Pradaxa (dabigatran etexilate mesylate)
Policy Number: C17731-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
9/1/2019	7/1/2020	7/1/2021
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
NA	RxPA	Q3 2020 20200722C17731-A

PRODUCTS AFFECTED:
Pradaxa (dabigatran etexilate mesylate)

DRUG CLASS:
Direct thrombin inhibitor

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy
The recommendation is that medications in this policy will be for pharmacy benefit coverage and member self-administered

AVAILABLE DOSAGE FORMS:
Oral capsules: 75mg, 110mg, and 150mg

FDA-APPROVED USES:
Reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, Treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have treated with a parenteral anticoagulant for 5 to 10 days, Reduce the risk of recurrence of DVT and PE in patients who have been previously treated, Prophylaxis of DVT and PE patients who have undergone total hip arthroplasty (THA)

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
atrial fibrillation, deep vein thrombosis treatment and prophylaxis, pulmonary embolism treatment and prophylaxis, stroke prophylaxis

REQUIRED MEDICAL INFORMATION:
FOR ALL INDICATIONS:

1. Prescriber attests that member is not currently pregnant and does not plan on becoming pregnant
   AND

2. Prescriber attests that member's renal function (creatinine clearance) will be assessed as clinically indicated and therapy dosing will be adjusted accordingly.
   AND
3. IF THIS NON-FORMULARY PRODUCT: Documentation of trial and failure or absolute contraindication to preferred formulary Direct Factor Xa Inhibitors Oral products

A. NONVALVULAR ATRIAL FIBRILLATION:
1. Documentation of diagnosis with non-valvular atrial fibrillation or flutter of < 48hours duration
   AND
2. Prescriber attests that member has moderate to high risk for stroke based on the member's CHA2DS2-VAScore used to assess member's stroke risk
   AND
3. Member does NOT have moderate to severe mitral stenosis, mechanical prosthetic or bioprosthetic heart valve- If member DOES have moderate to severe mitral stenosis, a mechanical prosthetic or bioprosthetic heart valve, warfarin MUST be used as the anticoagulant

B. TREATMENT OF DVT AND/OR PE:
1. Documentation of diagnosis of a DVT or PE
   AND
2. Prescriber attests that member has been treated with parenteral anticoagulation for 5-10 days

C. PROPHLAXIS OF DVT:
1. (a) Member has or is scheduled to have total hip or knee replacement surgery
   OR
   (b) Documentation member is at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months

D. CONTINUATION OF THERAPY UPON HOSPITAL DISCHARGE:
1. Documentation of recent hospital discharge (within 48 hours) in which Pradaxa was started

DURATION OF APPROVAL:
Initial authorization: Prophylactic use DVT and/or PE hip replacement -- 35 days, Prophylactic use DVT and/or PE after treatment for acute DVT and/or PE-- 6 months, atrial fibrillation, deep vein thrombosis, pulmonary embolism treatment -- 6 months, Stroke prophylaxis – 12 months

Continuation of Therapy (for the following indications ONLY): Prophylactic use DVT and/or PE after treatment for acute DVT and/or PE, atrial fibrillation, deep vein thrombosis, pulmonary embolism treatment or stroke prophylaxis: 12 months

QUANTITY:
Stroke prophylaxis: If CrCl > 30mL/min: 150mg twice daily, If CrCl 15-30mL/min: 75mg twice daily
Treatment of DVT or PE: If CrCl > 30mL/min: 150mg twice daily x 6 months, after 5-10 days of parenteral anticoagulation
DVT or PE prophylaxis: If CrCl > 30mL/min:150mg twice daily x 6 months, after previous treatment
DVT or PE prophylaxis following hip replacement: If CrCl >30mL/min: 110mg 1-4 hours post-surgery, then 220mg once daily for 28-35 days

PRESCRIBER REQUIREMENTS:
No requirements

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:
A. FOR ALL INDICATIONS:
1. Documentation of tolerability of therapy
   AND
2. Documentation showing continued medical necessity for indication and/or medical history.
   AND
3. Dosing is appropriate for listed diagnosis.
   AND
4. Compliance with therapy as verified by Prescriber and member's medication fill history (review member's prescription history for compliance). Therapy may be discontinued due to compliance issues or poor adherence upon agreement among treating physician, member, and Medical Director

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Pradaxa (dabigatran etexilate mesylate) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Other contraindications include active pathological bleeding, history of serious hypersensitivity reaction to Pradaxa, severe mitral stenosis or mechanical prosthetic heart valve and the use of Pradaxa should be avoided in patients with severe renal impairment (CrCl 15-30 mL/min).

OTHER SPECIAL CONSIDERATIONS:
The concomitant use with P-gp inducers (e.g. rifampin)
reduces exposure to Pradaxa and should be generally avoided**.** The concomitant use with P-gp inhibitors in patients with renal impairment is expected to produce increased exposure to Pradaxa. Consider reducing the dose to 75mg twice daily with concomitant P-gp inhibitor use (e.g. systemic ketoconazole). Discontinuing Pradaxa places patients at an increased risk of thrombotic events (stroke). If anticoagulation with Pradaxa must be discontinued for a reason other than pathological bleeding, consider coverage with another anticoagulation. Pradaxa can cause serious, sometimes, fatal bleeding. Promptly evaluate signs and symptoms of blood loss.

BACKGROUND:
None

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, member records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Pradaxa (dabigatran) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; March 2018.
2. Clinical Pharmacology. Elsevier. July 2019. Availablefrom: http://www.clinicalpharmacology.com