pennsylvania
DEPARTMENT OF HUMAN SERVICES

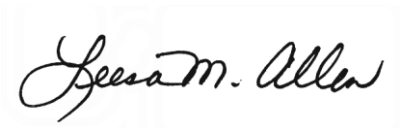
MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
July 5, 2016	July 11, 2016	*See below

SUBJECT

Prior Authorization of Anticoagulants - Pharmacy Services

BY



Leesa M. Allen, Deputy Secretary
Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate their MA enrollment every 5 years. Providers should log into PROMISe to check their revalidation date and submit a revalidation application at least 60 days prior. Enrollment (revalidation) applications may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Providers who enrolled on or before SEPTEMBER 25, 2011 must complete the revalidation process as soon as possible. DHS must complete the revalidation for all providers enrolled on or before September 25, 2011 by September 25, 2016.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the type of information needed to evaluate requests for prior authorization of prescriptions for Anticoagulants for medical necessity.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is changing the reference to “Direct Thrombin Inhibitors” to “novel oral anticoagulants (NOACs)” in the guidelines to determine medical necessity of an Anticoagulant to be consistent with current medical terminology. There are no other changes to the medical necessity guidelines.

*01-16-20	09-16-18	27-16-18	
02-16-17	11-16-17	30-16-17	
03-16-17	14-16-18	31-16-22	
08-16-18	24-16-20	32-16-16	33-16-17

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

PROCEDURE:

The procedures for prescribers to request prior authorization of Anticoagulants are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Anticoagulants) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Anticoagulants

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.papdl.com

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.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/quantitylimitslist/index.htm

3. A prescription for a novel oral anticoagulant (NOAC)

4. 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)

5. 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:

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

   AND

2. For a novel oral anticoagulant (NOAC), 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. Is being prescribed a dose that is consistent with package labeling

AND

c. Is age appropriate according to package labeling

AND

d. Does not have a contraindication to the prescribed oral anticoagulant

AND

3. For Pradaxa (dabigatran), whether the recipient does not have any of the following:

    a. 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

    b. History of prosthetic heart valve or mitral valve disease

    c. History of recurrent bleeds

    d. Advanced liver disease

    e. Concomitant use with a medication that may increase the risk of bleed, such as but not limited to heparin and chronic NSAID use

    f. Concomitant use with a P-glycoprotein (P-gp) inducer such as rifampin

AND

4. For Xarelto (rivaroxaban):

    a. Whether the recipient 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. A prosthetic heart valve
vi. Concomitant use with a combined P-gp and strong CYP3A4 Inhibitor (such as ketoconazole, itraconazole, lopinavir/ritonavir)
vii. Concomitant use with 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

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

AND

5. For Eliquis (apixaban), whether the recipient does not have any of the following:

    a. Severe hepatic impairment
    b. Concomitant use with other anticoagulants
    c. A prosthetic heart valve
    d. Concomitant use with a strong dual P-gp and CYP3A4 Inducer (such as carbamazepine, phenytoin, rifampin, and St. John's Wort)
    e. 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

AND

6. For Savaysa (edoxaban), whether the recipient does not have any of the following:

    a. Moderate Child Pugh B or more severe hepatic impairment

b. Creatinine clearance less than 15 mL/min or greater than 95 mL/min
c. Concomitant use of other anticoagulants or rifampin
d. A mechanical heart valve or moderate to severe mitral stenosis

AND

7. 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

8. 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

9. 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

E. References

1. Pradaxa Package Insert, Boehringer Ingelheim Pharmaceuticals, Inc. January 2015
2. ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation
3. Xarelto Package Insert. Janssen Pharmaceuticals, Inc. Titusville, NJ, January 2015
4. Anticoagulants, The Pharmacist's Letter. December 2012.
5. Eliquis package insert. Bristol-Myers Squibb, Princeton, NJ. August 2014.
6. New Drug Eliquis, The Pharmacist's Letter. February 2013.
7. Savaysa Prescribing Information, Daiichi Sankyo Co. January 2015