SmartPA Criteria Proposal

Drug/Drug Class:	Anticoagulants, Oral and Subcutaneous PDL Edit
First Implementation Date:	July 5, 2012
Proposed Date:	October 17, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐ Existing Criteria ☒ Revision of Existing Criteria ☐ 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 fever drug and food interactions. All anticoagulants have the potential to cause an increase in bleeding which may 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
• Eliquis®	• Arixtra®
• Enoxaparin	• Bevyxxa®
• Fragmin®	• Coumadin®
• Jantoven®	• Dabigatran Etexilate
• Pradaxa® capsules	• Fondaparinux
• Warfarin	• Lovenox®
• Xarelto® 10, 15, 20 mg Tabs	• **Pradaxa® pellets**
• Xarelto® Starter Pack	• 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
- **For Pradaxa pellets: participants < 10 years of age require therapeutic trial of Xarelto suspension**

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 capsules per day
PRADAXA 75 MG	DABIGATRAN	2 capsules per day
PRADAXA 110 MG	DABIGATRAN	2 capsules per day
PRADAXA PELLET 20 MG	**DABIGATRAN**	**2 packs per day**
PRADAXA PELLET 30 MG	**DABIGATRAN**	**4 packs per day**
PRADAXA PELLET 40 MG	**DABIGATRAN**	**4 packs per day**
PRADAXA PELLET 50 MG	**DABIGATRAN**	**4 packs per day**
PRADAXA PELLET 110 MG	**DABIGATRAN**	**4 packs per day**
PRADAXA PELLET 150 MG	**DABIGATRAN**	**2 packs 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:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: “Low Molecular Weight Heparins (LMWH)”, UMKC-DIC; Updated June 2023.
- Evidence-Based Medicine Analysis: “Direct Factor Xa Inhibitor Agents and Miscellaneous Anticoagulants”, UMKC-DIC; June 2023.
- 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; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.