low (0-1 point), low (2 points), moderate (3-4 points), or high (≥5 points).

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose/Limit/Maximum Dose
heparin	Prophylaxis of VTE: 5000 U SC BID-TID or adjusted dose to therapeutic aPTT depending on procedure, and patient risk factors.	This section intentionally left blank.

Drug	Dosing Regimen	Dose/Limit/Maximum Dose
	Treatment of VTE:5000 U IV, then continuous infusion adjusted dose to therapeutic aPTT	
warfarin	Oral prophylaxis and treatment: Dose adjusted to therapeutic INR (2-3 for treatment of VTE) based on procedure, condition, and patient risk factors.	This section intentionally left blank.
argatroban	Treatment of VTE: 2 mcg/kg/min IV infusion adjusted to therapeutic aPTT.	This section intentionally left blank.

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.

V. Dosage and Administration

A=Arixtra, F=Fragmin, L=Lovenox (all dosed subcutaneously)

Indication	Drug/Dosing Regimen	Maximum Dose
Hip fracture or replacement	**A** 2.5 mg QD **F** Preoperative varies. Postoperative 5000 IU/day **L** 30 mg BID or 40 mg QD	This section intentionally left blank.
Abdominal surgery	**A** 2.5 mg QD **F** 2500-5000 IU QD **L** 40 mg QD	This section intentionally left blank.
Knee replacement	**A** 2.5 mg QD **L** 30 mg BID	This section intentionally left blank.
High risk surgery/major gynecologic surgery or surgery with malignancy	**F** 5000 IU QD **L** 40 mg QD	This section intentionally left blank.
Acute medical illness	**A** 2.5 mg QD **F** 5000 IU QD **L** 40 mg QD	This section intentionally left blank.
Acute multiple trauma	**L** 30 mg BID	This section intentionally left blank.
Acute spinal cord injury	**F** 5000 IU QD	This section intentionally left blank.

Indication	Drug/Dosing Regimen	Maximum Dose
	L 30 mg BID or 40 mg QD	
Embolic stroke	**L** 30 mg BID	This section intentionally left blank.
Recurrent DVT on oral anticoagulation or oral therapy precluded	**F** 200 IU/kg QD (max 18,000 IU/day) **L** 1 mg/kg BID	This section intentionally left blank.
Unstable angina/non-Q wave MI	**F** 120 IU/kg BID (max 10,000 IU BID) **L** 1 mg/kg BID	This section intentionally left blank.
Acute coronary syndrome	**L** 1 mg/kg BID	This section intentionally left blank.
Pregnancy (prophylaxis)	**F** 5000 IU QD **L** 40 mg BID or QD	This section intentionally left blank.
Treatment of VTE	**A** Weight-based: 5 mg, 7.5 mg, or 10 mg QD **L** 1 mg/kg BID	This section intentionally left blank.
Extended treatment of symptomatic VTE in patients with cancer	**F** Month 1: 200 IU/kg QD **F** Month 2: 150 IU/kg QD **F** max 18,000 IU/day	This section intentionally left blank.
Short-term prophylaxis for transition to/from oral anticoagulation	**L** High-risk of clot 1 mg/kg BID **L** Low-risk of clot 30 mg BID or 40 mg QD	This section intentionally left blank.
Pediatric patients treatment	**F** 129 IU/kg QD **L** < 2 mo 1.5 mg/kg BID **L** > 2 mo 1 mg/kg BID	This section intentionally left blank.
Pediatric patients prophylaxis	**F** 92 IU/kg QD **L** < 2 mo 0.75 mg/kg Q 12 H **L** > 2 mo 0.5 mg/kg Q 12 H	This section intentionally left blank.

VI. Product Availability

Drug	Availability
Arixtra	Solution for injection, single-dose prefilled syringe: 2.5 mg/0.5 mL, 5 mg/0.4 mL, 7.5 mg/0.6 mL, 10 mg/0.8 mL
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 Single-dose graduated syringe: 10,000 IU/1 mL Multiple dose vial: 95,000 IU/3.8 mL
Lovenox	Solution for injection, vial: 300 mg/3 mL Prefilled syringes: 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL, 100 mg/1 mL, 120 mg/0.8 mL, 150 mg/1 mL

VII. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	01.24.17	11.17

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

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