UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Pradaxa

Program	Prior Authorization
Medication	Pradaxa (dabigatran etexilate)
Markets in Scope	Colorado, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Ohio, Pennsylvania- CHIP, Rhode Island, California, South Carolina
Issue Date	3/2011
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Indications

Stroke prevention in patients with non-valvular atrial fibrillation (AF): Indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE): Indicated for the treatment of DVT and PE in patients who have been treated with a parenteral anticoagulant for 5-10 days.

Reduction in the Risk of Recurrence of DVT or PE: Indicated to reduce the risk of recurrence of DVT and PE in patients who have been previously treated.

Prophylaxis of DVT or PE after orthopedic surgery: Indicated for the prophylaxis of DVT and PE, in patients who have undergone hip replacement surgery.

Off Label Uses

Prophylaxis of venous thromboembolism (VTE) after orthopedic surgery: Has been used for the prevention of acute venous thromboembolism (VTE) after total knee replacement

Pradaxa contains a black boxed warning for spinal/epidural hematoma and premature discontinuation of Pradaxa increasing the risk of thrombotic events. Please see full prescribing information for additional details.

2. Coverage Criteria:

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A. Continuation of Therapy Upon Hospital Discharge

1. Initial Authorization

a. Pradaxa will be approved as continuation of therapy upon hospital discharge

Authorization will be issued for 35 days.

B. Stroke and Systemic Embolism Prevention in Patients with Non-Valvular Atrial Fibrillation (AF)

1. Initial Authorization

a. Diagnosis of atrial fibrillation (AF)

-AND-

b. Patient does not have an artificial heart valve

-AND-

c. **One** of the following:

(1) History of failure, contraindication, or intolerance to **both** of the following:

- Eliquis
- Savaysa

-OR-

(2) Continuation of prior Pradaxa therapy

Authorization will be issued for 12 months.

C. Prophylaxis of venous thromboembolism (VTE) and pulmonary embolism (PE) after orthopedic surgery (hip replacement: labeled; knee replacement: off-label)

1. Initial Authorization

a. **One** of the following:

- Patient has or is scheduled to have total knee replacement surgery

- Patient has or is scheduled to have total hip replacement surgery

-AND-

b. Patient does not have an artificial heart valve

AND-

c. History of failure, contraindication, or intolerance to Eliquis

Authorization will be issued for 35 days.

D. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)

1. Initial Authorization

a. Diagnosis of **one** of the following:

- Deep vein thrombosis (DVT)
- Pulmonary embolism (PE)

-AND-

b. Patient does not have an artificial heart valve

-AND-

c. **One** of the following:

(1) History of failure, contraindication, or intolerance to **both** of the following:

- Eliquis
- Savaysa

-OR-

(2) Continuation of prior Pradaxa therapy

Authorization will be issued for 6 months.

E. Reduction in the risk of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE)

1. Initial Authorization

a. Previous diagnosis of **one** of the following:

- Deep vein thrombosis (DVT)
- Pulmonary embolism (PE)

-AND-

b. Patient does not have an artificial heart valve

-AND-

c. Patient must have been treated with an anticoagulant [e.g., warfarin, Eliquis (apixiban)] for at least 3 months prior to request

-AND-

c. **One** of the following:

(1) History of failure, contraindication, or intolerance to the following:

- Eliquis

-OR-

(2) Continuation of prior Pradaxa therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References

1. Pradaxa [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; July 2020.
2. Eliquis [package insert]. Princeton, NJ: Bristol-Myers Squibb; November 2019.
3. Savaysa [package insert]. Tokyo, Japan: Daiichi Sankyo, Inc.; April 2020.

4. Schulman S, Kearon C, Kakkar AK, et al. for the RE-COVER Study Group. Dabigatran versus warfarin in the treatment of acute venous thromboembolism. New Engl J Med. 2009.361:2342-52.
5. Ginsberg JS, Davidson BL, Comp PC, et al. The RE-MOBILIZE Writing Committee. 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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7. FDA Drug Safety Communication: Pradaxa (dabigatran etexilate) should not be used in patients with mechanical prosthetic heart valves. Food and Drug Administration Web site. http://www.fda.gov/Drugs/DrugSafety/ucm332912.htm Accessed January 7, 2013.
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9. 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. 2016;149(2 Suppl):e315S-352S.
10. Pai M, Douketis J. Prevention of venous thromboembolism in adult orthopedic surgical patients. Leung L, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on August 13, 2020.)
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12. Lip GY, Hull RD. Overview of the treatment of lower extremity deep vein thrombosis (DVT). Leung LL ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on August 13, 2020.)
13. Wann S, 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 in Collaboration With the Society of Thoracic Surgeons. Circulation. 2019;140:e125–e151. July 9, 2019.

Program	Prior Authorization – Pradaxa (dabigatran etexilate)
Change Control	
Date	Change
3/2011	New drug policy
3/2012	Annual Review. Added specification to diagnosis requirement, non-valvular atrial fibrillation.

3/2013	Added criteria for continuation after hospital discharge, treatment of acute VTE, and prophylaxis of VTE after orthopedic surgery. Updated criteria for atrial fibrillation, now includes conditions that are contraindicated for use with Pradaxa. Added dosing, availability, background, and endotes section. Updated references.
12/2015	Added requirement of a trial of the preferred alternative products or as continuation of existing therapy. Pradaxa is non-preferred and the plan has three other preferred products. Removed age requirement for Prophylaxis of venous thromboembolism (VTE) after orthopedic surgery. Renamed "Treatment of acute venous thromboembolism (VTE) (off-label)" to "Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)" as this is an FDA approved indication. Removed age requirement and requirement to for a trial of warfarin from this section. Added different preferred alternative trial requirement of the preferred alternative products or as continuation of existing therapy. Added new section for Reduction in the risk of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE) as this is an FDA approved indication. Includes requirement for a trial of the preferred alternatives Xarelto and Eliquis as these drugs are preferred and are FDA approved for this indication. Added formulary note outlining the preferred and non-preferred products in the anticoagulant class.
6/2016	Updated policy template. Updated prosthetic heart valve definition for Non-Valvular Atrial Fibrillation. Prophylaxis of venous thromboembolism (VTE) after orthopedic surgery- hip replacement: Updated to a labeled indication.
10/2016	Archive policy. High approval rate of prior authorizations.
3/2017	Reinstated policy. Updated policy template.
5/2018	Annual review. Updated background and references. Removed endnotes.
7/2018	Updated step therapy medications to reflect 10/1/18 PDL changes. Xarelto will become non-preferred at that time.

9/2019	Annual review. Updated references. Added heart valve contraindication to all criteria. Added step through Eliquis for prophylaxis of venous thromboembolism (VTE) and pulmonary embolism (PE).
9/2020	Annual review. Updated references.