

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Anticoagulants**

A. Prescriptions That Require Prior Authorization

Prescriptions for Anticoagulants which meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Anticoagulant. See Preferred Drug List (PDL) for the list of preferred Anticoagulants at: [www.providersynergies.com/services/documents/PAM\\_PDL.pdf](http://www.providersynergies.com/services/documents/PAM_PDL.pdf)
2. A prescription for an Anticoagulant with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: <http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm>
3. A prescription for Pradaxa (dabigatran)
4. A prescription for Xarelto (rivaroxaban)
5. A prescription for Eliquis (apixaban)
6. A prescription for an Oral Anticoagulant when there is a record of a recent paid claim for another Oral Anticoagulant in PROMISe, the Department's Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication)
7. A prescription for an Injectable Anticoagulant when there is a record of a recent paid claim for another Injectable Anticoagulant in PROMISe, the Department's Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication)

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Anticoagulant, the determination of whether the requested prescription is medically necessary will take into account the following:

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1. For a non-preferred Anticoagulant, whether the recipient has a history of therapeutic failure, contraindication or intolerance of the preferred Anticoagulants

**OR**

2. For Pradaxa (dabigatran), whether the recipient:
  - a. Is being treated for a condition that is a U.S. Food and Drug Administration (FDA) approved, or a medically accepted, indication

**AND**

- b. If being treated for non-valvular atrial fibrillation, has at least one of the following thromboembolic risk factors:
  - i. History of stroke, TIA, or systemic embolism
  - ii. Is 75 years of age or older
  - iii. History of symptomatic heart failure
  - iv. Left ventricular ejection fraction of < 40%
  - v. Is 65 years of age or older with the presence of one of the following:
    - a) Diabetes mellitus
    - b) Coronary artery disease (CAD)
    - c) Hypertension

**AND**

- c. Does not have a creatinine clearance less than:
  - i. 30 mL/min for a diagnosis of DVT or PE
  - ii. 15 mL/min for a diagnosis of non-valvular atrial fibrillation

**AND**

- d. Is being prescribed a dose that is consistent with package labeling

**AND**

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e. Is 18 years of age or older

**AND**

f. Does not have a history of prosthetic heart valve

**AND**

g. Does not have mitral valve disease

**AND**

h. Does not have:

i. Active pathological bleeding

**OR**

ii. A history of recurrent bleeds

**AND**

i. Does not have advanced liver disease

**AND**

j. Is not concurrently taking other medications that may increase the risk of bleed, such as but not limited to heparin and chronic NSAID use

**AND**

k. Is not currently taking a P-glycoprotein (P-gp) inducer such as Rifampin

**OR**

3. For Xarelto (rivaroxaban), whether the recipient:

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- a. Is being treated for a condition that is a U.S. Food and Drug Administration (FDA) approved, or a medically accepted, indication

**AND**

- b. Does not have any of the following :
  - i. Moderate Child Pugh B or more severe hepatic impairment
  - ii. Hepatic impairment associated with coagulopathy
  - iii. Creatinine clearance less than:
    - a. 30 mL/min for hip or knee replacement surgery, or a diagnosis of DVT or PE
    - b. 15 mL/min for a diagnosis of non-valvular atrial fibrillation
  - iv. Concomitant use of other anticoagulants
  - v. Active pathological bleeding
  - vi. A prosthetic heart valve
  - vii. Taking a drug that is a combined P-gp and strong CYP3A4 Inhibitor (such as ketoconazole, itraconazole, lopinavir/ritonavir) or a combined P-gp and strong CYP3A4 Inducer (such as carbamazepine, phenytoin, rifampin, and St. John's Wort) shown to be of clinical significance

**AND**

- c. Is not being administered the drug through a feeding tube that could empty directly into the proximal small intestine

**OR**

- 4. For Eliquis (apixaban), whether the recipient:
  - a. Is being treated for a condition that is a U.S. Food and Drug Administration (FDA) approved, or a medically accepted, indication

**AND**

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- b. Is being prescribed a dose that is consistent with package labeling

**AND**

- c. Does not have any of the following:
  - i. Severe hepatic impairment
  - ii. Creatinine clearance less than 15 mL/min
  - iii. Concomitant use with other anticoagulants
  - iv. Active pathological bleeding
  - v. A prosthetic heart valve
  - vi. Concomitant use with a strong dual P-gp and CYP3A4 Inducer (such as carbamazepine, phenytoin, rifampin, and St. John's Wort)
  - vii. Concomitant use with a strong dual P-gp and CYP3A4 Inhibitor (such as ketoconazole, itraconazole, lopinavir/ritonavir) and prescribing is not in accordance with package labeling

- 5. For therapeutic duplication, whether:

- a. For an Oral Anticoagulant, the recipient is being titrated to, or tapered from, another Oral Anticoagulant
- b. For an Injectable Anticoagulant, the recipient is being titrated to, or tapered from, another Injectable Anticoagulant

**OR**

- c. Supporting peer reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested
- 6. In addition, if a prescription for either a preferred or non-preferred Anticoagulant is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

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**OR**

7. Whether the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

C . Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guideline in Section B. above, to assess the medical necessity of the request for a prescription for a non-preferred Anticoagulant. If the guideline in Section B. is met, the reviewer will prior authorize the prescription. If the guideline is not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

Requests for prior authorization of Xarelto (rivaroxaban) and Eliquis (apixaban) will be approved as follows:

1. For recipients who have undergone hip replacement surgery, authorization will be limited to a total of 35 days post-operative therapy
2. For recipients who have undergone knee replacement surgery, authorization will be limited to a total of 12 days post-operative therapy

References

1. Pradaxa Package Insert, Boehringer Ingelheim Pharmaceuticals, Inc. October , 2010
2. ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation
3. Xarelto Package Insert. Janssen Pharmaceuticals, Inc. Titusville, NJ, July 2011

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4. Anticoagulants, The Pharmacist's Letter. December 2012.
5. Eliquis package insert. Bristol-Myers Squibb, Princeton, NJ. December 2012.
6. New Drug Eliquis, The Pharmacist's Letter. February 2013.
7. Xarelto package insert. Janssen Pharmaceuticals, Titusville, NJ. March 2013.