

Title: Low Molecular Weight Heparins (LMWH), fondaparinux (Arixtra)

Origination: 03/29/05	Revised: 09/01/10	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

Low molecular weight heparins (LMWH):

- Used for deep vein thrombosis (DVT) **prophylaxis** in patients at risk for thromboembolic complications, such as undergoing abdominal surgery; in patients undergoing hip replacement surgery, during and following hospitalization; in patients undergoing knee replacement surgery; in patients with severely restricted mobility during acute illness; and in patients at risk of ischemic complications due to unstable angina and non-Q-wave myocardial infarction.
- Used in the **treatment** of acute deep vein thrombosis (DVT) with or without pulmonary embolism (PE).

Arixtra:

- Fondaparinux is the first in a new class of agents, indirect factor Xa inhibitors.
- Used in the **treatment** of DVT or pulmonary embolism (PE), and for DVT and PE **prophylaxis** in patients undergoing abdominal surgery, hip fracture surgery, hip replacement, or knee replacement surgery.

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Up to a 21-day supply per two (2) months is covered without authorization. For Miami Dade County / Jackson Health Systems, up to a 30-day supply in two (2) months is covered without authorization. Any refills within two (2) months of original fill will require prior authorization.
- Any request exceeding a 21-day supply in two (2) months will be forwarded to a Clinical Pharmacist for review.

Background Information, continued:

Title: Low Molecular Weight Heparins (LMWH), fondaparinux (Arixtra)

Additional Information

- This Procedure is specific to knee replacement surgery, hip replacement or hip fracture surgery, abdominal surgery, and treatment of hypercoagulable states.
- Dosing Information (LMWH – enoxaparin [Lovenox])
 - **DVT Prophylaxis:**
 - 30 mg SC every 12 hours or 40 mg SC once daily
 - After acute myocardial infarction – 40mg SC once daily
 - **DVT and/or PE Treatment:**
 - 1mg/kg SC every 12 hours or 1.5 mg/kg SC every 24 hours
 - Unstable angina and myocardial infarction – 1 mg/kg every 12 hours
- Dosing Information (fondaparinux)
 - **DVT Prophylaxis** – 2.5 mg SC once daily
 - **DVT and/or PE Treatment**– weight based dosing:
 - 5 mg SC once daily for weight <50 kg
 - 7.5 mg SC once daily for weight 50-100kg
 - 10 mg SC once daily for weight >100kg
 - **Acute Coronary Syndrome:**
 - 2.5 mg SC once daily

Procedure:

- 1.0 Request for *initial therapy* for DVT and/or PE **prophylaxis with knee replacement surgery** using LMWH or fondaparinux requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 1.1 Date of surgery; may continue for up to two (2) weeks post-operatively; **OR**
 - 1.1 Without Pulmonary Emboli (PE) following knee surgery may continue up to 17 days.
- 2.0 Request for *initial therapy* for DVT and/or PE **prophylaxis with hip replacement or hip fracture surgery** with LMWH or fondaparinux requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 2.1 Date of surgery; may continue for up to four (4) weeks post-operatively; **OR**
 - 2.1 Without Pulmonary Emboli (PE) following hip replacement surgery may continue up to 17 days.

Title: Low Molecular Weight Heparins (LMWH), fondaparinux (Arixtra)

Procedure, continued:

- 3.0 Request for *initial therapy* for **treatment of a DVT with or without PE** with LMWH or fondaparinux requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 3.1 Therapeutic plan to initiate oral anticoagulant and INR if available; may continue until a therapeutic oral anticoagulant effect is achieved (e.g., INR is 2.0 to 3.0);
 - 3.2 May continue for up to 17 days after initiation of oral anticoagulation therapy;
- 4.0 Request for *initial therapy* for **unstable angina or non-Q-wave myocardial infarction** with LMWH or fondaparinux requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 4.1 Diagnosis of non-ST-segment elevation myocardial infarction (NSTEMI) **and** non-Q-wave myocardial infarction;
 - 4.2 If all criteria are met, therapy may be approved for two (2) weeks.
- 5.0 Request for *initial therapy* for DVT and/or PE **prophylaxis due to hypercoagulable state** with LMWH requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 5.1 Oral anticoagulant monotherapy has been tried and failed; **OR**
 - 5.1 Oral anticoagulant therapy is contraindicated or has caused complications or adverse effects;
 - 5.2 If all criteria are met, therapy may be approved for one (1) year.

Title: Low Molecular Weight Heparins (LMWH), fondaparinux (Arixtra)

Procedure, continued:

- 6.0 Request for *initial therapy* due to **increased risk after sustaining an acute myocardial infarction** with LMWH or fondaparinux requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 6.1 ST segment elevation;
 - 6.2 Severe left-ventricular dysfunction;
 - 6.3 Congestive Heart Failure;
 - 6.4 History of systemic or pulmonary embolism;
 - 6.5 2D echo evidence of mural thrombus;
 - 6.6 Atrial fibrillation;
 - 6.7 If all criteria are met, therapy may be approved for three (3) months.
- 7.0 Requests for duration of therapy longer than the indicated procedure are not covered except when no other treatment options are available and stopping treatment could lead to medical complications.

Title: Low Molecular Weight Heparins (LMWH), fondaparinux (Arixtra)

References:

1. Pfizer, Inc. Fragmin[®] (dalteparin) Solution for Injection. Package Insert. Revised April 2007.
2. Sanofi-Aventis. Lovenox[®] (enoxaparin) Solution for Injection. Package Insert. Revised May 2007.
3. Geerts WH, Pineo GH, Heit JA, et al. Prevention of venous thromboembolism. *Chest* 2004;126:338S-400S.
4. Cairns JA, Theroux P, Lewis HD, et al. Antithrombotic agents in coronary artery disease. *Chest* 2001;119 (suppl): 228S-252S.
5. Antman EM, McCabe CH, Gurfinkel EP et al. Enoxaparin prevents death and cardiac ischemic events in unstable angina/non-Q-wave myocardial infarction: results of the Thrombolysis in Myocardial Infarction (TIMI) 11B trial. *Circulation* 1999;100:1593-1601.
6. The Fifth Organization to Assess Strategies in Acute Ischemic Syndromes Investigators. Comparison of fondaparinux and enoxaparin in acute coronary syndromes. *N Engl J Med* 2006;354:1464-76.
7. The OASIS-6 Trial Group. Effects of fondaparinux on mortality and reinfarction in patients with acute ST-segment elevation myocardial infarction: the OASIS-6 randomized trial. *JAMA* 2006;295:1519-30.
8. GlaxoSmithKline. Arixtra. Prescribing Information. Revised October 2005.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.