

SmartPA Criteria Proposal

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|-----------------------------------|--|
| Drug/Drug Class: | Anticoagulants, Oral and Subcutaneous PDL Edit |
| First Implementation Date: | July 5, 2012 |
| Proposed Date: | September 15, 2022 |
| Prepared For: | MO HealthNet |
| Prepared By: | MO HealthNet/Conduent |
| Criteria Status: | <input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria |

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Anticoagulants inhibit various pathways of the coagulation cascade and are utilized for the prevention and treatment of thromboembolic conditions such as myocardial infarction (MI), stroke, and venous thromboembolism (VTE). The anticoagulants utilized to prevent or treat such thromboembolic conditions are classified as vitamin K antagonists (warfarin), direct oral anticoagulants (DOACs), low molecular weight heparin (LMWH) (dalteparin and enoxaparin), and synthetic pentasaccharide factor Xa inhibitor (fondaparinux). The DOACs are further subdivided into oral direct factor Xa inhibitors (apixaban, betrixaban, edoxaban, and rivaroxaban) and direct thrombin inhibitors (dabigatran). The DOACs offer some advantages over vitamin K antagonists such as fewer monitoring requirements, less frequent follow-up, and fewer drug and food interactions. All anticoagulants have the potential to cause an increase in bleeding which may be a serious adverse event. The risk of bleeding varies based on the particular anticoagulant utilized, patient age, and patient preexisting conditions.

Total program savings for the PDL classes will be regularly reviewed.

| Program-Specific Information: | Preferred Agents | Non-Preferred Agents |
|-------------------------------|--|---|
| | <ul style="list-style-type: none"> Eliquis® Enoxaparin Fragmin® Pradaxa® Warfarin Xarelto® 10, 15, 20 mg Tabs Xarelto® Starter Pack | <ul style="list-style-type: none"> Arixtra® Bevyxxa® Coumadin® Dabigatran Fondaparinux Jantoven® Lovenox® Savaysa® Xarelto® 2.5 mg Tabs Xarelto® Susp |

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 Clinical Edit

Data Sources: Only Administrative Databases

Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Anticoagulant Agents, Oral and Subcutaneous
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents
 - Documented trial period for preferred agents **OR**
 - Documented ADE/ADR to preferred agents **OR**
- For Xarelto 2.5 mg: documented diagnosis of coronary artery disease (CAD) or peripheral artery disease (PAD) (with concurrent utilization of aspirin 81 mg daily)
- **For Xarelto suspension: Clinical Consultant Review for participants aged 10 years or older**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

| Drug Description | Generic Equivalent | Max Dosing Limitation |
|-----------------------|--------------------|-----------------------|
| PRADAXA 150 MG | DABIGATRAN | 2 tablets per day |
| PRADAXA 75 MG | DABIGATRAN | 2 tablets per day |
| PRADAXA 110 MG | DABIGATRAN | 2 tablets per day |
| LOVENOX 30 MG/0.3 ML | ENOXAPARIN | 0.6 mL per day |
| LOVENOX 150 MG/1 ML | ENOXAPARIN | 2 mL per day |
| LOVENOX 120 MG/0.8 ML | ENOXAPARIN | 1.6 mL per day |
| LOVENOX 60 MG/0.6 ML | ENOXAPARIN | 1.2 mL per day |
| LOVENOX 80 MG/0.8 ML | ENOXAPARIN | 1.6 mL per day |
| LOVENOX 100 MG/1 ML | ENOXAPARIN | 2 mL per day |
| LOVENOX 40 MG/0.4 ML | ENOXAPARIN | 0.8 mL per day |
| LOVENOX 300 MG/3 ML | ENOXAPARIN | 3 mL per day |
| ARIXTRA 10 MG/0.8 ML | FONDAPARINUX | 0.8 mL per day |
| ARIXTRA 2.5 MG/0.5 ML | FONDAPARINUX | 0.5 mL per day |
| ARIXTRA 5 MG/0.4 ML | FONDAPARINUX | 0.4 mL per day |
| ARIXTRA 7.5 MG/0.6 ML | FONDAPARINUX | 0.6 mL per day |
| XARELTO 10 MG | RIVAROXABAN | 1 tablet per day |
| XARELTO 15 MG | RIVAROXABAN | 2 tablets per day |
| XARELTO 20 MG | RIVAROXABAN | 1 tablet per day |
| XARELTO 2.5 MG | RIVAROXABAN | 2 tablets per day |

Required Documentation

Laboratory Results:
 MedWatch Form:

Progress Notes:
 Other:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
 Rule Type: PDL

SmartPA PDL Proposal Form

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Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: “Low Molecular Weight Heparins (LMWH)”, UMKC-DIC; Updated August 2022.
- Evidence-Based Medicine Analysis: “Direct Factor Xa Inhibitor Agents and Miscellaneous Anticoagulants”, UMKC-DIC; August 2022.
- Evidence-Based Medicine and Fiscal Analysis: “Anticoagulants Agents: Oral and Subcutaneous – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- Centers for Disease Control and Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention: Heart Disease Statistics and Maps. Heart Disease Facts | cdc.gov. Accessed July 2022.
- US. Preventive Services Task Force. USPSTF Bulletin: Task Force Issues Draft Recommendation Statement on Aspirin Use to Prevent Cardiovascular Disease, October 2021. Task Force Issues Draft Recommendation Statement on Aspirin Use to Prevent Cardiovascular Disease (uspreventiveservicestaskforce.org).
- Stevens SM, Woller SC, Baumann Kreuziger L, et. al. Pulmonary Vascular Guidelines and Consensus Statements. Executive Summary: Antithrombotic Therapy for VTE Disease: Second Update of the CHEST Guideline and Expert Panel Report. CHEST 2021; 160(6):2247-2259.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.