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Oral Anticoagulant - Bevyxxa (betrixaban), Eliquis (apixaban), Pradaxa (dabigatran), Savaysa (edoxaban), Xarelto (rivaroxaban) Quantity Limit Program Summary

FDA APPROVED INDICATIONS AND DOSAGE[1-5]

Agent(s)	Indication(s)	Dosage
Bevyxxa® (betrixaban) Capsule	Prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE	160 mg orally initially followed by 80 mg orally once daily. Recommended duration of treatment is 35-42 days. Dose adjustments: Severe renal impairment (CrCl ≥ 15 to < 30 mL/min), or use with P-gp inhibitors: 80 mg orally initially followed by 40 mg orally once daily. Recommended duration of treatment is 35-42 days.
Eliquis® (apixaban) Tablet	Reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation	5 mg orally twice daily Dose adjustments: 2.5 mg orally twice daily in patients with at least two of the following characteristics: • Age ≥ 80 years • Body weight ≤ 60 kg • Serum creatinine ≥ 1.5 mg/dL
	Prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery	2.5 mg orally twice daily with initial dose 12 to 24 hours after surgery. Recommended duration: Hip replacement: 35 days of treatment Knee replacement: 12 days of treatment
	Treatment of DVT and PE	10 mg orally twice daily for 7 days, followed by 5 mg taken orally twice daily
	Reduce the risk of recurrent DVT and PE following initial therapy	2.5 mg orally twice daily after at least 6 months of treatment for DVT or PE

Agent(s)	Indication(s)	Dosage
Pradaxa® (dabigatran) Capsule	To reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation	For patients with CrCl > 30 mL/min: 150 mg orally twice daily For patients with concomitant use of P-gp inhibitors or with CrCl 15-30 mL/min: 75 mg orally twice daily
	For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with a parenteral anticoagulant for 5-10 days	For patients with CrCl > 30 mL/min: 150 mg orally twice daily
	To reduce the risk of recurrence of DVT and PE in patients who have been previously treated	
	For the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery	For patients with CrCl > 30 mL/min: 110 mg orally for the first day, then 220 mg orally once daily for 28-35 days
Savaysa® (edoxaban) Tablet	To reduce the risk of stroke and systemic embolism (SE) in patients with nonvalvular atrial fibrillation (NVAF)	60 mg orally once daily in patients with CrCl > 50 to ≤ 95 mL/min Do not use SAVAYSA in patients with CrCl > 95 mL/min Reduce dose to 30 mg orally once daily in patients with creatinine clearance 15 to 50 mL/min
	Treatment of DVT and PE following 5 to 10 days of initial therapy with a parenteral anticoagulant	60 mg orally once daily Reduce dose to 30 mg orally once daily for patients with CrCl 15 to 50 mL/min, weight ≤ 60 kg, or who are taking certain concomitant P-gp inhibitors
Xarelto® (rivaroxaban) Tablet Suspension	Reduction of risk of stroke and systemic embolism in adult patients with NVAF	CrCl > 50 mL/min: 20 mg orally once daily CrCl ≤ 50 mL/min: 15 mg orally once daily
	Treatment of DVT	15 mg orally twice daily for first 21 days, followed by 20 mg orally once daily CrCl < 15 mL/min: Avoid use
	Treatment of PE	
	Reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months	10 mg orally once daily, after at least 6 months of standard anticoagulant treatment CrCl < 15 mL/min: Avoid use

Agent(s)	Indication(s)	Dosage
	Prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery	CrCl < 15 mL/min: Avoid use Hip replacement: 10 mg orally once daily for 35 days, 6-10 hours after surgery once hemostasis has been established Knee replacement: 10 mg orally once daily for 12 days, 6-10 hours after surgery once hemostasis has been established
	Reduction of risk of major cardiovascular (CV) events (CV death, myocardial infarction [MI], and stroke) in adult patients with chronic coronary artery disease (CAD)	2.5 mg orally twice daily, in combination with aspirin (75-100 mg) once daily
	Reduction of risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in adult patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD	2.5 mg orally twice daily, in combination with aspirin (75-100 mg) once daily
	Prophylaxis of venous thromboembolism (VTE) and VTE-related death during hospitalization and post-hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding	10 mg orally once daily, in hospital and after hospital discharge, for a total recommended duration of 31 to 39 days CrCl < 15 mL/min: Avoid use

Agent(s)	Indication(s)	Dosage
	Treatment of VTE and the reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years after at least 5 days of initial parenteral anticoagulant treatment	2.6 kg to 2.9 kg: 0.8 mg three times daily 3 kg to 3.9 kg: 0.9 mg three times daily 4 kg to 4.9 kg: 1.4 mg three times daily 5 kg to 6.9 kg: 1.6 mg three times daily 7 kg to 7.9 kg: 1.8 mg three times daily 8 kg to 8.9 kg: 2.4 mg three times daily 9 kg to 9.9 kg: 2.8 mg three times daily 10 kg to 11.9 kg: 3 mg three times daily 12 kg to 29.9 kg: 5 mg twice daily 30 kg to 49.9 kg: 15 mg once daily Greater than or equal to 50 kg: 20 mg once daily
	Thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease who have undergone the Fontan procedure	7 kg to 7.9 kg: 1.1 mg twice daily 8 kg to 9.9 kg: 1.6 mg twice daily 10 kg to 11.9 kg: 1.7 mg twice daily 12 kg to 19.9 kg: 2 mg twice daily 20 kg to 29.9 kg: 2.5 mg twice daily 30 kg to 49.9 kg: 7.5 mg once daily Greater than or equal to 50 kg: 10 mg once daily

REFERENCES

1. Pradaxa prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. November 2019.
2. Xarelto prescribing information. Janssen Pharmaceuticals, Inc. December 2021.
3. Eliquis prescribing information. Bristol-Myers Squibb Company. April 2021.
4. Savaysa prescribing information. Daiichi Sankyo Co., LTD. March 2021.
5. Bevyxxa prescribing information. Portola Pharmaceuticals, Inc. August 2020.

Oral Anticoagulant – Bevyxxa (betrixaban), Eliquis (apixaban), Pradaxa (dabigatran), Savaysa (edoxaban), Xarelto (rivaroxaban) Quantity Limit

TARGET AGENT(S)
Bevyxxa® (betrixaban)
Eliquis® (apixaban)
Pradaxa® (dabigatran)
Savaysa® (edoxaban)
Xarelto® (rivaroxaban)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Bevyxxa (betrixaban)			
40 mg capsule	83370018200120	M, N, O, or Y	43 capsules/42 days
80 mg capsule	83370018200140	M, N, O, or Y	43 capsules/42 days
Eliquis (apixaban)			
2.5 mg tablet	83370010000320	M, N, O, or Y	2 tablets
5 mg tablet	83370010000330	M, N, O, or Y	74 tablets/30 days for initiation 2 tablets/day for maintenance
Starter Pack	8337001000B720	M, N, O, or Y	1 pack/180 days
Pradaxa (dabigatran)			
75 mg capsule	83337030200120	M, N, O, or Y	2 capsules
110 mg capsule	83337030200130	M, N, O, or Y	71 capsules/90 days
150 mg capsule	83337030200140	M, N, O, or Y	2 capsules
Savaysa (edoxaban)			
15 mg tablet	83370030200315	M, N, O, or Y	1 tablet
30 mg tablet	83370030200330	M, N, O, or Y	1 tablet
60 mg tablet	83370030200350	M, N, O, or Y	1 tablet
Xarelto (rivaroxaban)			
Starter Pack	8337006000B720	M, N, O, or Y	51 tablets/30 days
2.5 mg tablets	83370060000310	M, N, O, or Y	2 tablets
10 mg tablets	83370060000320	M, N, O, or Y	1 tablet
15 mg tablets	83370060000330	M, N, O, or Y	2 tablets
20 mg tablets	83370060000340	M, N, O, or Y	1 tablet
1 mg/mL suspension	83370060001920	M, N, O, or Y	620 mL (4 bottles)/30 days)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Bevyxxa, Eliquis, and Savaysa
Quantities above the program quantity limit for **Bevyxxa**, **Eliquis, and Savaysa** will be approved when ONE of the following is met:

1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR**

2. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication

Pradaxa
Quantities above the program quantity limit for **Pradaxa** will be approved when ONE of the following is met:

1. The indicated use is prophylaxis of DVT and PE in patients who have undergone hip replacement surgery **AND** the prescriber has provided information in support of therapy with a higher quantity (duration) for the requested indication
   OR
2. The indicated use is to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation OR treatment of DVT and PE OR reduction in the risk of recurrence of DVT and PE **AND** BOTH of the following:
   a. The requested dosage form is NOT 110 mg
      AND
   b. ONE of the following:
      i. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
         OR
      ii. The requested quantity (dose) requested is greater than the maximum FDA labeled dose for the requested indication **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication

   OR
3. The indicated use is other than those listed above **AND** the prescriber has provided information in support of therapy with a higher quantity (dose) for the requested indication

Xarelto
Quantities above the program quantity limit for **Xarelto** will be approved when ONE of the following is met:

1. The indicated use is prophylaxis of DVT which may lead to PE in a patient undergoing hip or knee replacement surgery **AND** the prescriber has provided information in support of therapy with a higher quantity (duration) for the requested indication
   OR
2. The indicated use is reduction of risk of stroke and systemic embolism in a patient with nonvalvular atrial fibrillation OR treatment of DVT/PE **AND** ONE of the following:
   a. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      OR
   b. The requested quantity (dose) requested is greater than the maximum FDA labeled dose for the requested indication **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication

   OR
3. The indicated use is reduction in the risk of recurrence of DVT and/or PE in a patient at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months **AND** the prescriber has provided information in support of therapy with a higher quantity (dose) for the requested indication
   OR

4. The indicated use is reduction of risk of major cardiovascular events (CV death, MI, and stroke) in a patient with chronic CAD or PAD **AND** the prescriber has provided information in support of therapy with a higher quantity (dose) for the requested indication
   OR
5. The indicated use is prophylaxis of VTE and VTE-related death during hospitalization and post-hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding **AND** the prescriber has provided information in support of therapy with a higher quantity (dose) for the requested indication
   OR
6. The indicated use is other than those listed above **AND** the prescriber has provided information in support of therapy with a higher quantity (dose) for the requested indication

Length of Approval: 12 months or as requested by the prescriber, whichever is shorter