MEDICAL MUTUAL®

Drug Policy

Policy: SD	Pradaxa (dabigatran capsules)	Annual Review Date: 03/16/2023 Last Revised Date: 05/18/2023

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.

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 ONE of the following criteria (A or B):
   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 1 year 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:

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

1. Pradaxa® capsules [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; March 2018.
2. Guyatt GH, Akl EA, Crowther M, et al, for the American College of Chest Physicians Antithrombotic Therapy and Prevention of Thrombosis Panel. Executive summary: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. 2012;141:7S-47S.
3. Kearon C, Akl EA, Ornelas J, et al. Antithrombotic therapy for VTE disease: CHEST Guideline and Expert Panel Report. *Chest*. 2016;149(2):315-352.
4. The NCCN Cancer-Associated Venous Thromboembolic Disease Clinical Practice Guidelines in Oncology (Version 1.2020—April 16, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on November 2, 2020.
5. Lip G, Banerjee A, Boriani G, et al. Antithrombotic therapy for atrial fibrillation: CHEST guideline and expert panel report. *Chest*. 2018;154(5):1121-1201.
6. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2019;74(1):104-132.
7. Moores LK, Tritschler T, Brosnahan S, et al. Prevention, diagnosis, and treatment of VTE in patients with Coronavirus Disease 2019: CHEST Guideline and Expert Panel Report. *Chest*. 2020 Sep;158(3):1143-1163.
8. Spyropoulos AC, Levy JH, Ageno W, et al. Scientific and Standardization Committee communication: Clinical guidance on the diagnosis, prevention, and treatment of venous thromboembolism in hospitalized patients with COVID-19. *J Thromb Haemost*. 2020; 18: 1859– 1865.
9. Barnes GD, Burnett A, Allen A, et al. Thromboembolism and anticoagulant therapy during the COVID-19 pandemic: interim clinical guidance from the anticoagulation forum. *J Thromb Thrombolysis*. 2020 Jul;50(1):72-81.
10. Eriksson BI, Dahl OE, Rosencher N, et al, for the RE-MODEL Study Group. Oral dabigatran etexilate vs. subcutaneous enoxaparin for the prevention of venous thromboembolism after total knee replacement: the RE-MODEL randomized trial. *J Thromb Haemost*. 2007;5:2178-2185.
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.
12. Burness CD, McKeage K. Dabigatran Etexilate. A review of its use for the prevention of venous thromboembolism after total hip or knee replacement surgery. *Drugs*. 2012;72(7):963-986.