

# Drug Policy

<b>Policy:</b>  <b>SD</b>	<b>Pradaxa (dabigatran capsules)</b>	<b>Annual Review Date:</b>  <b>03/20/2024</b>  <b>Last Revised Date:</b>  <b>03/20/2024</b>
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## OVERVIEW

Pradaxa is a direct thrombin inhibitor. It has the following indications: to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with a parenteral anticoagulant for 5 to 10 days; to reduce the risk of recurrence of DVT and PE in patients who have been previously treated; and for the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery. Dosing for prophylaxis of DVT and PE after hip replacement surgery is once daily (QD); the recommended dose is twice daily (BID) for all other indications.

## POLICY STATEMENT

This policy involves the use of Pradaxa. Prior authorization is recommended for pharmacy benefit coverage of Pradaxa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pradaxa capsules is recommended in those who meet the following criteria:

- 1. Atrial Fibrillation (or Atrial Flutter).** Approve for 1 year if the patient has tried Eliquis or Xarelto.
- 2. Deep Vein Thrombosis or Pulmonary Embolism, Treatment.** Approve for 1 year if the patient meets one of the following (A or B):
  - A)** The patient has tried Eliquis or Xarelto; OR
  - B)** The patient is currently receiving Pradaxa for this condition.
- 3. Deep Vein Thrombosis or Pulmonary Embolism, To Reduce the Risk of Recurrence.** Approve for 1 year if the patient has tried Eliquis or Xarelto.

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- 4. Deep Vein Thrombosis or Pulmonary Embolism, Prophylaxis Following Hip Replacement Surgery.** Approve for 60 days if the patient meets one of the following (A or B):
- A) The patient has tried Eliquis or Xarelto; OR
  - B) The patient is currently receiving Pradaxa for this condition.

## Other Uses with Supportive Evidence

- 5. Deep Vein Thrombosis in Patients Undergoing Knee Replacement Surgery, Prophylaxis.** Approve for 60 days if the patient meets one of the following (A or B):
- A) The patient has tried Eliquis or Xarelto; OR
  - B) The patient is currently receiving Pradaxa for this condition.
- 6. Treatment or Prevention of Other Thromboembolic-Related Conditions (e.g., superficial vein thrombosis, splanchnic vein thrombosis, hepatic vein thrombosis, prophylaxis of venous thromboembolism in high-risk patients,).** Approve for 6 months if the patient meets the following criteria:
- A) The patient meets one of the following for the condition (i or ii):
    - i. The patient has tried warfarin, fondaparinux, or a low molecular weight heparin (LMWH) product (e.g., enoxaparin, Fragmin® [dalteparin injection]); OR
    - ii. The patient has tried Eliquis or Xarelto; OR

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pradaxa oral pellets is recommended in those who meet the following criteria:

- 7. Pediatric Venous Thromboembolic Events (VTE).** Approve for 6 months in patients aged 3 months up to 12 years after at least 5 days of parenteral anticoagulant

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Pradaxa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## Documentation Requirements:

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The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

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11. RE-MOBILIZE Writing Committee, Ginsberg JS, Davidson BL, Comp PC, et al. Oral thrombin inhibitor dabigatran etexilate vs. North American Enoxaparin regimen for prevention of venous thromboembolism after knee arthroplasty surgery. *J Arthroplasty*. 2009;24(1):1-9.
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