Anticoagulant
Pradaxa (dabigatran etexilate mesylate)
Savaysa (edoxaban)
Xarelto (rivaroxaban) suspension and 2.5 mg tablets
Effective 07/01/2022

Plan	☒ MassHealth UPPL ☐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 chronic coronary artery disease (CAD) or peripheral artery disease (PAD). – **Xarelto 2.5 mg tablets**
- Treatment or reduction of risk of recurrent DVT and/or PE in pediatric patients – **Xarelto suspension**
- Thromboprophylaxis in pediatric patients with congenital heart disease after the Fontan procedure – **Xarelto suspension**

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

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.

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:

Savaysa® (edoxaban)

1. Member has a diagnosis of ONE of the following diagnosis:
    a. Nonvalvular atrial fibrillation
    b. Deep vein thrombosis (DVT) and/or pulmonary embolism (PE)
2. Appropriate dosing
3. Provider attestation to member having inadequate response, adverse drug reaction or contraindication to ALL of the following
    a. Eliquis® (apixaban)
    b. Pradaxa® (dabigatran etexilate mesylate)
    c. Xarelto® (rivaroxaban)

Xarelto® (rivaroxaban) 2.5mg tablet

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. Member is also receiving concomitant aspirin therapy
3. Quantity limit of 2 tablets/day

Xarelto® (rivaroxaban suspension)

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

1. Member is using Xarelto suspension for the treatment or reduction of risk of recurrent DVT and/or PE
2. Member is < 18 years of age
3. Member has received or will receive ≥ 5 days of injectable or intravenous anticoagulation prior to starting Xarelto
4. If member is ≥ 12 years and < 18 years of age, **ONE** of the following:
    a. Inadequate response, adverse reaction, or contraindication to Pradaxa capsules
    b. Medical necessity for use of Xarelto suspension formulation as noted by **ONE** of the following:
        i. Member utilizes tube feeding (G-tube/J-tube)
        ii. Member has a swallowing disorder or condition affecting ability to swallow tablets
5. If current weight is ≥ 30 kg, medical necessity for use of Xarelto suspension instead of Xarelto 10 mg, 15 mg, and 20 mg tablets as noted by **ONE** of the following:
    a. Member utilizes tube feeding (G-tube/J-tube)
    b. Member has a swallowing disorder or condition affecting ability to swallow tablets
6. Appropriate dosing (weight required)

Continuation of Therapy

Savaysa, Xarelto 2.5 mg tablet: Reauthorization requires physician attestation of continuation of therapy.

Xarelto suspension: Reauthorization requires physician attestation of continuation of therapy AND the following:

Treatment or reduction of risk of recurrent DVT and/or PE in pediatric patients:

1. Updated member weight
2. Appropriate dosing
3. If current weight is ≥ 30 kg or if member is ≥ 18 years of age, continued medical necessity for use of Xarelto suspension instead of Xarelto 10 mg, 15 mg, 20 mg tablets as noted by **ONE** of the following:
    a. Member utilizes tube feeding (G-tube/J-tube)
    b. Member has a swallowing disorder or condition affecting ability to swallow tablets

Thromboprophylaxis in pediatric patients with congenital heart disease after the Fontan procedure:

1. Updated member weight
2. Appropriate dosing
3. If current weight is ≥ 50 kg or if member is ≥ 18 years of age, continued medical necessity for use of Xarelto suspension instead of Xarelto 10 mg tablet as noted by **ONE** of the following:
    a. Member utilizes tube feeding (G-tube/J-tube)
    b. Member has a swallowing disorder or condition affecting ability to swallow tablets

Limitations

1. Initial approvals:
    a. Savaysa: up to 6 months
    b. Xarelto 2.5mg for reduction of risk of major CV events in chronic CAD/PAD: up to 6 months
    c. Xarelto suspension for the treatment or reduction of risk of recurrent DVT and/or PE in pediatric patients: up to 6 months
    d. Xarelto suspension for thromboprophylaxis in pediatric patients with congenital heart disease after the Fontan procedure: up to 12 months
2. Reauthorizations will be for 12 months
    a. Savaysa: up to 12 months
    b. Xarelto 2.5mg for reduction of risk of major CV events in chronic CAD/PAD: up to 12 months

c. Xarelto suspension for the treatment or reduction of risk of recurrent DVT and/or PE in pediatric patients: up to 12 months
d. Xarelto suspension for thromboprophylaxis in pediatric patients with congenital heart disease after the Fontan procedure: up to 12 months

3. The following quantity limits apply:

Xarelto 2.5 tablets	60 tablets per 30 days

4. Availability and Dosage:

Drug	Dosing
Savaysa (edoxaban) Tablet: 15 mg, 30 mg, 60 mg	Nonvalvular atrial fibrillation: For CrCl 51 to 95 mL/min: 60 mg once daily For CrCl 15 to 50 mL/min: 30 mg once daily For CrCl > 95 mL/min: do not use Treatment of DVT and PE For CrCl 51 to 95 mL/min: 60 mg once daily following 5 to 10 days of initial therapy with a parenteral anticoagulant For CrCl 15 to 50 mL/min, patients weighing ≤ 60 kg or individuals taking concomitant P-glycoprotein inhibitors (e.g., verapamil and quinidine or the short-term concomitant administration of azithromycin, clarithromycin, erythromycin, oral itraconazole or oral ketoconazole): 30 mg once daily following 5 to 10 days of initial therapy with a parenteral anticoagulant
Xarelto (rivaroxaban) Tablet: 2.5 mg, 10 mg, 15 mg, 20 mg Starter Pack (ONLY approved for treatment of DVT/PE): 42 x 15 mg tablets plus 9 x 20 mg tablets Suspension: 1 mg/mL	Prophylaxis of DVT, which may lead to PE in patients undergoing hip replacement surgery: 10 mg once daily with or without food beginning at least 6 to 10 hours after surgery for a total duration of 35 days Reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation: For patients with CrCl >50 mL/min: 20 mg once daily with the evening meal; for patients with CrCl 15 to 50 mL/min: 15 mg once daily with the evening meal Reduction in the risk of recurrence of DVT/PE: 10 mg once daily with food Reduction of risk of major CV events in chronic CAD/PAD: 2.5 mg BID plus ASA once daily (75 mg-100 mg) Treatment of DVT/PE: 15 mg twice daily with food, for first 21 days. After 21 days, transition to 20 mg once daily with food, for remaining treatment

Abbreviations: CAD=coronary artery disease, CrCl=creatinine clearance, CV=cardiovascular, DVT=deep vein thrombosis, PAD=peripheral artery disease, PE=pulmonary embolism

Appendix

Xarelto (rivaroxaban): Pediatric Dosing

Treatment of and reduction in risk of recurrent DVT/PE

Dosage Form	Body Weight	Dosage			Total Daily Dose
		Once a Day	Twice Daily	Three Times Daily	
Oral Suspension Only (1 mg/mL)	2.6 kg to 2.9 kg			0.8 mg	2.4 mg
	3 kg to 3.9 kg			0.9 mg	2.7 mg
	4 kg to 4.9 kg			1.4 mg	4.2 mg
	5 kg to 6.9 kg			1.6 mg	4.8 mg
	7 kg to 7.9 kg			1.8 mg	5.4 mg
	8 kg to 8.9 kg			2.4 mg	7.2 mg
	9 kg to 9.9 kg			2.8 mg	8.4 mg
	10 kg to 11.9 kg			3 mg	9 mg
	12 kg to 29.9 kg		5 mg		10 mg
Oral Suspension or Tablets	30 kg to 49.9 kg	15 mg			15 mg
	≥ 50 kg	20 mg			20 mg

Thromboprophylaxis after Fontan procedure

Dosage Form	Body Weight	Dosage		Total Daily Dose
		Once a Day	Twice Daily	
Oral Suspension Only (1 mg/mL)	7 kg to 7.9 kg		1.1 mg	2.2 mg
	8 kg to 9.9 kg		1.6 mg	3.2 mg
	10 kg to 11.9 kg		1.7 mg	3.4 mg
	12 kg to 19.9 kg		2 mg	4 mg
	20 kg to 29.9 kg		2.5 mg	5 mg
	30 kg to 49.9 kg	7.5 mg		7.5 mg
Oral Suspension or Tablets	≥ 50 kg	10 mg		10 mg

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. Pradaxa® Capsules [package insert]. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc.; 2021 Jun.
2. Angiomax® [package insert]. Bedford (OH): BenVenue Laboratories; 2019 Jun.

3. Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically [cited 2021 Aug 6]. Available from: http://www.thomsonhc.com/.
4. Argatroban [package insert]. Woodcliff Lake (NJ): Eagle Pharmaceuticals; 2019 Dec.
5. Halton J, Brandão LR, Luciani M, Bomgaars L, Chalmers E, Mitchell LG, et al. Dabigatran etexilate for the treatment of acute venous thromboembolism in children (DIVERSITY): a randomised, controlled, open-label, phase 2b/3, non-inferiority trial. Lancet Haematol. 2021 Jan;8(1):22-33.
6. Brandão LR, Albisetti M, Halton J, Bomgaars L, Chalmers E, Mitchell LG, et al. Safety of dabigatran etexilate for the secondary prevention of venous thromboembolism in children. Blood. 2020 Feb 13; 135(7): 491–504.
7. Xarelto® [package insert]. Titusville (NJ): Janssen Pharmaceuticals Inc; January 2022.
8. Eliquis® [package insert]. Princeton (NJ) and New York (NY): Bristol-Myers Squibb Company and Pfizer, Inc.; 2021 Apr.
9. Savaysa® [package insert]. Basking Ridge (NJ): Daiichi Sankyo, Inc.: 2021 Mar.
10. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation [published online January 28, 2019]. *Circulation*. https://doi.org/10.1161/CIR.0000000000000665.
11. Stevens SM, Woller SC, Baumann Kreuziger L, Bounameaux H, Doerschug K, Geersing GJ, et al. Antithrombotic Therapy for VTE disease: Second Update of the CHEST Guideline and Expert Panel Report-Executive Summary. CHEST 2021 Jul 31:S0012-3692(21)01507-5. doi: 10.1016/j.chest.2021.07.056. Epub ahead of print.
12. Monagle P, Lensing AW, Thelen K, Martinelli I, Male C, Santamaría A, et al. Bodyweight-adjusted rivaroxaban for children with venous thromboembolism (EINSTEIN-Jr): results from three multicentre, single-arm, phase 2 studies. Lancet Haematol 2019; 6:500–509

Review History

09/30/2020 – Created and Reviewed Nov P&T Mtg; MH Partial Unified Formulary. Effective 1/1/2021
11/17/2021 – Updated and Reviewed Nov P&T Mtg; Matched MH UPPL. Added PA for Savaysa, new agents Arixtra, Fragmin and Lovenox were added. Effective 01/01/2022
05/18/2022 – Reviewed and Updated for May P&T; Matched MH UPPL. Added PA for Xarelto suspension. Updated references. The pediatric dosing section was added to the guideline. Effective 07/01/2022

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