Anticoagulant
Pradaxa (dabigatran etexilate mesylate)
Savaysa (edoxaban)
Xarelto 2.5mg (rivaroxaban)
Effective 01/01/2021

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Xarelto and Savaysa are factor Xa inhibitors which inhibit platelet activation and fibrin clot formation. Pradaxa is a thrombin inhibitor which blocks free and fibrin bound thrombin. These medications are indicated for:

- Treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) – **Pradaxa and Savaysa**
- Prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. – **Pradaxa, Xarelto, and Savaysa**
- Prophylaxis of DVT and/or PE in patients who have undergone total hip arthroplasty. - **Xarelto and Pradaxa**
- Prophylaxis of venous thromboembolism (VTE) – **Xarelto**
- Reduction in the risk of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE) – **Xarelto**
- Reduction of risk of major cardiovascular (CV) events (CV death, myocardial infarction, and stroke) in patients with coronary artery disease (chronic) or peripheral artery disease. - **Xarelto**

No PA	PA required
Pradaxa® (dabigatran etexilate mesylate 110 mg) ≤ 70 capsules/365 days	Pradaxa® (dabigatran etexilate mesylate 75 mg, 150 mg)
Eliquis® (apixaban) [PD]	Pradaxa® (dabigatran etexilate mesylate 110 mg) > 70 capsules/365 days
Xarelto® (rivaroxaban 10 mg, 15 mg, 20 mg, starter pack)	Savaysa® (edoxaban)
	Xarelto® (rivaroxaban 2.5 mg tablet)

[PD] Preferred Drug. Trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. **Please note, for Anticoagulants, a trial with a preferred agent is not required prior to approval of a non-preferred agent.**

Coverage Guidelines

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with the requested medication, for up to 6 months, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided for the following drug and/or diagnosis specific criteria:

Pradaxa® (dabigatran etexilate mesylate) & Savaysa® (edoxaban)

Nonvalvular atrial fibrillation, deep vein thrombosis (DVT) and/or pulmonary embolism (PE)

1. Member has a diagnosis of ONE of the following:
    a. Nonvalvular atrial fibrillation (Savaysa, Pradaxa 75mg and 150mg)
    b. Deep vein thrombosis (DVT) and/or pulmonary embolism (PE) (Savaysa, Pradaxa 150mg)
2. **ONE** of the following†:
    a. Adverse reaction (bleeding complications on warfarin) or contraindication (bleeding risk factors*, pregnancy, major drug-drug interactions**, hypersensitivity) to warfarin
    b. Medical necessity for anticoagulation that does not require INR monitoring [i.e. difficulty obtaining INR monitoring (homebound, homeless, poor venous access, combative with blood draws, or frequent/extended travel that would make routine INR monitoring unfeasible)]
    c. Inadequate response to ≥ 30 days of warfarin for reasons other than noncompliance (i.e. thromboembolic event while taking warfarin or consistent inability to maintain a therapeutic INR during the 30-day trial)

†Prescriber documents bypassing warfarin trial due to updated CHEST 2018 guidelines or AHA/ACC/HRS 2019 guidelines noting NOACs preferred over warfarin for AF (with the exception of those with moderate-to-severe mitral stenosis or a mechanical heart valve) or DVT/PE and no cancer diagnosis

Reduction in the risk of recurrence of DVT and/or PE following 6 months of treatment

1. Member is using medication for reduction in the risk of recurrence of DVT and/or PE following 6 months of treatment
2. The request is for Pradaxa 150mg
3. **ONE** of the following†:
    d. Member has just completed treatment for DVT or PE with one of the novel oral anticoagulants (NOACS) (e.g. apixaban, dabigatran or rivaroxaban)
    e. Adverse reaction (bleeding complications on warfarin) or contraindication (bleeding risk factors*, pregnancy, major drug-drug interactions**, hypersensitivity) to warfarin
    f. Medical necessity for anticoagulation that does not require INR monitoring [i.e. difficulty obtaining INR monitoring (homebound, homeless, poor venous access, combative with blood draws, or frequent/extended travel that would make routine INR monitoring unfeasible)]
    g. Inadequate response to ≥ 30 days of warfarin for reasons other than noncompliance (i.e. thromboembolic event while taking warfarin or consistent inability to maintain a therapeutic INR during the 30-day trial)

†Prescriber documents bypassing warfarin trial due to updated CHEST 2016 guidelines noting NOACs preferred over warfarin for DVT/PE and no cancer diagnosis

Pradaxa® (dabigatran etexilate mesylate) 110mg > 70 capsules/365 days

Prescriber provides documentation of **ALL** of the following:

1. The member is using Pradaxa 110mg for prophylaxis deep vein thrombosis (DVT) and/or pulmonary embolism (PE) in total hip replacement surgery
2. If the request is for > 70 capsules/365 days, then is the member undergoing another hip replacement surgery

Xarelto® (rivaroxaban) 2.5mg tablets

Prescriber provides documentation of **ALL** the following:

1. Member is using Xarelto 2.5mg for the reduction of risk of major CV events in chronic CAD/PAD
2. **ONE** of the following:
    a. Concomitant diagnosis of atrial fibrillation or venous thromboembolic disease
    b. Member is currently stabilized on the requested agent (specific to 2.5 mg strength)
3. Member is also receiving concomitant aspirin therapy
4. Quantity limit of 60 tablets/30 days

Continuation of Therapy

Reauthorization requires physician attestation of continuation of therapy.

Limitations

1. Initial approvals:
    a. Pradaxa® (dabigatran etexilate mesylate):
        - Hip replacement surgery (110 mg capsule): 70 capsules/365 days
        - All other approvals may be granted for up to 6 months
    b. Savaysa® (edoxaban): Approvals may be granted for up to 6 months
    c. Xarelto® (rivaroxaban): Approvals for 2.5 mg tablet may be granted for up to 6 months
2. Reauthorizations will be for 12 months
    a. Pradaxa® (dabigatran etexilate mesylate), Savaysa® (edoxaban):
        - Atrial fibrillation: Approve for up to 1 year
    b. Pradaxa® (dabigatran etexilate mesylate):
        - Reduction in the risk of recurrence of DVT/PE: Approve for up to 1 year
    c. Xarelto® (rivaroxaban) 2.5 mg tablet:
        - Reduction in the risk of major CV events in chronic CAD/PAD: Approve for up to 1 year
3. The following quantity limits apply:

Xarelto 2.5 tablets	60 tablets per 30 days
Pradaxa 110 mg capsule	70 capsules per 365 days

Appendix

***Bleeding risk factors**

Bleeding risk factors can include prescriber noting any of the following: history of bleeding on warfarin; hypertension (systolic BP >160 mm Hg); abnormal liver function; drug or alcohol abuse; elevated INRs that require reversal of anticoagulation by vitamin K administration or by withholding warfarin doses.

****Major drug-drug interactions**

Major drug-drug interactions should be considered for concurrent chronic medications that are listed on the severity scale from Micromedex as contraindicated or major (i.e. amiodarone, simvastatin, tamoxifen, sertraline, etc.).

References

1. Xarelto (rivaroxaban) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; January 2019.
2. Pradaxa (dabigatran) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; July 2020.
3. Savaysa (edoxaban) [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo; April 2020.
4. Eliquis (apixaban) [product monograph]. Montreal, Canada: Bristol-Myers Squibb Canada Co; October 2019.

Review History

09/30/2020 – Created and Reviewed Nov P&T Mtg; MH Partial Unified Formulary. Effective 1/1/2021

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