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

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
11-01-2024

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Eliquis® (apixaban) Tablet	Reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation Prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery Treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy		1
Pradaxa® (dabigatran)* Capsule	To reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5-10 days To reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated For the prophylaxis of DVT and PE in adult patients who have undergone hip replacement surgery For the treatment of venous thromboembolic events (VTE) in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days To reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have previously been treated	* generic available	2
Pradaxa® (dabigatran) Oral Pellets	For the treatment of venous thromboembolic events (VTE) in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days To reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated		5
Savaysa® (edoxaban) Capsule	To reduce the risk of stroke and systemic embolism (SE) in patients with nonvalvular atrial fibrillation (NVAF) For the treatment of deep vein thrombosis (DVT) and pulmonary		3

Agent(s)	FDA Indication(s)	Notes	Ref#
	embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant		
Xarelto® (rivaroxaban) Tablet Suspension	To reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation Treatment of deep vein thrombosis (DVT) Treatment of pulmonary embolism (PE) Reduction in the risk of recurrence of DVT or PE Prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients Reduction of risk of major cardiovascular events in patients with coronary artery disease (CAD) Reduction of risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD Treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years Thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure		4

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

REFERENCES

Number	Reference
1	Eliquis prescribing information. Cardinal Health 107, LLC. November 2021.
2	PRADAXA Capsule prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. November 2023.
3	Savaysa prescribing information. Daiichi Sankyo Co., LTD. October 2023.
4	Xarelto prescribing information. Janssen Pharmaceuticals, Inc. February 2023.
5	PRADAXA Oral Pellets prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. November 2023.

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Eliquis	Apixaban Tab 2.5 MG	2.5 MG	60	Tablets	30	DAYS			
Eliquis	Apixaban Tab 5 MG	5 MG	74	Tablets	30	DAYS		2 tablets/day for maintenance	
Eliquis starter pack	Apixaban Tab Starter Pack	5 MG	1	Pack	180	DAYS			
Pradaxa	dabigatran etexilate mesylate cap	110 MG ; 150 MG ; 75 MG	60	Capsules	30	DAYS			
Pradaxa	Dabigatran Etexilate Mesylate Cap 110 MG (Etexilate Base Eq)	110 MG	120	Capsules	30	DAYS			
Pradaxa	dabigatran etexilate mesylate pellet pack	20 MG	60	Packets	30	DAYS			
Pradaxa	dabigatran etexilate mesylate pellet pack	30 MG	120	Packets	30	DAYS			
Pradaxa	dabigatran etexilate mesylate pellet pack	40 MG	120	Packets	30	DAYS			
Pradaxa	dabigatran etexilate mesylate pellet pack	50 MG	120	Packets	30	DAYS			
Pradaxa	dabigatran etexilate mesylate pellet pack	110 MG	120	Packets	30	DAYS			
Pradaxa	dabigatran etexilate mesylate pellet pack	150 MG	60	Packets	30	DAYS			
Savaysa	edoxaban tosylate tab	15 MG ; 30 MG ; 60 MG	30	Tablets	30	DAYS			
Xarelto	Rivaroxaban For Susp	1 MG/ML	4	Bottles	30	DAYS			
Xarelto	Rivaroxaban Tab 10 MG	10 MG	30	Tablets	30	DAYS			
Xarelto	Rivaroxaban Tab 15 MG	15 MG	60	Tablets	30	DAYS			
Xarelto	Rivaroxaban Tab 2.5 MG	2.5 MG	60	Tablets	30	DAYS			
Xarelto	Rivaroxaban Tab 20 MG	20 MG	30	Tablets	30	DAYS			
Xarelto starter pack	Rivaroxaban Tab Starter Therapy Pack 15 MG & 20 MG	15 & 20 MG	51	Tablets	30	DAYS			

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Eliquis	Apixaban Tab 2.5 MG	2.5 MG	HIM ; ResultsRx
Eliquis	Apixaban Tab 5 MG	5 MG	HIM ; ResultsRx
Eliquis starter pack	Apixaban Tab Starter Pack	5 MG	HIM ; ResultsRx
Pradaxa	dabigatran etexilate mesylate cap	110 MG ; 150 MG ; 75 MG	HIM ; ResultsRx
Pradaxa	Dabigatran Etexilate Mesylate Cap 110 MG (Etexilate Base Eq)	110 MG	HIM ; ResultsRx
Pradaxa	dabigatran etexilate mesylate pellet pack	40 MG	HIM ; ResultsRx
Pradaxa	dabigatran etexilate mesylate pellet pack	50 MG	HIM ; ResultsRx
Pradaxa	dabigatran etexilate mesylate pellet pack	20 MG	HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Pradaxa	dabigatran etexilate mesylate pellet pack	110 MG	HIM ; ResultsRx
Pradaxa	dabigatran etexilate mesylate pellet pack	30 MG	HIM ; ResultsRx
Pradaxa	dabigatran etexilate mesylate pellet pack	150 MG	HIM ; ResultsRx
Savaysa	edoxaban tosylate tab	15 MG ; 30 MG ; 60 MG	HIM ; ResultsRx
Xarelto	Rivaroxaban For Susp	1 MG/ML	HIM ; ResultsRx
Xarelto	Rivaroxaban Tab 10 MG	10 MG	HIM ; ResultsRx
Xarelto	Rivaroxaban Tab 15 MG	15 MG	HIM ; ResultsRx
Xarelto	Rivaroxaban Tab 2.5 MG	2.5 MG	HIM ; ResultsRx
Xarelto	Rivaroxaban Tab 20 MG	20 MG	HIM ; ResultsRx
Xarelto starter pack	Rivaroxaban Tab Starter Therapy Pack 15 MG & 20 MG	15 & 20 MG	HIM ; ResultsRx

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Eliquis and Savaysa	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: 12 months or as requested by the prescriber, whichever is shorter
Pradaxa	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The indicated use is prophylaxis of DVT and PE in an adult patient who has undergone hip replacement surgery **AND** the prescriber has provided information in support of therapy with a higher quantity (duration) for the requested indication **OR** 3. The indicated use is to reduce the risk of stroke and systemic embolism in an adult patient 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: 1. BOTH of the following: i. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** ii. There is support for why 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. BOTH of the following:

Module	Clinical Criteria for Approval
	i. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** ii. There is support for therapy with a higher dose for the requested indication **OR** 4. The indicated use is other than those listed above **AND** there is support for therapy with a higher quantity (dose) for the requested indication **Length of Approval**: 12 months or as requested by the prescriber, whichever is shorter
Xarelto	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. 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** 3. 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. BOTH of the following: i. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** ii. There is support for why 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. BOTH of the following: i. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** ii. There is support for therapy with a higher dose for the requested indication **OR** 4. The indicated use is other than those listed above **AND** there is support for therapy with a higher quantity (dose) for the requested indication **Length of Approval:** 12 months or as requested by the prescriber, whichever is shorter