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Policy Number: C20784-A

## Direct Oral Anticoagulants

### PRODUCTS AFFECTED

Dabigatran, Eliquis (apixaban), Pradaxa (dabigatran), Savaysa (edoxaban), Xarelto (rivaroxaban)

### COVERAGE POLICY

*Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.*

#### **Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

#### **DIAGNOSIS:**

Non-valvular atrial fibrillation, Treatment of deep vein thrombosis (DVT), Treatment of pulmonary embolism (PE), Prophylaxis of DVT in patients undergoing knee or hip replacement surgery, Coronary artery disease (CAD) or peripheral artery disease (PAD), Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients, Reduce the risk of recurrence of DVT and PE, Anticoagulation in COVID-19 patients

#### **REQUIRED MEDICAL INFORMATION:**

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the

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medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

### A. FOR ALL INDICATIONS:

1. Prescriber attests to evaluating the members current prescription and OTC medication regimen for concurrent use of anticoagulant agents  
AND
2. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial and failure or absolute contraindication to a majority (not more than 3) of the preferred formulary/PDL Direct Factor Xa Inhibitor oral products OR Documentation of recent hospital discharge (within 48 hours) in which therapy was started as an inpatient and member has not yet had follow-up with physician.

MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

### B. NONVALVULAR ATRIAL FIBRILLATION:

1. Documentation of diagnosis with non-valvular atrial fibrillation or flutter of < 48 hours duration  
AND
2. Prescriber attests that member has intermediate to high risk for stroke based on the prescriber utilizing a validated scoring tool to assess member's stroke risk (see Appendix)  
AND
3. Documentation the member does NOT have moderate to severe mitral stenosis, mechanical prosthetic valves or bioprosthetic valves. If member DOES have moderate to severe mitral stenosis, mechanical prosthetic valves or bioprosthetic valves, warfarin MUST be used as the anticoagulant.

### C. TREATMENT OF DVT AND/OR PE:

1. Documentation of diagnosis of a DVT or PE

### D. PROPHYLAXIS OF THROMBOSIS:

1. (a) Documentation member has or is scheduled to have total knee replacement surgery  
OR  
(b) Documentation member has or is scheduled to have total hip replacement surgery  
OR  
(c) Documentation member is at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months  
OR  
(d) Documentation member has congenital heart disease and has had a Fontan procedure

### E. CANCER-ASSOCIATED VENOUS THROMBOEMBOLISM:

1. Prescriber attests that member has an acute symptomatic or incidentally detected superficial vein thrombosis, deep vein thrombosis, pulmonary embolism, or splanchnic vein thrombosis  
AND
2. Documentation member has cancer other than basal-cell or squamous cell skin cancer that is active or had been diagnosed within the previous 2 years

### F. THROMBOPROPHYLAXIS IN COVID-19 POSITIVE MEMBER (8,9) (XARELTO ONLY):

1. Documentation member had tested positive for COVID-19 infection and was recently discharged from an inpatient hospital stay or member is receiving acute medical therapy in an outpatient setting  
AND

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2. Prescriber provides documentation with medical record that member has a Modified International Medical Prevention Registry on Venous Thromboembolism (IMPROVE) VTE risk score  $\geq 4$  and is considered at high-risk for VTE (See appendix)  
AND
3. Therapy requested is rivaroxaban 10 mg once daily for 31-39 days  
*NOTE: For non-hospitalized members with COVID-19, anticoagulants and antiplatelet therapy should not be initiated for the prevention of VTE or arterial thrombosis unless the member has other indications for the therapy or is participating in a clinical trial. After hospital discharge, VTE prophylaxis is not recommended for members with COVID-19. For certain high-VTE risk members without COVID-19, post-discharge prophylaxis has been shown to be beneficial. NIH Antithrombotic Therapy in Patients with COVID-19 Last Updated: October 10, 2023-<https://www.covid19treatmentguidelines.nih.gov/adjunctive-therapy/antithrombotic-therapy/>*

## G. REDUCTION OF RISK IN MAJOR CARDIOVASCULAR EVENTS:

1. (a) Documentation of a diagnosis of chronic (>6 months) coronary artery disease AND member is < 65 years of age with documented atherosclerosis or revascularization involving at least 2 vascular beds or at least 2 additional risk factors: 1) Current smoker (within 1 year of request), 2) Diabetes mellitus, 3) Renal dysfunction with estimated glomerular filtration rate <60 ml/min, 4) Heart failure or 5) Non-lacunar ischemic stroke  $\geq 1$  month ago  
OR  
(b) Documentation of a diagnosis of chronic (>6 months) coronary artery disease AND member is  $\geq 65$  years of age  
OR  
(c) Documentation of a diagnosis of chronic (>6 months) peripheral artery disease  
AND
2. Documentation member will concurrently be utilizing aspirin  
AND
3. Member does NOT have any of the following: Need for dual antiplatelet therapy, other non-aspirin antiplatelet therapy or oral anticoagulant therapy, Stroke within 1 month or any history of hemorrhagic or lacunar stroke, Severe heart failure with known ejection fraction <30% or New York Heart Association (NYHA) class III or IV symptoms or Estimated glomerular filtration rate (eGFR) < 15 mL/min

## CONTINUATION OF THERAPY:

### A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation  
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity  
AND
3. Documentation showing continued medical necessity for indication and/or medical history.  
AND
4. Dosing is appropriate for listed diagnosis, age, weight, and renal function as applicable

## DURATION OF APPROVAL:

Initial authorization:

Prophylactic use DVT and/or PE knee: 12 days

Prophylactic use DVT and/or PE hip replacement: 35 days

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Prophylactic use DVT and/or PE after treatment for acute DVT and/or PE: 6 months  
Deep vein thrombosis, pulmonary embolism treatment: 6 months  
Atrial fibrillation, Stroke prophylaxis: 12 months  
Cancer-Associated venous thromboembolism: 6 months  
Risk Reduction in CV events: 12 months  
Thromboprophylaxis in COVID-19 positive member (Xarelto only): total treatment duration up to 39 days

### Continuation of Therapy (for the following indications ONLY):

Prophylactic use DVT and/or PE after treatment for acute DVT and/or PE, Deep vein thrombosis, pulmonary embolism treatment: 12 months  
Atrial fibrillation, stroke prophylaxis: 12 months  
Cancer-Associated venous thromboembolism: 12 months  
Risk Reduction in CV events: 12 months

\*\*\*\*Duration of therapeutic anticoagulation (first episode, general recommendations): Optimal duration of therapy is unknown and is dependent on many factors, such as whether provoking events were present, member risk factors for recurrence and bleeding, and individual preferences: Provoked venous thromboembolism: 3 months (provided the provoking risk factor is no longer present) <sup>11</sup> Unprovoked pulmonary embolism or deep vein thrombosis (proximal or isolated distal): ≥3 months depending on risk of venous thromboembolism (VTE) recurrence and bleeding. <sup>11, 12, 13</sup>

### **PRESCRIBER REQUIREMENTS:**

No requirements

### **AGE RESTRICTIONS:**

Xarelto and Eliquis ONLY- TREATMENT OF AND REDUCTION IN RISK OF RECURRENT VTE: no limit

Xarelto ONLY - THROMBOPROPHYLAXIS WITH CONGENITAL HEART DISEASE: 2 years of age and older

PRADAXA ONLY - Treatment of VTE: 8 years of age and older; Reduction in the Risk of Recurrence of VTE: 8 years of age and older

ALL OTHER INDICATIONS: 18 years of age and older

### **QUANTITY:**

Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

### **PLACE OF ADMINISTRATION:**

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

## **DRUG INFORMATION**

### **ROUTE OF ADMINISTRATION:**

Oral

### **DRUG CLASS:**

Direct Factor Xa Inhibitors, Thrombin Inhibitors - Selective Direct & Reversible

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### **FDA-APPROVED USES:**

ELIQUIS (apixaban) is indicated:

- to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation.
- for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in adult patients who have undergone hip or knee replacement surgery
- for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE in adult patients following initial therapy.
- treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least 5 days of initial anticoagulant treatment

PRADAXA (dabigatran etexilate) is indicated:

- 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 been previously treated

SAVAYSA (edoxaban) is indicated:

- 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

*Limitation of Use for NVAf: Savaysa should not be used in patients with creatinine clearance (CrCL) > 95 mL/min because of increased risk of ischemic stroke compared to warfarin at the highest dose studied (60 mg)*

XARELTO (rivaroxaban) is indicated:

- to reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation
- for treatment of deep vein thrombosis (DVT)
- for treatment of pulmonary embolism (PE)
- for reduction in the risk of recurrence of DVT or PE
- for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
- for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients
- to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD)
- to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD
- for treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years
- for thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure

### **COMPENDIAL APPROVED OFF-LABELED USES:**

Cancer-induced VTE, VTE prophylaxis in COVID-19 patients

## APPENDIX

### APPENDIX:

**Reserved for State specific information.** Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

### State Specific Information

#### State Marketplace

**Illinois** (Source: [Illinois General Assembly](#))

“(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan.”

### Appendix 1:

Stroke risk scores for patients with atrial fibrillation (Joglar et al., 2023)

ATRIA indicates Anticoagulation and Risk Factors in Atrial Fibrillation: anemia, renal disease, elderly (age  $\geq 75$ y), any previous bleeding, hypertension

CHA<sub>2</sub>DS<sub>2</sub>-VASc, indicates congestive heart failure, hypertension, age  $\geq 75$  y (doubled), diabetes mellitus, prior stroke or transient ischemic attack or thromboembolism (doubled), vascular disease, age 65 to 74 y, sex category

GARFIELD-AF, Global Anticoagulant Registry in the Field-Atrial Fibrillation; and TIA, transient ischemic attack.

Table 8. Three Validated Risk Models for Stroke

Risk Factor	CHA <sub>2</sub> DS <sub>2</sub> -VASc	ATRIA	GARFIELD
Age $\geq 85$ y		6	0.98
Age $\geq 75$ y	2	5	0.59
Age 65-74 y	1	3	0.20
Female sex	1	1	
Hypertension	1	1	0.16
Renal disease		1	0.35
Risk Factor	CHA <sub>2</sub> DS <sub>2</sub> -VASc	ATRIA	GARFIELD
Diabetes	1	1	0.21
Current smoking			0.48

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Congestive heart failure	1	1	0.23
Previous stroke or TIA	2	2–8	0.80
Vascular disease	1		0.20
Dementia			0.51
Previous bleeding			0.30
Proteinuria		1	
<b>Low risk score</b>	<b>0</b>	<b>0–5</b>	<b>0–0.89</b>
<b>Intermediate risk score</b>	<b>1</b>	<b>6</b>	<b>0.90–1.59</b>
<b>High risk score</b>	<b>≥2</b>	<b>7–15</b>	<b>≥1.60</b>

### Appendix 2:

#### Modified IMPROVE VTE risk score

VTE risk factor	VTE risk score
Previous VTE	3
Known thrombophilia <sup>a</sup>	2
Current lower limb paralysis or paresis <sup>b</sup>	2
History of cancer <sup>c</sup>	2
ICU/CCU stay	1
Complete immobilization <sup>d</sup> ≥ 1 d	1
Age ≥60 y	1

Abbreviations: CCU, cardiac care unit; ICU, intensive care unit; IMPROVE, International Medical Prevention Registry on Venous Thromboembolism; NIH, National Institutes of Health; VTE, venous thromboembolism. <sup>a</sup>A congenital or acquired condition leading to excess risk of thrombosis (e.g., factor V Leiden, lupus anticoagulant, factor C or factor S deficiency). <sup>b</sup>Leg falls to bed by 5 seconds but has some effort against gravity (taken from NIH stroke scale). <sup>c</sup>Cancer (excluding nonmelanoma skin cancer) present at any time in the past 5 years (cancer must be in remission to meet eligibility criteria). <sup>d</sup>Immobilization is being confined to bed or chair with or without bathroom privileges.

### Appendix 3:

NCCN Guidelines Version 03.2025 Cancer Associated Venous Thromboembolic Disease VTE-D 1 OF 7, VTE-D 2 OF 7

## BACKGROUND AND OTHER CONSIDERATIONS

### BACKGROUND:

None

### CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Direct Oral Anticoagulants are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

Contraindications to Eliquis (apixaban) include: active pathological bleeding and severe hypersensitivity reaction to Eliquis (apixaban). For patients receiving Eliquis at a dose of 2.5 mg twice daily, avoid coadministration with combined P-gp and strong CYP3A4 inhibitors. Avoid concomitant use of Eliquis with combined P-gp and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) because such drugs will decrease exposure to apixaban. Contraindications to Savaysa (edoxaban) include: active pathological bleeding. Avoid co-administration of anticoagulants, antiplatelet drugs, thrombolytics and SSRIs or SNRIs due to the increased risk of bleeding. Avoid the concomitant use of Savaysa with rifampin.

Contraindications to Xarelto (rivaroxaban) include: active pathological bleeding and severe hypersensitivity reaction to rivaroxaban. Avoid concomitant administration of XARELTO with known combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole and ritonavir). Avoid concomitant use of XARELTO with drugs that are combined P-gp and strong CYP3A inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's wort). Avoid concurrent use of Xarelto with other anticoagulants due to increased bleeding risk unless benefit outweighs risk. Avoid the use of Xarelto in patients with CrCl <15 mL/min. Avoid the use of Xarelto in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy.

Contraindications to Pradaxa (dabigatran) include: active pathological bleeding, severe hypersensitivity reaction to dabigatran, and mechanical prosthetic heart valve. The concomitant use of Pradaxa with P-gp inducers (e.g., rifampin) reduces exposure to dabigatran and should generally be avoided. Avoid use of Pradaxa Capsules and P-gp inhibitors in patients with severe renal impairment (CrCl 15-30 mL/min).

Review renal dose adjustment recommendations per label for the requested agent for member's with CrCl > 95 ml/min (Savaysa), ≤ 50 ml/min (Xarelto, Pradaxa) or SCr > 1.5mg/dL (Eliquis).

### Exclusions/Discontinuation:

Use direct oral anticoagulants (DOACs) with caution in pregnant patients because of the potential for pregnancy related hemorrhage and/or emergent delivery. In pregnant women, DOACs should be used only if the potential benefit justifies the potential risk to the mother and fetus. The anticoagulant effect of DOACs cannot be monitored with standard laboratory testing. Promptly evaluate any signs or symptoms suggesting blood loss (e.g., a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).

Because of the unknown exposure risk and potential for serious adverse reactions in nursing infants, including hemorrhage, advise patients that breastfeeding is not recommended during treatment with DOACs.

### OTHER SPECIAL CONSIDERATIONS:

Eliquis (apixaban) has a Black Box Warning for premature discontinuation of Eliquis increases the risk of thrombotic events, and spinal/epidural hematoma.

Pradaxa (dabigatran) has a Black Box Warning for premature discontinuation of Pradaxa increases the

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risk of thrombotic events, and spinal/epidural hematoma.

Savaysa (edoxaban) has a Black Box Warning for reduced efficacy in nonvalvular atrial fibrillation patients with creatinine clearance (CrCl) > 95 ml/min, premature discontinuation of Savaysa increases the risk of ischemic events and spinal/epidural hematoma.

Xarelto (rivaroxaban) has a Black Box Warning for premature discontinuation of Xarelto increases the risk of thrombotic events, and spinal/epidural hematoma.

### CODING/BILLING INFORMATION

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPSC CODE	DESCRIPTION
NA	

### AVAILABLE DOSAGE FORMS:

Dabigatran Etextilate Mesylate CAPS 75MG, 110MG, 150MG  
Eliquis DVT/PE Starter Pack TBPK 5MG  
Eliquis TABS 2.5MG, 5MG  
Eliquis CPSP 0.15MG  
Eliquis TBSO 0.5MG  
Eliquis (1.5 MG Pack) TBSO 3 x 0.5MG  
Eliquis (2 MG Pack) TBSO 4 x 0.5MG  
Pradaxa CAPS 75MG, 110MG, 150MG  
Pradaxa PACK 20MG, 30MG, 40MG, 40MG, 50MG, 110MG, 150MG  
Savaysa TABS 15MG, 30MG, 60MG  
Xarelto Starter Pack TBPK 15 & 20MG  
Xarelto SUSR 1MG/ML  
Xarelto TABS 2.5MG, 10MG, 15MG, 20MG

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q1 2026
REVISION- Notable revisions: Required Medical Information Drug Class Appendix Available Dosage Forms References	Q1 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Appendix Other Special Considerations Available Dosage Forms References	Q1 2024

## Drug and Biologic Coverage Criteria

REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Age Restrictions FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Available Dosage Forms	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file