BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

**Pharmacy Medical Necessity Policy**

# Anticoagulants – Unified Formulary

**Policy Number:** 9.619
**Version Number:** 1.2
**Version Effective Date:** 1/1/2022

| Product Applicability | ☐ **All Plan+ Products** |
|---|---|
| **Well Sense Health Plan**<br>☐ New Hampshire Medicaid | **Boston Medical Center HealthNet Plan**<br>☒ MassHealth ACO<br>☒ MassHealth MCO<br>☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct<br>☐ Senior Care Options |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit |

Note: Disclaimer and audit information is located at the end of this document.

## Prior Authorization Policy

**Reference Table:**

| Drugs that require PA | No PA |
|---|---|
| Direct Thrombin Inhibitors (DTIs) | |
| | Pradaxa® (dabigatran etexilate mesylate) § |
| Factor Xa Inhibitor | |
| Savaysa® (edoxaban) | Eliquis® (apixaban) |
| Xarelto® (rivaroxaban 2.5 mg tablet) | Xarelto® (rivaroxaban 10 mg, 15 mg, 20 mg, starter pack) |
| | Arixtra®# (fondaparinux) |
| Low Molecular Weight Heparins (LMWHs) | |
| | Fragmin® (dalteparin) |
| | Lovenox®# (enoxaparin) |
| Vitamin K Antagonists (VKAs) | |
| | Warfarin |

+ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

§ Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent is required

# This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule or liquid) does not have an FDA "A"-rated generic equivalent.

**Approval Criteria:**

| | |
|---|---|
| **Savaysa® (edoxaban)** | **Initial Authorization:**<br>1. The member has a diagnosis of nonvalvular atrial fibrillation OR is being treated for deep vein thrombosis (DVT) or pulmonary embolism (PE); **AND**<br>2. The request is for an appropriate dose; **AND**<br>3. Documentation provided of inadequate response, adverse drug reaction, or contraindication to ALL of the following (pharmacy claims are not sufficient):<br>a. Eliquis (apixaban)<br>b. Pradaxa (dabigatran etexilate mesylate)<br>c. Xarelto (rivaroxaban)<br><br>**Continuation of Therapy:**<br>1. The member has a diagnosis of nonvalvular atrial fibrillation OR is being treated for deep vein thrombosis (DVT) or pulmonary embolism (PE); **AND**<br>2. The request is for an appropriate dose; **AND**<br>3. Prescriber attests continuation of therapy is medically necessary |
| **Xarelto® (rivaroxaban)**<br>**2.5 mg tablets** | **Initial authorization and continuation of therapy:**<br>1. The member has a diagnosis of coronary artery disease (CAD) or peripheral artery disease (PAD) and requires a reduction of risk of major cardiovascular event; **AND**<br>2. Member is also receiving concomitant aspirin therapy; **AND**<br>3. Request is not for greater than quantity limit of 2 tablets/day |
| **Duration of Authorization:** | Initial authorization will be granted for 6 months<br>Reauthorizations will be granted for 12 months. |

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|---|---|---|---|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee |

| Policy Revisions History | | | |
|---|---|---|---|
| **Review Date** | **Summary of Revisions** | **Revision Effective Date** | **Approved by** |
| 12/1/2020 | Created new policy to align with MH PDL requirements | 1/1/2021 | P&T Committee |
| 3/3/2021 | Updated policy to reflect changes from MH. Updated to reflect removal of PA for Pradaxa all strengths. Brand preferred guidance added to table for Pradaxa. Preferred drug status removed from Eliquis (implemented on 3/22/21) | 3/3/2021 | P&T Committee |
| 9/27/2021 | Updated policy to reflect changes from MH (dated 9/10/21). Criteria for Savaysa and Xarelto updated to less stringent requirements (Savaysa no longer requires adverse reaction to warfarin, medical necessity for no INR monitoring, or inadequate response to warfarin). Xarelto 2.5mg no longer requires concomitant diagnosis of a-fib or VTE OR stability on 2.5mg dosing. Off-label indication section for Xarelto updated. | 12/1/2021 | P&T Committee |
| 10/1/2021 | Annual review; Updated policy to reflect MH 1/1/2022 policy updates to Savaysa criteria and alignment of LMWHs, Arixtra® (fondaparinux) and warfarin in UPPL. Updated criteria for clarity and removed appendices | 1/1/2022 | P&T Committee |

## Next Review Date

11/2022

## References


1. Arixtra (fondaparinux) [prescribing information]. Morgantown, WV: Mylan Institutional LLC; August 2020.

2. Eliquis (apixaban) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; April 2021.
3. Lovenox (enoxaparin sodium) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; May 2020.
4. Fragmin (dalteparin sodium) [prescribing information]. New York, NY: Pfizer; June 2020.
5. Pradaxa (dabigatran) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2021. 3 Pharmacy Medical Necessity Guidelines: Anticoagulants
6. Savaysa (edoxaban) [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo; March 2021.
7. Xarelto (rivaroxaban) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2021.

## Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.