Clinical Policy: Fondaparinux (Arixtra)
Reference Number: ERX.SPMN.231
Effective Date: 01/17
Last Review Date:

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

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that fondaparinux (Arixtra®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
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;
         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.

   Approval duration: 3 months

B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
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.

   Approval duration: 6 months
B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently, receiving medication via health plan benefit and documentation supports positive response to therapy; or
   2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Arixtra (fondaparinux sodium) is a sterile solution containing fondaparinux sodium. It is a synthetic and specific inhibitor of activated factor X (Xa). The antithrombotic activity of fondaparinux sodium is the result of antithrombin III (ATIII)-mediated selective inhibition of factor Xa. By selectively binding to ATIII, fondaparinux sodium potentiates (about 300 times) the innate neutralization of factor Xa by ATIII. Neutralization of Factor Xa interrupts the blood coagulation cascade and thus inhibits thrombin formation and thrombus development. Fondaparinux sodium does not inactivate thrombin (activated factor II) and has no known effect on platelet function. At the recommended dose, fondaparinux sodium does not affect fibrinolytic activity or bleeding time.

FDA Approved Indications:
Fondaparinux (Arixtra) is a synthetic factor Xa inhibitor/solution for subcutaneous injection indicated for:
- 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;
- Treatment of acute DVT when administered in conjunction with warfarin sodium;
- Treatment of acute PE when administered in conjunction with warfarin sodium when initial therapy is administered in the hospital.

Appendices

Appendix A: Abbreviation Key
CrCl: creatinine clearance
DVT: deep vein thrombosis
PE: pulmonary embolism
VTE: venous thromboembolism

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.

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<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J1652</td>
<td>Injection, fondaparinux sodium, 0.5 mg</td>
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Fondaparinux

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<th>Reviews, Revisions, and Approvals</th>
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<td>Policy created.</td>
<td>12/16</td>
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References

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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