Clinical Policy: Dabigatran (Pradaxa)

Reference Number: PA.CP.PMN.49
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
Dabigatran (Pradaxa®) is a direct thrombin inhibitor.

FDA approved indication
Pradaxa is indicated:

- To reduce the risk of stroke and systemic embolism in patients with non-valvular 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 5-10 days
- To reduce the risk of recurrence of DVT and PE in patients who have been previously treated
- For the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Pradaxa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Valvular Atrial Fibrillation, Deep Venous Thrombosis, Pulmonary Embolism (must meet all)**:**

1. Member is being treated for one of the following conditions (a, b, or c):
   a. Reduce the risk of stroke and systemic embolism in member with non-valvular atrial fibrillation;
   b. Treatment and risk reduction of DVT or PE;
   c. Prophylaxis of DVT or PE in those who have undergone hip replacement surgery; and
2. Failure of a ≥ 30 day trial of warfarin (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced; OR
3. Failure of a trial of Eliquis and Xarelto (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced; and
4. Dose does not exceed 300 mg/day (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Non-Valvular Atrial Fibrillation, Deep Venous Thrombosis, Pulmonary Embolism (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy PA.LTSS.PHAR.01 applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg/day (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or Continuity of Care policy PA.LTSS.PHAR.01 applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CrCl: creatinine clearance
DVT: deep venous thrombosis
INR: international normalized ratio
PE: pulmonary embolism

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Non-valvular atrial fibrillation	For patients with CrCl >30 mL/min: 150 mg orally, twice daily For patients with CrCl 15-30 mL/min: 75 mg orally, twice daily	300 mg/day
Treatment of DVT and PE	For patients with CrCl >30 mL/min: 150 mg orally, twice daily after 5-10 days of parenteral anticoagulation	300 mg/day
Reduction in the risk of recurrence of DVT and PE	For patients with CrCl >30 mL/min: 150 mg orally, twice daily after	300 mg/day

	previous treatment	
Prophylaxis of DVT and PE following hip replacement surgery	For patients with CrCl >30 mL/min: 110 mg orally first day, then 220 mg once daily	300 mg/day

VI. Product Availability

Capsules: 75 mg, 110 mg, and 150 mg

VII. References

1. Pradaxa Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; November 2015. Available at: https://www.pradaxa.com/. Accessed February 7, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 8, 2018.
3. Falck-Ytter Y, Francis CW, Johanson NA et al. Prevention of VTE in orthopedic surgery patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012 Feb;141(2 Suppl):e278S-325S. doi: 10.1378/chest.11-2404.
4. Kearon C, Akl EA, Comerota AJ et al. Antithrombotic therapy for VTE disease: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012 Feb;141(2 Suppl):e419S-94S. doi: 10.1378/chest.11-2301.
5. Wann LS, Curtis AB, Ellenbogen KA et al. 2011 ACCF/AHA/HRS focused update on the management of patients with atrial fibrillation (update on dabigatran): a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. J Am Coll Cardiol. 2011 Mar 15;57(11):1330-7. doi: 10.1016/j.jacc.2011.01.010. Epub 2011 Feb 14.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: listed out preferred agents Eliquis and Xarelto; changed optional trial of preferred Xa inhibitor or warfarin to trial of both; references reviewed and updated.	02.07.18	