Pharmacy Medical Necessity Guidelines: Anticoagulants

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Eliquis (apixaban) is a factor Xa inhibitor indicated to reduce the risk of systemic embolism in patients with nonvalvular atrial fibrillation, prophylaxis of deep venous thrombosis (which may lead to pulmonary embolism) in patients who have undergone hip or knee replacement surgery, and treatment of DVT and PE and reduction of recurrent DVT and PE following initial therapy.

Pradaxa (dabigatran) is a direct thrombin inhibitor indicated to prevent systemic embolism in the presence of non-valvular atrial fibrillation, treat and prevent deep venous thrombosis (DVT) and pulmonary embolism (PE), prevent DVT and PE in patients who have undergone hip replacement surgery.

Savaysa (edoxaban) is a factor Xa inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. It is also indicated for the treatment of DVT and PE following 5-10 days of initial treatment with a parenteral anticoagulant. Savaysa should not be used in patients with atrial fibrillation and a CrCl > 95 mL/minute due to an increased rate of ischemic stroke with Savaysa 60 mg daily compared to patients treated with warfarin.

Xarelto is a factor Xa inhibitor indicated for the following: reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation, treatment of DVT, treatment of PE, reduction of risk of DVT or PE, prophylaxis of DVT (which may lead to PE) in patients undergoing knee or hip replacement surgery, prophylaxis of VTE in acutely ill medical patients, and reduction of risk major CV events in patients with chronic coronary artery disease (CAD) or peripheral artery disease (CAD).

Medication Name	Available Formulations	Indication	Dosing
Eliquis (apixaban)	**Tablets:** 2.5 mg, 5 mg, Starker Pack	Reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation	5 mg twice daily 2.5 mg twice daily if ≥ 80 y.o., ≤ 60 kg, or serum creatinine ≥ 1.5 mg/dL
		Prophylaxis of DVT after hip or knee replacement surgery	2.5 mg twice daily **Hip replacement:** x 35 days **Knee replacement:** x 12 days
		Treatment of DVT and PE	10 mg twice daily for first 7 days, then 5 mg twice daily
		Reduction in risk of recurrence of DVT and PE	2.5 mg twice daily after at least 6 months of treatment for DVT or PE

Medication Name	Available Formulations	Indication	Dosing
Pradaxa (dabigatran)	**Capsules:** 75 mg, 110 mg, 150 mg	Reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation	**CrCl > 30 mL/min:** 150 mg twice daily **CrCl 15-30 mL/min:** 75 mg twice daily
		Treatment of DVT and PE in patients who have been treated with a parenteral anticoagulant for 5-10 days	**CrCl > 30 mL/min:** 150 mg twice daily
		Reduce the risk of recurrence of DVT and PE in patients who have been previously treated	**CrCl > 30 mL/min:** 150 mg twice daily
		Prophylaxis of DVT and PE in patients who have undergone hip replacement surgery	**CrCl > 30 mL/min:** 110 mg on first day, then 220 mg once daily
Savaysa (edoxaban)	**Tablets:** 15 mg, 30 mg, 60 mg	Reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation	60 mg once daily **CrCl 15-50 mL/min:** 30 mg once daily **do not use if CrCl > 95 mL/minute**
		Treatment of DVT and PE following 5-10 days of initial therapy with a parenteral anticoagulant	60 mg once daily **15-50 mL/min:** 30 mg once daily **≤ 60 kg:** 30 mg once daily **Concomitant use with certain P-gp inhibitors:** 30 mg once daily
Xarelto (rivaroxaban)	**Tablets:** 2.5 mg, 10 mg, 15 mg, 20 mg	Reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation	**CrCl > 50 mL/min:** 20 mg once daily **CrCl ≤ 50 mL/min:** 15 mg once daily
		Treatment of DVT or PE	**CrCl ≥ 15 mL/min:** 15 mg twice daily x 21 days, then 20 mg once daily **CrCl < 15 mL/min:** avoid
		Reduction of risk of DVT and/or PE in patients at continued risk for DVT and/or PE	**CrCl ≥ 15 mL/min:** 10 mg once daily, after at least 6 months of standard anticoagulant treatment **CrCl < 15 mL/min:** avoid
		Prophylaxis of DVT following hip or knee replacement surgery	10 mg once daily **Hip replacement:** 35 days **Knee replacement:** 12 days CrCl < 15 mL/min: avoid
		Prophylaxis of VTE in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding	**CrCl ≥ 15 mL/min:** 10 mg once daily, in hospital and after hospital discharge, for total recommended duration of 31-39 days **CrCl < 15 mL/min:** avoid
		Reduction of risk of major CV events (CV death, MI, and stroke) in chronic CAD or PAD	2.5 mg twice daily, in combination with aspirin

Eliquis is the preferred anticoagulant for Tufts Health Together and is covered without Prior Authorization. Xarelto 10 mg, 15 mg, and 20 mg tablets are also covered without Prior Authorization, as are Pradaxa 110 mg capsules up to a quantity of 70 capsules per year. Xarelto 2.5 mg tablets and all other novel oral anticoagulants require Prior Authorization.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred anticoagulant when the following criteria are met and limitations do not apply:

Pradaxa (dabigatran)

Nonvalvular Atrial Fibrillation

1. The member has a diagnosis of nonvalvular atrial fibrillation

AND

2. The request is for 75 or 150 mg capsules

AND

3. The Member has one of the following:
    a. Adverse reaction (bleeding complications on warfarin) or contraindication (bleeding risk factors*, pregnancy, major drug-drug interactions**, hypersensitivity) to warfarin

    OR

    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])

    OR

    c. Inadequate response to at least 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).

Treatment of DVT and/or PE

1. The member has a diagnosis of deep venous thrombosis (DVT) or pulmonary embolism (PE)

AND

2. The request is for 150 mg capsules

AND

3. The member has one of the of the following:
    a. Adverse reaction (bleeding complications on warfarin) or contraindication (bleeding risk factors*, pregnancy, major drug-drug interactions**, hypersensitivity) to warfarin

    OR

    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])

    OR

    c. Inadequate response to at least 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)

Reduction in the Risk of Recurrence of DVT and/or PE After 6 Months of Treatment

1. The Member requires treatment to reduce the risk of recurrent DVT or PE following at least six months of treatment

AND

2. The request is for 150 mg capsules

AND

3. The Member has one of the following;
    a. Member has just completed treatment for DVT or PE with one of the novel oral anticoagulants (NOACs) (e.g., apixaban, dabigatran, or rivaroxaban)

    OR

    b. Adverse reaction (bleeding complications on warfarin) or contraindication (bleeding risk factors*, pregnancy, major drug-drug interactions**, hypersensitivity) to warfarin

    OR

    c. 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]).

    OR

d. Inadequate response to at least 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)

Savaysa (edoxaban)

Non valvular atrial fibrillation

1. The member has a diagnosis of nonvalvular atrial fibrillation

AND

2. The Member has one of the following:
   a. Adverse reaction (bleeding complications on warfarin) or contraindication (bleeding risk factors*, pregnancy, major drug-drug interactions**, hypersensitivity) to warfarin

OR

   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])

OR

   c. Inadequate response to at least 30 days of warfarin for reasons other than noncompliance (i.e., thromboembolic event while taking wayfaring or consistent inability to maintain a therapeutic INR during the 30-day trial).

Treatment of DVT and/or PE

1. The member has a diagnosis of deep venous thrombosis (DVT) or pulmonary embolism (PE)

AND

2. The member has one of the of the following:
   a. Adverse reaction (bleeding complications on warfarin) or contraindication (bleeding risk factors*, pregnancy, major drug-drug interactions**, hypersensitivity) to warfarin

OR

   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])

OR

   c. Inadequate response to at least 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)

Xarelto (rivaroxaban) 2.5 mg tablet

1. The member has a diagnosis of chronic coronary artery disease (CAD) or peripheral artery disease (PAD) and requires a reduction of risk of major cardiovascular events

AND

2. The member has one of the following:
   a. Concomitant diagnosis of atrial fibrillation or venous thromboembolic disease

OR

   b. Member is currently stabilized on Xarelto 2.5 mg tablet

AND

3. The member is also receiving concomitant aspirin therapy.

**Bleeding risk factors include: history of bleeding on warfarin, hypertension (systolic blood pressure > 160 mmHg), 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 with warfarin include amiodarone, simvastatin, tamoxifen, and sertraline*

LIMITATIONS

1. The following quantity limitations apply:

Medication Name	Quantity Limit
Eliquis Starter Pack	1 pack per life of plan
Eliquis 2.5 mg, 5 mg tablet	60 tablets per 30 days
Pradaxa 75 mg, 110 mg, 150 mg capsule	60 capsules per 30 days

Medication Name	Quantity Limit
	110 mg capsules covered without PA up to 70 capsules per 365 days
Savaysa 15 mg, 30 mg, 60 mg tablet	30 tablets per 30 days
Xarelto 10 mg, 15 mg, 20 mg tablet	30 tablets per 30 days
Xarelto 2.5 mg tablet	60 tablets per 30 days
Xarelto Starter Pack	51 tablets per 21 days (1 fill per life of plan)

CODES

None

REFERENCES

1. Eliquis (apixaban) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; November 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. Xarelto (rivaroxaban) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2020.

APPROVAL HISTORY

November 24, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.