Original Effective Date: 06/01/2016
Current Effective Date: 03/07/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
Policy Number: C9084-A

Arixtra (fondaparinux)

PRODUCTS AFFECTED

Arixtra (fondaparinux), fondaparinux

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Venous thrombosis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. VENOUS THROMBOSIS:
1. (a) Documented diagnosis of any of the following requiring prophylaxis of deep vein thrombosis (DVT):

i. Member is undergoing hip fracture surgery
ii. Member is undergoing hip replacement surgery
iii. Member is undergoing knee replacement surgery
iv. Member is undergoing abdominal surgery and member is at risk for thromboembolic complications

OR

(b)Documentation member requires prophylaxis of venous thromboembolism (VTE) in the presence of cancer

OR

(c)Documented diagnosis of any of the following requiring treatment: DVT or pulmonary embolism (PE), Noncatheter-related superficial vein thrombus in close proximity to the deep venous system in the presence of cancer, superficial vein thrombosis (SVT) of the lower limb requiring anticoagulation

OR

(d)Documented diagnosis of heparin-induced thrombocytopenia (HIT) with or without thrombosis

OR

(e)Documentation member has splanchnic vein thrombosis in the presence of cancer AND member has a history of a trial, failure or intolerance to enoxaparin

AND

2. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Arixtra (fondaparinux) include: Severe renal impairment (creatinine clearance < 30 mL/min) in prophylaxis or treatment of venous thromboembolism, Active major bleeding, Bacterial endocarditis, Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium, Body weight < 50 kg (venous thromboembolism prophylaxis only), History of serious hypersensitivity reaction (e.g., angioedema, anaphylactoid/anaphylactic reactions) to fondaparinux sodium]

CONTINUATION OF THERAPY:

A. PROPHYLAXIS OF VENOUS THROMBOEMBOLISM IN PRESENCE OF CANCER, HEPARIN INDUCED THROMBOCYTOPENIA COMPLICATED BY THROMBOSIS (HITT) ONLY:

1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
2. Documentation of continued need for anticoagulation therapy

DURATION OF APPROVAL:

Initial authorization: Duration needed for indication course of treatment up to 2 months, Continuation of therapy (PROPHYLAXIS OF VENOUS THROMBOEMBOLISM IN PRESENCE OF CANCER, HEPARIN-INDUCED THROMBOCYTOPENIA COMPLICATED BY THROMBOSIS (HITT) ONLY): Duration needed for indication course of treatment up to an additional 6 months

PRESCRIBER REQUIREMENTS:

No requirements

AGE RESTRICTIONS:

No requirements

QUANTITY:

Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and

patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous Injection

DRUG CLASS:
Synthetic Heparinoid-Like Agents

FDA-APPROVED USES:
Indicated for prophylaxis of deep vein thrombosis (DVT) in patients undergoing hip fracture surgery (including extended prophylaxis), hip replacement surgery, knee replacement surgery, or abdominal surgery and treatment of DVT or acute pulmonary embolism (PE) when administered in conjunction with warfarin

COMPENDIAL APPROVED OFF-LABELED USES:
Heparin-induced thrombocytopenia, Superficial vein thrombosis

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
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.

Superficial Vein Thrombosis
Per CHEST 2021 second update of guideline for Antithrombotic Therapy for VTE Disease, in patients with superficial venous thrombosis (SVT) of the lower limb at increased risk of clot progression to DVT or PE, anticoagulation is recommended. Fondaparinux is the recommended anticoagulant treatment over other regimens such as prophylactic or therapeutic LMWH.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Arixtra (fondaparinux) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Arixtra (fondaparinux) include: Severe renal impairment (creatinine clearance <30 mL/min) in prophylaxis or treatment of venous thromboembolism, Active major bleeding, Bacterial endocarditis, Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium, Body weight <50 kg (venous thromboembolism prophylaxis only), History of serious hypersensitivity reaction (e.g., angioedema, anaphylactoid/anaphylactic reactions) to fondaparinux sodium.

OTHER SPECIAL CONSIDERATIONS:
Arixtra (fondaparinux) has a black box warning for spinal/epidural hematomas.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:
Arixtra SOLN 2.5MG/0.5ML
Arixtra SOLN 5MG/0.4ML
Arixtra SOLN 7.5MG/0.6ML
Arixtra SOLN 10MG/0.8ML
Fondaparinux Sodium SOLN 2.5MG/0.5ML
Fondaparinux Sodium SOLN 5MG/0.4ML
Fondaparinux Sodium SOLN 7.5MG/0.6ML
Fondaparinux Sodium SOLN 10MG/0.8ML

REFERENCES

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9. National Comprehensive Cancer Network. 2024. Cancer-Associated Venous Thromboembolic Disease (Version 2.2023). [online] Available at: < vte.pdf (nccn.org) > [Accessed 9 January 2024].

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Drug Class References	Q1 2024
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Continuation of therapy Duration of Approval Compendial Approved Off-Labeled Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file