Clinical Policy: Dabigatran (Pradaxa)
Reference Number: CP.PMN.49
Effective Date: 05/12
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® that Pradaxa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-~~v~~Valvular ~~a~~Atrial ~~f~~Fibrillation, Deep V~~v~~enous ~~t~~Thrombosis, Pulmonary ~~e~~Embolism (must meet all)**:**

~~1. Age ≥ 18 years;~~

~~2.~~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;

2. Member meets one of the following (a or b):

~~3.~~ Failure of a ≥ 30 day trial of a ~~of maximally tolerated dose of~~ preferred factor Xa inhibitor OR warfarin ~~for ≥ 30 days~~at up to maximally indicated doses~~,~~ unless ~~member experiences clinically significant adverse effects or has contraindication(s)~~ contraindicated or clinically significant adverse effects are experienced;

a. ~~, **OR**~~

~~4.~~b. Member cannot achieve therapeutic INR despite adequate titration and adherent use of warfarin, unless contraindicated;~~.~~

~~5.~~3. Dose does not exceed 300 mg/day (2 tablets/day).

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Approval duration: 12 months

B. Other diagnoses/indications
1. Refer to 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-~~v~~Valvular Aatrial Ffibrillation, Deep ~~v~~Venous ~~t~~Thrombosis, Pulmonary ~~e~~Embolism (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
~~1.~~2.Documentation of positive response to therapy;
~~2.~~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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to 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 – CP.PMN.53 or evidence of coverage documents~~;~~

~~**B.** [Indications/diagnoses/situations in which drug is unsafe/ineffective]~~

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 ~~A~~atrial ~~F~~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

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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 ~~R~~risk of ~~R~~recurrence of DVT and PE~~:~~	For patients with CrCl >30 mL/min: 150 mg orally, twice daily after previous treatment	300 mg~~-~~/day
Prophylaxis of DVT and PE f~~F~~ollowing ~~H~~hip ~~R~~replacement ~~S~~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. Workflow Document

Pradaxa WF.docx

Field Code Changed

VIII. References

1. Pradaxa® P~~p~~rescribing I~~i~~nformation. ~~-~~Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; November 2015. Available at: https://www.pradaxa.com/. Accessed ~~February 8, 2016.~~ January 2017.
2. Pradaxa® Drug Monograph. Clinical Pharmacology. Accessed ~~February 2016~~January 2017. http://www.clinicalpharmacology-ip.com/
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.
~~2.~~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.
~~3. Pradaxa® Drug Monograph. UpToDate. Accessed February 2016. http://www.uptodate.com/~~

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4. Manning WJ, Singer DE. Atrial fibrillation: anticoagulant therapy to prevent embolization. Zimetaum PJ, Kasner SE (Ed), UpToDate. Waltham MA. Accessed February 2016.
5. Lip GYH, Hull RD. Overview of the treatment of lower extremity deep vein thrombosis (DVT). Leung LLK, Mandel J (Ed), UpToDate. Waltham MA. Accessed February 2016.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
References updated to reflect current literature search.	05/13	05/13
Black box warning added to "Special Instructions" section. Updated references.	05/14	05/14
Updated FDA approved indications, updated criteria to include the additional indication and trail/fail of preferred factor Xa inhibitor.	05/15	05/15
Converted to new template; Added newly approved indication of prophylaxis of DVT or PE in those who have undergone hip replacement surgery; Updated references.	02/16	05/16
~~Clinical changes made to criteria:~~ - Converted to new template - Removed age criteria as age is not an absolute contraindication per FDA labeling - Updated references	03~~1~~/17	05/17

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of

insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.