MEDICAL MUTUAL®

Drug Policy

Policy:	Dabigatran Prior Authorization Policy	Annual Review Date:
SD	• dabigatran etexilate mesylate capsules - Boehringer Ingelheim, generic • Pradaxa® Oral Pellets (dabigatran etexilate oral pellets – Boehringer Ingelheim)	03/20/2025 Last Revised Date: 03/20/2025

OVERVIEW

Dabigatran capsules (Pradaxa, generic), a direct thrombin inhibitor, is indicated for the following uses:[1]

- **Non-valvular atrial fibrillation**, to reduce the risk of stroke and systemic embolism in adults.
- **Prophylaxis of deep vein thrombosis (DVT) and pulmonary embolism (PE)**, in adults who have undergone hip replacement surgery.
- **Treatment of DVT and PE** in adults who have been treated with a parenteral anticoagulant for 5 to 10 days, as well as **reduction in the risk of recurrence of DVT and PE** in patients who have been previously treated.
- **Treatment of venous thromboembolic events (VTE)**, in pediatric patients 8 to < 18 years of age who have been treated with a parenteral anticoagulant for ≥ 5 days, as well as **to reduce the risk of recurrence of VTE** in pediatric patients 8 to < 18 years of age who have been previously treated.

Pradaxa oral pellets, a direct thrombin inhibitor, is indicated for the following uses:[15]

- **VTE**, treatment in pediatric patients 3 months to < 12 years of age who have been treated with a parenteral anticoagulant for ≥ 5 days, as well as **to reduce the risk of recurrence of VTE** in pediatric patients 3 months to < 12 years of age who have been previously treated.

It is noted in the prescribing information for dabigatran capsules and Pradaxa oral pellets that not all dosage forms are approved for the same indications and age groups.[1,15] Due to differences in bioavailability, the individual products are not substitutable on a mg-per-mg basis. Dabigatran capsules are available in the following strengths: 75 mg, 110 mg, and 150 mg. Pradaxa oral pellets are available in the following strengths per packet: 20 mg, 30 mg, 40 mg, 50 mg, 110 mg, and 150 mg.

POLICY STATEMENT

This policy involves the use of dabigatran. Prior authorization is recommended for pharmacy benefit coverage of dabigatran. 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.

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RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of dabigatran capsules is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Atrial Fibrillation (or Atrial Flutter).** Approve for 1 year if the patient is ≥ 18 years of age.

2. **Deep Vein Thrombosis or Pulmonary Embolism, Treatment.** Approve for 1 year if the patient is ≥ 8 years of age.

3. **Deep Vein Thrombosis or Pulmonary Embolism, To Reduce the Risk of Recurrence.** Approve for 1 year if the patient is ≥ 8 years of age.

4. **Deep Vein Thrombosis or Pulmonary Embolism in a Patient Undergoing Hip Replacement Surgery, Prophylaxis.** Approve for 60 days if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

5. **Deep Vein Thrombosis in a Patient Undergoing Knee Replacement Surgery, Prophylaxis.** Approve for 60 days if the patient is ≥ 18 years of age.

6. **Treatment or Prevention of Other Thromboembolic-Related Conditions.** Approve for 6 months if the patient meets BOTH of the following (A and B):
   Note: Examples of other thromboembolic-related conditions include superficial vein thrombosis, splanchnic vein thrombosis, hepatic vein thrombosis, or prophylaxis of venous thromboembolism in a high-risk patient.
   A) Patient is ≥ 8 years of age; AND
   B) Patient meets ONE of the following (i or ii):
      i. Patient has tried warfarin, fondaparinux, or a low molecular weight heparin product (e.g., enoxaparin, Fragmin [dalteparin injection]); OR
      Note: A patient who has tried Eliquis (apixaban tablets), Xarelto (rivaroxaban tablets), or Savaysa (edoxaban tablets) is not required to try warfarin, fondaparinux, or a low molecular weight heparin product.
      ii. Patient has been started on dabigatran capsules for the treatment of an acute thromboembolic condition.

II. Coverage of Pradaxa oral pellets is recommended in those who have had a trial of Eliquis or Xarelto OR the patient is currently receiving the Pradaxa oral pellets AND meet one of the following criteria:

FDA-Approved Indications

1. **Venous Thromboembolic Events, Treatment.** Approve for 1 year if the patient is ≥ 3 months to < 12 years of age.
   Note: Examples of venous thromboembolic events include deep vein thrombosis, cerebral venous thrombosis or sinus thrombosis, pulmonary embolism, and central-venous thrombosis.

2. **Venous Thromboembolic Events, To Reduce the Risk of Recurrence.** Approve for 1 year if the patient is ≥ 3 months to < 12 years of age.
   Note: Examples of venous thromboembolic events include deep vein thrombosis, cerebral venous thrombosis or sinus thrombosis, pulmonary embolism, and central-venous thrombosis.

Other Uses with Supportive Evidence

3. **Treatment or Prevention of Other Thromboembolic-Related Conditions.** Approve for 6 months if the patient meets BOTH of the following (A and B):
   Note: Examples of other thromboembolic-related conditions include superficial vein thrombosis, splanchnic vein thrombosis, hepatic vein thrombosis, or prophylaxis of venous thromboembolism in a high-risk patient.
   A) Patient is ≥ 3 months to < 12 years of age; AND
   B) Patient meets ONE of the following (i or ii):
      i. Patient has tried warfarin, fondaparinux, or a low molecular weight heparin product (e.g., enoxaparin, Fragmin [dalteparin injection]); OR
      Note: A patient who has tried Eliquis (apixaban tablets), Xarelto (rivaroxaban tablets and oral suspension), or Savaysa (edoxaban tablets) is not required to try warfarin, fondaparinux, or a low molecular weight heparin product.
      ii. Patient has been started on Pradaxa oral pellets for the treatment of an acute thromboembolic condition.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of dabigatran capsules and Pradaxa oral pellets is not recommended in the following situations:

1. **Venous Thromboembolism in an Acutely Ill Medical Patient, Prophylaxis.** (Note: This includes post-discharge thromboprophylaxis for a patient hospitalized with coronavirus disease 2019 [COVID-19]). Xarelto is labeled for prophylaxis of venous thromboembolism in acutely ill medical patients and is supported in clinical practice guidelines, including guidelines which address prophylaxis of venous thromboembolism in COVID-19 patients.[8-11]

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:
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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