



ISSUE DATE November 18, 2015	EFFECTIVE DATE October 26, 2015	NUMBER *See below
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SUBJECT Prior Authorization of Angiotensin Modulators - Pharmacy Service	BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs
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IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of Angiotensin Modulators, including the type of medical information needed to evaluate requests 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:

The Department of Human Services (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

*01-15-34	09-15-32	27-15-26	
02-15-26	11-15-25	30-15-25	
03-15-26	14-15-27	31-15-33	
08-15-32	24-15-27	32-15-26	33-15-31

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>

DISCUSSION:

During the September 10, 2015 meeting, the DUR Board recommended updates to the guidelines to determine medical necessity of Angiotensin Modulators to include Entresto (sacubitril/ valsartan), a new medication in this class. The guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Angiotensin Modulators are included in the attached updated provider handbook pages.

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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:
www.providersynergies.com/services/documents/PAM_PDL.pdf
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)

B. Review of Documentation for Medical Necessity

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

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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

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

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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

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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 a history of therapeutic failure, contraindication or intolerance to an ACE inhibitor or angiotensin receptor blocker

AND

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- 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

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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.

C . Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for an Angiotensin Modulator. If the guidelines in Section B 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,

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the services are medically necessary to meet the medical needs of the recipient.

References:

1. Tekturna package insert. Novartis Pharmaceuticals Corporation, East Hanover, NJ. March 2012
2. Tekturna HCT package insert. Novartis Pharmaceuticals Corporation, East Hanover, NJ. March 2012
3. <http://www.fda.gov/drugs/drugsafety/ucm300889.htm>, accessed May 2012
4. Entresto prescribing information. Novartis July 2015
5. Colucci, W.C. et.al. Use of angiotensin II receptor blocker and neprilysin inhibitor in heart failure with reduced ejection fraction. Up To Date, accessed August 7, 2015.
6. Practice Changing UpDates. Cardiovascular Medicine (July 2015) Angiotensin receptor-neprilysin inhibitor for heart failure. Up To Date, accessed August 7, 2015.
7. Mandrola, J. The Benefits of Slow Medicine Apply to Entresto. Medscape, July 16, 2015.
8. Stiles, S. After Sinking in, PARADIGM-HF Critiqued at HFSA Sessions. Medscape September 25, 2014.

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