Clinical Policy: Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants and Antiplatelet Agents

Reference Number: OH.PHAR.PPA.28
Effective Date: 01.20
Last Review Date: 01.22
Line of Business: Medicaid

Revision Log

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

BLOOD AGENTS: ORAL ANTICOAGULANTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON PREFERRED"
ELIQUIS® (apixaban) PRADAXA® (dabigatran) WARFARIN (generic of Coumadin®) XARELTO® (rivaroxaban)	SAVAYSA® (edoxaban)

BLOOD AGENTS: PLATELET AGGREGATION INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON PREFERRED"
ASPIRIN ASPIRIN/DIPYRIDAMOLE ER BRILINTA® (ticagrelor) CLOPIDOGREL (generic of Plavix®) PRASUGREL (generic of Effient®)	YOSPRALA™ (aspirin/omeprazole) ZONTIVITY® (vorapaxar sulfate)

Description

The following oral anticoagulants and platelet aggregation inhibitors require prior authorization: SAVAYSA® (edoxaban), YOSPRALA™ (aspirin/omeprazole), and ZONTIVITY® (vorapaxar sulfate).

FDA Approved Indication(s)

		Apixaban	Clopidogrel	Dabigatran	Edoxaban	Prasugrel	Rivaroxaban	Ticagrelor	Vorapaxar	Warfarin
Reduction of atherosclerotic events:	After cardiac valve replacement									✓
	In established peripheral arterial disease		✓						✓	
	In non-STEMI ACS		✓			✓		✓		✓
	In non-valvular atrial fibrillation	✓		✓	✓		✓ (15 & 20mg)			✓

	In recent MI or stroke		I						I (MI only)	I
	In STEMI ACS		I			I		I		I
Thrombosis Risk and Treatment	Treatment of venous thrombosis, pulmonary embolism	I		I (in patients who have been treated with a parenteral anticoagulant for 5-10 days)	I (in patients who have been treated with a parenteral anticoagulant for 5-10 days)		I (15 & 20mg)			I
	Prophylaxis of DVT in patients undergoing total hip or knee replacement	✓		✓ (in hip replacement only)			✓ (10mg)			I
	Reduce risk of recurrence of DVT and PE in patients who have been previously treated	I		I			I (10mg)			

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation®, that SAVAYSA® (edoxaban), YOSPRALA™ (aspirin/omeprazole), and ZONTIVITY® (vorapaxar sulfate) are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. PA Required Agents (must meet all)**:**

1. Requested medication must be used for an approved FDA indication and duration;
2. Documented therapeutic failure of a 14-day trial with **two** medications not requiring prior approval, unless one of the following are met: (a, b, or c):
    a. Allergy to medications not requiring prior approval;
    b. Contraindication to all medications not requiring prior approval;

c. History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PA: Prior Authorization

Appendix B: Therapeutic Alternatives
Refer to tertiary resources such as UpToDate or Clinical Pharmacology

Appendix C: Contraindications/Boxed Warnings
Refer to tertiary resources such as UpToDate or Clinical Pharmacology

IV. Dosage and Administration

Refer to tertiary resources such as UpToDate or Clinical Pharmacology

V. Product Availability

Refer to tertiary resources such as UpToDate or Clinical Pharmacology

VI. References

Refer to manufacturer prescribing information

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy	10.19	
Annual review – no changes deemed necessary	11.20	
ODM Q4 P&T update. Removed Aspirin requirement with Xarelto 2.5 mg. Added Aspirin/Dipyridamole ER to list of preferred medications. Added "Requested medication must be used for an approved FDA indication and duration" to approval criteria. Removed duration limit of 35 days with Xarelto 10 mg.	01.22	N/A

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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