ARIXTRA® (FONDAPARINUX)

Length of Authorization

Initial Approval: 3 months	Continued Approval: 6 months

FDA Indications

Fondaparinux (Arixtra)

1. Prophylaxis of DVT, which may lead to PE in patients undergoing:
   - Hip fracture surgery, including extended prophylaxis;
   - Hip replacement surgery;
   - Knee replacement surgery;
   - Abdominal surgery who are at risk for thromboembolic complications;
2. Treatment of acute DVT when administered in conjunction with warfarin sodium;
3. Treatment of acute PE when administered in conjunction with warfarin sodium when initial therapy is administered in the hospital.

Clinical Criteria for Initial Approval

This medication will be approved for prior authorization when the following criteria are met:

A. Venous Thrombosis (must meet all):
   1. Fondaparinux 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:
            a. Hip fracture surgery
            b. Hip replacement surgery
            c. Knee replacement surgery
            d. Abdominal surgery and member is at risk for thromboembolic complications
         ii. Venous thromboembolism (VTE) in the presence of cancer

      b. Treatment of one of the following:
         i. DVT or pulmonary embolism (PE), **AND** both of the following:
            a. Unless contraindicated, concomitant warfarin sodium therapy is initiated when appropriate, usually within 72 hours of Arixtra initiation; **AND**
            b. Arixtra 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. Noncatheter-related superficial vein thrombus in close proximity to the deep venous system in the presence of cancer;
         iii. Splanchnic vein thrombosis in the presence of cancer.

Clinical Criteria for Continued Approval
This medication will have continued coverage with prior authorization when the following criteria are met: 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.