



Oral Anticoagulant Quantity Limit Program Summary

This program applies to Medicaid.

POLICY REVIEW CYCLE

Effective Date
9/1/2023

Date of Origin
7/1/2012

FDA APPROVED 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 Reduce 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 embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant.		3
Xarelto® (rivaroxaban)	To reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation Treatment of deep vein thrombosis (DVT)		4

Agent(s)	FDA Indication(s)	Notes	Ref#
Tablet	Treatment of pulmonary embolism (PE)		
Suspension	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		

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

REFERENCES

Number	Reference
1	Eliquis prescribing information. Bristol-Myers Squibb Company. August 2021.
2	Pradaxa Capsule prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. June 2021.
3	Savaysa prescribing information. Daiichi Sankyo Co., LTD. March 2021.
4	Xarelto prescribing information. Janssen Pharmaceuticals, Inc. February 2023.
5	Pradaxa Oral Pellets prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. March 2022.

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
Eliquis	Apixaban Tab 5 MG	5 MG	74	Tablets	30	DAYS			
Eliquis ; Eliquis starter pack	apixaban tab ; apixaban tab starter pack	2.5 MG ; 5 MG	60	Tablets	30	DAYS			
Eliquis starter pack	Apixaban Tab Starter Pack	5 MG	1	Pack	180	DAYS			
Pradaxa	dabigatran etexilate mesylate cap ;	110 MG ; 150	60	Capsules	30	DAYS			

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
	dabigatran etexilate mesylate pellet pack	MG ; 20 MG ; 30 MG ; 40 MG ; 50 MG ; 75 MG							
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 5 MG	5 MG	Medicaid
Eliquis ; Eliquis starter pack	apixaban tab ; apixaban tab starter pack	2.5 MG ; 5 MG	Medicaid
Eliquis starter pack	Apixaban Tab Starter Pack	5 MG	Medicaid
Pradaxa	dabigatran etexilate mesylate cap ; dabigatran etexilate mesylate pellet pack	110 MG ; 150 MG ; 20 MG ; 30 MG ; 40 MG ; 50 MG ; 75 MG	Medicaid
Pradaxa	Dabigatran Etexilate Mesylate Cap 110 MG (Etexilate Base Eq)	110 MG	Medicaid
Pradaxa	dabigatran etexilate mesylate pellet pack	40 MG	Medicaid
Pradaxa	dabigatran etexilate mesylate pellet pack	50 MG	Medicaid
Pradaxa	dabigatran etexilate mesylate pellet pack	110 MG	Medicaid
Pradaxa	dabigatran etexilate mesylate pellet pack	20 MG	Medicaid
Pradaxa	dabigatran etexilate mesylate pellet pack	150 MG	Medicaid
Pradaxa	dabigatran etexilate mesylate pellet pack	30 MG	Medicaid
Savaysa	edoxaban tosylate tab	15 MG ; 30 MG ; 60 MG	Medicaid
Xarelto	Rivaroxaban For Susp	1 MG/ML	Medicaid

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xarelto	Rivaroxaban Tab 10 MG	10 MG	Medicaid
Xarelto	Rivaroxaban Tab 15 MG	15 MG	Medicaid
Xarelto	Rivaroxaban Tab 2.5 MG	2.5 MG	Medicaid
Xarelto	Rivaroxaban Tab 20 MG	20 MG	Medicaid
Xarelto starter pack	Rivaroxaban Tab Starter Therapy Pack 15 MG & 20 MG	15 & 20 MG	Medicaid

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Eliquis and Savaysa	<p>Quantities above the program quantity limit for Eliquis and Savaysa will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 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 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 <p>Length of Approval: 12 months or as requested by the prescriber, whichever is shorter</p>
Pradaxa	<p>Quantities above the program quantity limit for Pradaxa will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 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 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: <ol style="list-style-type: none"> The requested dosage form is NOT 110 mg AND ONE of the following: <ol style="list-style-type: none"> 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 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 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 <p>Length of Approval: 12 months or as requested by the prescriber, whichever is shorter</p>
Xarelto	<p>Quantities above the program quantity limit for Xarelto will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 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 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: <ol style="list-style-type: none"> The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND the requested quantity (dose) cannot

Module	Clinical Criteria for Approval
	<p>be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit OR</p> <p>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</p> <p>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</p> <p>Length of Approval: 12 months or as requested by the prescriber, whichever is shorter</p>