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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 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.

#### **FOR ALL INDICATIONS:**

1. Prescriber attests that member is not currently pregnant and does not plan on becoming

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pregnant

AND

2. Prescriber attests to evaluating the members current prescription and OTC medication regimen for concurrent use of anticoagulant agents  
AND
3. 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.

### A. 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 moderate to high risk for stroke based on the prescriber utilizing the member's CHA2DS2-VASc score used to assess member's stroke risk.  
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

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

1. Documentation of diagnosis of a DVT or PE

### C. 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

### D. 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

### E. THROMBOPROPHYLAXIS IN COVID-19 POSITIVE MEMBER (8,9):

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
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 10mg 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*

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*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/>*

### F. 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 ≥ 1 month ago  
OR  
(b) Documentation of a diagnosis of chronic (>6 months) coronary artery disease AND member is ≥ 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 100mg once daily  
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.

### DURATION OF APPROVAL:

Initial authorization:

Prophylactic use DVT and/or PE knee – 12 days

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

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: 3 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

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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 ONLY- TREATMENT OF AND REDUCTION IN RISK OF RECURRENT VTE: no limit, THROMBO PROPHYLAXIS WITH CONGENITAL HEART DISEASE: 2 years 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 Oral anticoagulants

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

ELIQUIS (apixaban) is indicated:

- to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
- for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in 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 following initial therapy.

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

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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 chronic 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:

#### 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

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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.

### NCCN Guidelines Version 02.2023 Cancer Associated Venous Thromboembolic Disease

#### THERAPEUTIC ANTICOAGULATION FOR VTE

##### General Guidelines

- Anticoagulation options recommended for management of VTE in patients with cancer include regimens involving only one agent (monotherapy) as well as regimens that use more than one type of agent (combination therapy). This section lists the recommended regimens, including dosing and duration, as well as a list of contraindications and warnings to help guide treatment selection.<sup>1</sup>
  - ▶ Duration of Anticoagulation as Recommended by Guideline:
    - ◊ At least 3 months or as long as active cancer or cancer therapy.
    - ◊ For non-catheter-associated DVT or PE recommend indefinite anticoagulation while cancer is active, under treatment, or if risk factors for recurrence persist.
    - ◊ For symptomatic catheter-associated DVT, consider anticoagulation treatment for at least 3 months or as long as the catheter is in place.
    - ◊ Providers should continue to discuss with patients the risks/benefits of anticoagulation to determine the appropriate duration of therapy. [Elements for Consideration in Decision Not to Treat \(VTE-J\)](#).
- Select regimen based on these factors (not in order of importance): Renal failure (CrCl <30 mL/min), hepatic disease (elevated transaminases or bilirubin, Child-Pugh B and C liver impairment, or cirrhosis), inpatient/outpatient status, U.S. FDA approval, cost, patient preference, ease of administration, monitoring, bleeding risk assessment, and ability to reverse anticoagulation. [Contraindications and Warnings on VTE-D, 3 of 6](#).
- Baseline laboratory testing: CBC with platelet count, renal and hepatic function panel, aPTT, and PT/international normalized ratio (INR).
- Follow institutional standard operating procedures (SOPs) for dosing schedules. If there are no SOPs, then use the American College of Chest Physicians (ACCP) recommendations.<sup>2</sup>
- Following initiation of anticoagulant: hemoglobin, hematocrit, and platelet count at least every 2 to 3 days for the first 14 days and every 2 weeks thereafter or as clinically indicated.
- DOACs, LMWH, and warfarin have all been used to treat patients with SPVT. Although published experience in the treatment of SPVT with DOACs is limited, results appear to be comparable to LMWH and warfarin. Therefore, we suggest that DOACs can be used for long-term treatment of SPVT in appropriate candidates in the recommended doses. In the absence of contraindications, NCCN suggests that DOACs, LMWH, and warfarin can be considered for treatment of SPVT. In patients with cancer, DOACs and LMWH are preferable to warfarin.

#### THERAPEUTIC ANTICOAGULATION FOR VTE (CONTINUED)

##### DOACs (preferred for patients without gastric or gastroesophageal lesions)<sup>a</sup>

- Apixaban (category 1)<sup>b</sup>
  - ▶ 10 mg PO every 12 hours for 7 days followed by 5 mg PO every 12 hours<sup>3-8</sup>
- Edoxaban (category 1)
  - ▶ Initial therapy with LMWH<sup>c,9,10</sup> or UFH<sup>d,11</sup> for at least 5 days followed by edoxaban 60 mg PO daily (or 30 mg PO daily in patients with Cockcroft-Gault estimated CrCl 30–50 mL/min or weight <60 kg or concomitant potent P-glycoprotein (P-gp) inhibitors)<sup>e,12,13,14</sup>
- Rivaroxaban
  - ▶ 15 mg PO every 12 hours for the first 21 days followed by 20 mg daily<sup>15-18</sup>

##### LMWH (preferred for patients with gastric or gastroesophageal lesions)

- Dalteparin (category 1)
  - ▶ 200 units/kg SC daily for 30 days, then switch to 150 units/kg once daily<sup>c,f,10,19,20</sup>
- Enoxaparin
  - ▶ 1 mg/kg SC every 12 hours (BMI <40 kg/m<sup>2</sup>) or 0.8 mg/kg SC every 12 hours (BMI ≥40 kg/m<sup>2</sup>) (can consider decreasing intensity to 1.5 mg/kg daily after first month)<sup>9,9,21,22-24</sup>

##### DOACs (if above regimens not appropriate or unavailable)<sup>a</sup>

- Dabigatran
  - ▶ Initial therapy with LMWH<sup>c,9,10</sup> or UFH<sup>d,11</sup> for at least 5 days followed by dabigatran 150 mg PO every 12 hours<sup>e,25,26</sup>

##### Fondaparinux<sup>27,28</sup>

- 5 mg SC daily (<50 kg)
  - 7.5 mg SC daily (50–100 kg)
  - 10 mg SC daily (>100 kg)
- ##### UFH (category 2B)<sup>11</sup>
- IV 80 units/kg bolus, followed by 18 units/kg/h adjusted to target aPTT of 2–2.5 X control or per hospital SOPs, followed by SC 250 units/kg every 12 hours (category 2B)
  - SC 333 units/kg load, followed by 250 units/kg every 12 hours<sup>29</sup>

##### Warfarin<sup>h,30-32</sup>

- Start warfarin concurrently with LMWH, fondaparinux, or UFH (see dosing below)
- Warfarin 5 mg daily adjusted to INR 2–3 (2.5 mg daily initial dose for liver disease or use with interacting medications)
  - ▶ LMWH<sup>9,10</sup> + warfarin<sup>h</sup> options:
    - ◊ Dalteparin 200 units/kg SC daily<sup>10</sup> or 100 units/kg SC every 12 hours
    - ◊ Enoxaparin 1 mg/kg SC every 12 hours<sup>9</sup>
  - ▶ Fondaparinux + warfarin<sup>h,27,28</sup>
    - ◊ 5 mg SC daily (<50 kg)
    - ◊ 7.5 mg SC daily (50–100 kg)
    - ◊ 10 mg SC daily (>100 kg)
  - ▶ UFH<sup>11</sup> + warfarin<sup>h</sup> options:
    - ◊ IV 80 units/kg bolus, followed by 18 units/kg/h adjusted to target aPTT of 2–2.5 X control or per hospital SOPs
    - ◊ SC 333 units/kg load, followed by 250 units/kg every 12 hours

## BACKGROUND AND OTHER CONSIDERATIONS

### 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).

Contraindications to Savaysa (edoxaban) include active pathological bleeding.

Contraindications to Xarelto (rivaroxaban) include active pathological bleeding and severe hypersensitivity reaction to rivaroxaban.

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Contraindications to Pradaxa (dabigatran) include active pathological bleeding and severe hypersensitivity reaction to dabigatran and mechanical prosthetic heart valve.

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).

### 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 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

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

HCPCS CODE	DESCRIPTION
NA	

### AVAILABLE DOSAGE FORMS:

Dabigatran Etexilate Mesylate CAPS 75MG, 150MG  
Eliquis DVT/PE Starter Pack TBPK 5MG  
Eliquis TABS 2.5MG, 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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## Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Appendix Other Special Considerations Available Dosage Forms References	Q1 2024
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