Reference number(s)
1519-A

This document applies to the following:

Formulary	Applies
Advanced Control (ACF)	☑
Advanced Control Formulary Chart (ACFC)	☑
Advanced Control – Choice (ACCF)	☑
Basic Control (BC)	☐
Basic Control Chart (BCC)	☐
Standard Control (SF)	☑
Standard Control Formulary Chart (SFC)	☑
Standard Control – Choice (SCCF)	☑
Value (VF)	☑
Value Formulary Chart (VFC)	☐

Formulary	Applies
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Aetna Fully Insured Advanced Control Formulary (Aetna FI ACF)	☑
Aetna Fully Insured Advanced Control Formulary Chart (Aetna FI ACFC)	☑
Aetna Fully Insured Standard Opt-Out (Aetna FI SOO)	☐

Medical Necessity Criteria
Pradaxa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Pradaxa (Brand Only)	dabigatran	capsule
Pradaxa	dabigatran	oral pellets

Indications

FDA-approved Indications

Pradaxa Capsules

Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation in Adult Patients

Pradaxa Capsules is indicated to reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation.

Treatment of Deep Venous Thrombosis and Pulmonary Embolism in Adult Patients

Pradaxa Capsules is indicated for the treatment of deep venous thrombosis and pulmonary embolism in adult patients who have been treated with a parenteral anticoagulant for 5-10 days.

Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism in Adult Patients

Pradaxa Capsules is indicated to reduce the risk of recurrence of deep venous thrombosis and pulmonary embolism in adult patients who have been previously treated.

Prophylaxis of Deep Vein Thrombosis and Pulmonary Embolism in Adult Patients Following Hip Replacement Surgery

Pradaxa Capsules is indicated for the prophylaxis of deep vein thrombosis and pulmonary embolism in adult patients who have undergone hip replacement surgery.

Treatment of Venous Thromboembolic Events in Pediatric Patients

Pradaxa Capsules is indicated for the treatment of venous thromboembolic events (VTE) in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days.

Reduction in the Risk of Recurrence of Venous Thromboembolic Events in Pediatric Patients

Pradaxa Capsules is indicated to reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated.

Pradaxa Oral Pellets

Treatment of Venous Thromboembolic Events in Pediatric Patients

Pradaxa Oral Pellets are indicated for the treatment of venous thromboembolic events (VTE) in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days.

Reduction in the Risk of Recurrence of Venous Thromboembolic Events in Pediatric Patients

Pradaxa Oral Pellets are indicated to reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated.

Compendial Uses

Pradaxa Capsules can be used for prophylaxis of postoperative deep vein thrombosis (DVT) and pulmonary embolism (PE) in adult patients undergoing total knee replacement surgery.[3-6]

Coverage Criteria

Adult Deep Venous Thrombosis (DVT), Pulmonary Embolism (PE), Risk Reduction of Stroke and Systemic Embolism

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient cannot be treated with a formulary drug (Available Formulary Alternatives: generic dabigatran capsules, Eliquis, Xarelto).
- The patient has experienced an inadequate treatment response (i.e., failure to adequately resolve thrombus) or intolerance to ALL of the following: generic dabigatran capsules, Eliquis, AND Xarelto. [ACTION REQUIRED: Documentation is required for approval.]
- The request is for Pradaxa capsules.
- The requested drug is being prescribed for ANY of the following:
    - To reduce the risk of stroke and systemic embolism in an adult patient with non-valvular atrial fibrillation.
    - The treatment of deep venous thrombosis (DVT) or pulmonary embolism (PE) in an adult patient who has been treated with a parenteral anticoagulant for 5-10 days.
    - To reduce the risk of recurrence of DVT or PE in an adult patient who has been previously treated.
    - The prophylaxis of DVT and PE in an adult patient following hip replacement surgery or total knee replacement surgery.

Pediatric Venous Thromboembolic Events (VTE)

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient cannot be treated with a formulary drug (Available Formulary Alternatives: generic dabigatran capsules, Eliquis, Xarelto).
- The patient meets ONE of the following:
    - If the request is for Pradaxa capsules, the requested drug is being prescribed for a pediatric patient age 8 to less than 18 years of age.
    - If the request is for Pradaxa oral pellets, the requested drug is being prescribed for a pediatric patient age 3 months to less than 12 years of age.
- The requested drug is being prescribed for ANY of the following:
    - The treatment of venous thromboembolic events (VTE) in a pediatric patient who has been treated with a parenteral anticoagulant for at least 5 days.
    - The reduction in the risk of recurrence of VTE in a pediatric patient who has been previously treated.

Duration of Approval (DOA)

- 1519-A:
  - Prophylaxis of DVT/PE following hip replacement surgery/knee replacement surgery: DOA: 1 month
  - All other approved indications: DOA: 12 months

References

1. Pradaxa Capsules [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; November 2023.
2. Pradaxa Oral Pellets [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; November 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed April 4, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 04/04/2024).
5. Dabigatran. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. c2024- [2024 April 4]. Available from: http://www.clinicalkey.com.
6. 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;141(2 Suppl):e278S-e325S.

Document History

Written by: UM Development (CF/NB)

Date Written: 10/2016

Revised: (JH) 05/2017, 04/2018 (no clinical changes), (MAC) 4/2019 (no clinical changes), 11/2019 (added BF to title, no clinical changes), 04/2020 (added denial reasons and compendia indication), 04/2021 (no clinical changes), 07/2021 (Pradaxa label update/oral pellet formulation); (DS) 09/2021 (added Eliquis to target box; removed Eliquis and Warfarin from formulary alts); (RZ) 04/2022 (added BC to title and LOB header); 04/2022 (no clinical changes); (DRS) 05/2022 (removed BC formulary, added VF formulary, removed Eliquis from target, added Eliquis as formulary alt), (DFW) 09/2022 (removed BF); (MRS) 04/2023 (no clinical changes); (ASA) (added ACCF and SCCF to title and LOB header); (MRS) 04/2024 (no clinical changes), 12/2024 (added ACFC and SFC to title and LOB header, removed generic dabigatran capsules and added as formulary alternative, updated try/fail requirement)

Reviewed: Medical Affairs (SD) 10/2016; (ME) 05/2017; (SD) 08/2017; (MF) 04/2020; (CHART) 04/22/2021, 07/22/21, 09/30/2021, 04/28/2022, 05/26/2022; (CDPR) 09/2022; (CHART) 04/27/2023; (APN) 09/2023; (CHART) 04/25/2024; (CDPR) 01/10/2025

External Review: 10/2016, 08/2017, 08/2018, 08/2019, 12/2019 (FYI), 08/2021 (FYI), 08/2022 (FYI), 08/2022, 10/2022 (FYI), 08/2023, 10/2023 (FYI)

CRITERIA FOR APPROVAL

1	The patient's drug benefit plan provides coverage for other drugs which may be considered for treating your patient. Can your patient be treated with a formulary drug? Available Formulary Alternatives: generic dabigatran capsules, Eliquis, Xarelto [NOTE: If yes, then provide your patient with a new prescription for the formulary product.] [If Yes, then no further questions. If No, then go to 2.] Tech Note: If the prescriber agrees to treat the patient with a formulary product, inform the prescriber that coverage for the prescribed, non-formulary drug/product is not provided.	Yes	No
2	Which drug is being requested? [] Pradaxa capsules (If checked, go to 3) [] Pradaxa oral pellets (If checked, go to 8)		
3	Is the requested drug being prescribed for a pediatric patient age 8 to less than 18 years of age? [If Yes, then go to 9. If No, then go to 4.]	Yes	No
4	Has the patient experienced an inadequate treatment response (i.e., failure to adequately resolve thrombus) or intolerance to ALL of the following: A) generic dabigatran capsules, B) Eliquis, AND C) Xarelto? ACTION REQUIRED: If yes, then documentation is required for approval. Document the patient's inadequate treatment response or intolerance to generic dabigatran capsules, Eliquis, AND Xarelto by providing the drug name and associated reason for failure of each: _____	Yes	No

	[If Yes, then go to 5. If No, then no further questions.]		
5	Has documentation of the patient's inadequate treatment response or intolerance to generic dabigatran capsules, Eliquis, AND Xarelto, including the reason for failure of each, been submitted to CVS Health? [If Yes, then go to 6. If No, then no further questions.] Tech Note: Documentation of the patient's inadequate treatment response or intolerance to generic dabigatran capsules, Eliquis, AND Xarelto, including the reason for failure of each is required for approval.	Yes	No
6	Is the requested drug being prescribed for ANY of the following: A) to reduce the risk of stroke and systemic embolism in an adult patient with non-valvular atrial fibrillation, B) treatment of deep venous thrombosis (DVT) or pulmonary embolism (PE) in an adult patient who has been treated with a parenteral anticoagulant for 5-10 days, C) to reduce the risk of recurrence of deep venous thrombosis (DVT) or pulmonary embolism (PE) in an adult patient who has been previously treated? [If Yes, then no further questions. If No, then go to 7.]	Yes	No
7	Is the requested drug being prescribed for the prophylaxis of deep venous thrombosis (DVT) and pulmonary embolism (PE) in an adult patient following hip replacement surgery or total knee replacement surgery? [No further questions]	Yes	No
8	Is the requested drug being prescribed for a pediatric patient age 3 months to less than 12 years of age? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Is the requested drug being prescribed for ANY of the following: A) treatment of venous thromboembolic events (VTE) in a pediatric patient who has been treated with a parenteral anticoagulant for at least 5 days, B) reduction in the risk of recurrence of venous thromboembolic events (VTE) in a pediatric patient who has been previously treated?	Yes	No

[No further questions]

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	[Please select the appropriate denial close option. Inform prescriber to provide patient with a new prescription for the preferred product.]. Deny	Go to 2	Your plan only covers this drug when you meet one of these conditions: A) You have tried other drugs your plan covers (preferred drugs), and they did not work well for you, or B) Your doctor gives us a medical reason you cannot take those other drugs. For your plan, you may need to try 3 preferred drugs. We have denied your request for this drug because your doctor told us that you will be taking a preferred drug instead. Your doctor can send us any new or missing information for us to review. The preferred drugs for your plan are: generic dabigatran capsules, Eliquis, and Xarelto. Your doctor may need to get approval from your plan for preferred drugs. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Non-formulary/non-preferred - Member can switch to a preferred drug - multiple]
2.	1=3 ;2=8		
3.	Go to 9	Go to 4	
4.	Go to 5	Deny	Your plan only covers this drug when you have tried 3 other drugs your plan covers (preferred drugs), and they did not work well for you. For your plan, you may need to try up to 3 preferred drugs. We have denied your request because you have not tried the preferred drugs. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. The preferred drugs for your plan are: generic dabigatran capsules, Eliquis, and Xarelto. Your doctor may need to get approval from your plan for preferred drugs. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.

			[Short Description: Non-formulary/non-preferred]
5.	Go to 6	Deny	Your plan only covers this drug when records with the reason that generic dabigatran capsules, Eliquis, and Xarelto did not work for you are sent to us. Your records must be provided and must show what your doctor tells us. We denied your request because we did not receive your records or the records did not show what your doctor has told us. Your request has been denied. Your doctor can send us any new or missing information for us to review. This drug is not a preferred drug on your plan. The preferred drugs for your plan are: generic dabigatran capsules, Eliquis, and Xarelto. Your doctor may need to get approval from your plan for preferred drugs. Your doctor told us that you have tried the preferred drugs or have a medical reason to avoid them. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Inadequate Response or Intolerance Documentation]
6.	Approve, 12 Months	Go to 7	
7.	Approve, 1 Months	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses for adults are: A) Decreasing the risk of stroke and clots with non-valvular atrial fibrillation, B) Treating deep venous thrombosis (DVT) and pulmonary embolism (PE), C) Decreasing the risk of getting another DVT or PE, and D) Preventing DVT and PE after hip or knee replacement surgery. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. This drug is not a preferred drug on your plan. The preferred drugs for your plan are: generic dabigatran capsules, Eliquis, and Xarelto. Your doctor may need to get approval from your plan for preferred drugs. Your doctor told us that you have tried the preferred drugs or have a medical reason to avoid them. For this drug, you may have to meet other

			criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis, Pradaxa for adults]
8.	Go to 9	Deny	Your plan only covers this drug if you are 3 months to less than 12 years old. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Age, Pradaxa pellets]
9.	Approve, 12 Months	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for treating venous thromboembolic events (VTE) and decreasing the risk of getting another VTE. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis, Pradaxa for peds]

