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<input type="checkbox"/> ACFC	<input type="checkbox"/> SFC	<input type="checkbox"/> Marketplace (MF)	<input checked="" type="checkbox"/> Aetna FI ACFC
<input checked="" type="checkbox"/> ACCF	<input checked="" type="checkbox"/> SCCF	<input type="checkbox"/> Aetna SG ACA (Aetna Health Exchanges)	<input type="checkbox"/> Aetna FI SOO
<input type="checkbox"/> BC	<input checked="" type="checkbox"/> VF	<input type="checkbox"/> Aetna IVL	
<input type="checkbox"/> BCC	<input type="checkbox"/> VFC		

## MEDICAL NECESSITY CRITERIA

DRUG CLASS	MEDICAL NECESSITY CRITERIA
BRAND NAME (generic)	PRADAXA (all dosage forms) (dabigatran)
<b>Status: CVS Caremark® Criteria</b> <b>Type: Medical Necessity Criteria</b>	

### POLICY

#### FDA-APPROVED INDICATIONS

##### **Pradaxa Capsules**

Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation in Adult Patients

Pradaxa Capsules is indicated to reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation.

Treatment of Deep Venous Thrombosis and Pulmonary Embolism in Adult Patients

Pradaxa Capsules is indicated for the treatment of deep venous thrombosis and pulmonary embolism in adult patients who have been treated with a parenteral anticoagulant for 5-10 days.

Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism in Adult Patients

Pradaxa Capsules is indicated to reduce the risk of recurrence of deep venous thrombosis and pulmonary embolism in adult patients who have been previously treated.

Prophylaxis of Deep Vein Thrombosis and Pulmonary Embolism in Adult Patients Following Hip Replacement Surgery

Pradaxa Capsules is indicated for the prophylaxis of deep vein thrombosis and pulmonary embolism in adult patients who have undergone hip replacement surgery.

Treatment of Venous Thromboembolic Events in Pediatric Patients

Pradaxa Capsules is indicated 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.

Reduction in the Risk of Recurrence of Venous Thromboembolic Events in Pediatric Patients

Pradaxa Capsules is indicated to reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated.

##### **Pradaxa Oral Pellets**

Treatment of Venous Thromboembolic Events in Pediatric Patients

Pradaxa Oral Pellets are indicated 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.

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### Reduction in the Risk of Recurrence of Venous Thromboembolic Events in Pediatric Patients

Pradaxa Oral Pellets are indicated 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.

### Compendial Uses

**Pradaxa Capsules** can be used for prophylaxis of postoperative deep vein thrombosis (DVT) and pulmonary embolism (PE) in adult patients undergoing total knee replacement surgery.<sup>3-6</sup>

## **COVERAGE CRITERIA**

### **Adult Deep Venous Thrombosis (DVT), Pulmonary Embolism (PE), Risk Reduction of Stroke and Systemic Embolism**

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient cannot be treated with a formulary drug (Available Formulary Alternatives: Eliquis or Xarelto)
- The patient meets ONE of the following:
  - The patient has experienced an intolerance to Eliquis AND Xarelto [ACTION REQUIRED: Documentation is required for approval.]
  - The patient has experienced an inadequate treatment response (i.e., failure to adequately resolve thrombus) to ONE of the following: Eliquis, Xarelto [ACTION REQUIRED: Documentation is required for approval.]
- The request is for Pradaxa capsules
- The requested drug is being prescribed for ANY of the following:
  - To reduce the risk of stroke and systemic embolism in an adult patient with non-valvular atrial fibrillation
  - The treatment of deep venous thrombosis (DVT) or pulmonary embolism (PE) in an adult patient who has been treated with a parenteral anticoagulant for 5-10 days
  - To reduce the risk of recurrence of DVT or PE in an adult patient who has been previously treated
  - The prophylaxis of DVT and PE in an adult patient following hip replacement surgery or total knee replacement surgery

### **Pediatric Venous Thromboembolic Events (VTE)**

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient cannot be treated with a formulary drug (Available Formulary Alternatives: Eliquis or Xarelto)
- The patient meets ONE of the following:
  - If the request is for Pradaxa capsules, the requested drug is being prescribed for a pediatric patient age 8 to less than 18 years of age
  - If the request is for Pradaxa oral pellets, the requested drug is being prescribed for a pediatric patient age 3 months to less than 12 years of age
- The requested drug is being prescribed for ANY of the following:
  - The treatment of venous thromboembolic events (VTE) in a pediatric patient who has been treated with a parenteral anticoagulant for at least 5 days
  - The reduction in the risk of recurrence of VTE in a pediatric patient who has been previously treated

## **DURATION OF APPROVAL (DOA)**

- 1519-A:
  - Prophylaxis of DVT/PE following hip replacement surgery/knee replacement surgery: DOA: 1 month
  - All other approved indications: DOA: 12 months

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## REFERENCES

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