IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 Angiotensin Modulators for medical necessity.

SCOPE:

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

BACKGROUND:

The Department of Human Services (department) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to new drugs in therapeutic classes already included in the

*01-17-34 09-17-32 27-17-30
02-17-29 11-17-29 30-17-30
03-17-29 14-17-29 31-17-34
08-17-35 24-17-30 32-17-29 33-17-33

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
Preferred Drug List (PDL), changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred, new quantity limits, and new classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or modification to existing guidelines to determine medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the May 17, 2017 meeting, the P&T Committee recommended approval of the following: 1. Change the designation of the angiotensin receptor--neprilysin inhibitor (ARNI) Entresto (sacubitril/valsartan) from non-preferred to preferred but continue to require prior authorization; 2. Exempt Qbrelis (lisinopril oral solution) and Epaned (enalapril oral solution) from the requirement for prior authorization in response to the Food and Drug Administration (FDA) approved indication for a pediatric population; and, 3. Edit the medical necessity guideline for an ARNI related to therapeutic failure to reflect the FDA package labeling related to tolerability to an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker. The P&T Committee recommendations were subject to public review and comment, and subsequently approved for implementation by the department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Angiotensin Modulators 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 chapters related to Angiotensin Modulators) 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
Angiotensin Modulators
I. Requirements for Prior Authorization of Angiotensin Modulators (Formerly referred to as ACE Inhibitors)

A. Prescriptions That Require Prior Authorization

Prescriptions for Angiotensin Modulators that meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Angiotensin Modulator, including Angiotensin Modulators in combination with HCTZ, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred Angiotensin Modulators at: https://papdl.com/preferred-drug-list

2. A prescription for a preferred Angiotensin Modulator with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf

3. A prescription for an ACE Inhibitor when there is a record of a recent paid claim for another ACE Inhibitor, an ARB, or an Angiotensin Modulator Combination in PROMISe, the department’s Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication)

4. A prescription for an ARB when there is a record of a recent paid claim for another ARB, an ACE Inhibitor, or an Angiotensin Modulator Combination in PROMISe, the department’s Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication)

5. A prescription for an angiotensin receptor-neprilysin inhibitor (ARNI)

B. Exemptions From Prior Authorization

The following are exempt from prior authorization:

1. A prescription for Qbrelis (lisinopril oral solution) when prescribed for a child under 9 years of age

2. A prescription for Epaned (enalapril oral solution) when prescribed for a child under 6 years of age

C. Review of Documentation for Medical Necessity

July 25, 2017
(Replacing October 26, 2015)
In evaluating a request for prior authorization of a prescription for a non-preferred Angiotensin Modulator, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For an initial request for approval of an Aliskiren Agent - Whether the recipient:
   a. Is 18 year of age or older
      
      AND

   b. Is not pregnant
      
      AND

   c. Has a documented diagnosis of uncontrolled hypertension despite treatment with the following drug classes at maximum tolerated Food and Drug Administration (FDA) approved doses unless contraindicated: Calcium Channel blockers, Beta Blockers, Diuretics, ACE Inhibitors, and Angiotensin Receptor Blockers (ARBs).
      
      AND

   d. Is not taking Cyclosporine, Itraconazole, or high doses of diuretics
      
      AND

   e. If diabetic, is not taking an ACE Inhibitor or an ARB
      
      AND

   f. Was evaluated for secondary causes of hypertension (including renal artery stenosis, pheochromocytoma, Cushing’s syndrome, and hyperaldosteronism)
      
      AND

   g. Has baseline kidney function and electrolyte testing
      
      AND

   h. Does not have a CrCl <30 mL/minute
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OR

i. If taking an ACE Inhibitor or ARB, does not have a CrCl <60 mL/minute

AND

j. Does not have a history of allergy to ACE Inhibitors or ARBs

2. For a request for a renewal of a prescription for an Aliskiren Agent – Whether the recipient:
   a. Is not pregnant
   
   AND
   b. Is not taking Cyclosporine, Itraconazole, or high doses of diuretics

   AND
   c. If diabetic, is not taking an ACE Inhibitor or an ARB

   AND
   d. Has repeat kidney function and electrolyte testing

   AND
   e. Does not have a CrCl <30 mL/minute

   OR
   f. If taking an ACE Inhibitor or an ARB, does not have a CrCl <60mL/minute

3. For an initial request for approval of an angiotensin receptor-neprilysin inhibitor (ARNI), whether the recipient:
   a. Is prescribed the requested ARNI for treatment of a condition that is a U.S. Food and Drug Administration (FDA) approved or a medically accepted indication

   AND
b. Is prescribed the medication by or in consultation with a cardiologist

AND

c. Is 18 years of age or older

AND

d. Has no contraindication to the prescribed ARNI

AND

e. Is not pregnant or breastfeeding

AND

f. Does not have severe hepatic impairment

AND

g. Has baseline kidney function and electrolyte testing

AND

h. Is prescribed a dose appropriate for their renal function according to package labeling

AND

i. Has a systolic blood pressure greater than 100 mmHg

AND

j. Has a documented plasma B-type natriuretic peptide (BNP) level of at least 150 pg per milliliter (or an N-terminal pro-BNP [NT-proBNP] level ≥600 pg per milliliter) or, if they have been hospitalized for heart failure within the previous 12 months, a BNP of at least 100 pg per milliliter (or an NT-proBNP ≥400 pg per milliliter).

AND

k. Has evidence of tolerability to an ACE inhibitor or an ARB
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AND

I. Is currently receiving optimally tolerated doses of all of the following:

i. Beta blocker (carvedilol, metoprolol succinate sustained release, bisoprolol)
ii. Mineralocorticoid receptor blocker
iii. Diuretic

OR

m. Has a contraindication or intolerance to optimally titrated doses of all of the following:

i. Beta blocker (carvedilol, metoprolol succinate sustained release, bisoprolol)
ii. Mineralocorticoid receptor blocker
iii. Diuretic

4. For a request for a renewal of a prescription for an ARNI whether the recipient:

a. Is prescribed the medication by or in consultation with a cardiologist

AND

b. Has no contraindication to the prescribed ARNI

AND

c. Is not pregnant or breastfeeding

AND

d. Does not have severe hepatic impairment

AND

e. Has repeat kidney function and electrolyte testing

AND

f. Is prescribed a dose appropriate for their renal function according to package labeling

July 25, 2017
(Replacing October 26, 2015)
5. For all other non-preferred Angiotensin Modulators - Whether the recipient has a history of therapeutic failure or intolerance of the preferred Angiotensin Modulators.

6. For therapeutic duplication, whether:

   a. For an ACE Inhibitor, the recipient is being titrated to, or tapered from, another ACE Inhibitor, an ARB, or an Angiotensin Modulator Combination
   
   b. For an ARB, the recipient is being titrated to, or tapered from, another ARB, an ACE Inhibitor, or an Angiotensin Modulator Combination

   OR

   c. Supporting peer reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested

7. In addition, if a prescription for either a preferred or non-preferred Angiotensin Modulator 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

8. 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.

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C. above, to assess the medical necessity of the request for a prescription for an Angiotensin Modulator. If the guidelines in Section C. are met, the reviewer will prior authorize the prescription. If the guidelines are 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.
References: