Anticoagulant Agents (Pradaxa®, Savaysa®)

Policy # 00525
Original Effective Date: 01/01/2017
Current Effective Date: 03/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the anticoagulant products, Pradaxa®‡ (dabigatran), generic dabigatran, and Savaysa®‡ (edoxaban), to be **eligible for coverage**** when the patient selection criteria are met**.**

Patient Selection Criteria

Coverage eligibility Pradaxa (dabigatran), generic dabigatran, or Savaysa (edoxaban) will be considered when the following criteria are met:

- There is clinical evidence or patient history that suggests the use of Xarelto®‡ (rivaroxaban) or Eliquis®‡ (apixaban) will be ineffective or cause an adverse reaction to the patient; OR
- The requested drug is Pradaxa (dabigatran) or generic dabigatran AND the patient is younger than 18 years of age and older than 3 months of age.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Pradaxa (dabigatran), generic dabigatran, or Savaysa (edoxaban) WITHOUT clinical evidence or patient history that suggests the use of Xarelto (rivaroxaban) or Eliquis (apixaban) will be ineffective or cause an adverse reaction to the patient to be **not medically necessary.****

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Background/Overview

Listed below are the FDA approved indications for Eliquis, Xarelto, Pradaxa, and Savaysa:

Drug	Indication	MOA
Eliquis (apixaban)	• Reduce risk of stroke and systemic embolism in those with non-valvular atrial fibrillation • Prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients that have undergone hip or knee replacement surgery • Treatment of DVT • Treatment of PE • Reduction in the risk of recurrent DVT and PE following initial therapy	Factor Xa Inhibitor
Xarelto (rivaroxaban)	• Reduce risk of stroke and systemic embolism in those with non-valvular atrial fibrillation • Prophylaxis of DVT, which may lead to PE, in patients undergoing hip or knee replacement surgery • Treatment of DVT • Treatment of PE • Reduction in the risk of recurrence of DVT and of PE following initial 6 months treatment for DVT and/or PE • Prophylaxis of VTE in acutely ill medical patients • Reduce risk of major cardiovascular events in patients with coronary artery disease (CAD) or peripheral artery disease (PAD) • Treatment of VTE and reduction of risk of recurrent VTE in pediatric patients • Thromboprophylaxis in pediatric patients with congenital heart disease after the Fontan procedure	Factor Xa inhibitor
Savaysa (edoxaban)	• Reduce risk of stroke and systemic embolism in those with non-valvular atrial fibrillation	Factor Xa Inhibitor

	• Treatment of DVT/PE in patients following 5-10 days of initial therapy with a parenteral anticoagulant	
Pradaxa (dabigatran)	• Reduce risk of stroke and systemic embolism in those with non-valvular atrial fibrillation • Treatment of DVT/PE in patients who have been treated with a parenteral anticoagulant for 5-10 days • Reduce the risk of recurrence of DVT and PE in patients who have been previously treated • Prophylaxis of DVT and PE in patients that have undergone hip replacement surgery • Treatment of VTE in pediatric patients age 3 months to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days • Reduce the risk of recurrence of VTE in pediatric patients 3 months to less than 18 years of age who have been previously treated	Direct Thrombin Inhibitor

DVT= deep vein thrombosis, PE= pulmonary embolism

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Pradaxa was approved in 2010, Xarelto in 2011, Eliquis in 2012, and Savaysa in 2015. Please refer to the chart above for the FDA approved indications.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The patient selection criteria presented in this policy take into consideration the patient's age as well as clinical evidence or patient history that suggests the use of Xarelto (rivaroxaban) or Eliquis (apixaban) will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above-mentioned caveats, there is no advantage of using Pradaxa (dabigatran), generic dabigatran, or Savaysa (edoxaban) over Xarelto (rivaroxaban) or Eliquis (apixaban).

References

1. Xarelto [package insert]. Janssen Ortho, LLC. Gurabo, Puerto Rico. Updated November 2022.
2. Eliquis [package insert]. Bristol Myers Squibb. Princeton, New Jersey. Updated July 2016.
3. Pradaxa [package insert]. Boehringer Ingelheim. Ridgefield, Connecticut. Updated June 2021.
4. Savaysa [package insert]. Daiichi Sankyo. Parsippany, New Jersey. Updated September 2015.

Policy History

Original Effective Date: 01/01/2017
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09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. New Policy.
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Updated background information to reflect new indications for Xarelto.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Updated criteria and background information to include new pediatric indication for Pradaxa.

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09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Added new Pradaxa generic to policy. Updated background information to include new Xarelto pediatric indications.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2025

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.