

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
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)

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:

1. For Pradaxa (dabigatran), whether the recipient:
 - a. Has a diagnosis of non-valvular atrial fibrillation

AND

 - b. 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

c. Has a creatinine clearance \geq 15 ml/min

AND

d. Is 18 years of age or older

AND

e. Does not have a history of prosthetic heart valve

AND

f. Does not have mitral valve disease

AND

g. Does not have:

i. Active pathological bleeding

OR

ii. A history of recurrent bleeds

AND

h. Does not have advanced liver disease

AND

i. 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

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

OR

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

OR

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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

a. Had hip or knee replacement surgery

OR

b. Has a diagnosis of non-valvular atrial fibrillation

OR

c. Has a diagnosis of deep vein thrombosis (DVT) or pulmonary embolism (PE)

AND

d. 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. 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

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

4. For Eliquis (apixaban), whether the recipient:

a. Has a diagnosis of non-valvular atrial fibrillation

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- b. Does not have any of the following:
 - i. Severe hepatic impairment
 - ii. Creatinine clearance less than 15 mL/min or on dialysis
 - 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. 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.

OR

6. 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) will be approved as follows:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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
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.