PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
ANGIOTENSIN MODULATORS

Proposed Effective Date: January 1, 2020

Revisions are noted with a ~~strikethrough~~ for deletions and ~~**bold and underline**~~ for additions.

I. Requirements for Prior Authorization of Angiotensin Modulators

A. Revisions to Prescriptions That Require Prior Authorization

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

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

2. An Angiotensin Modulator with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. An ~~ACE Inhibitor~~ **Angiotensin Modulator** when there is a record of a recent paid claim for another ~~ACE inhibitor, an angiotensin receptor blocker (ARB),~~ **Angiotensin Modulator** or an Angiotensin Modulator Combination in DHS' Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

~~4. An ARB when there is a record of a recent paid claim for another ARB, an ACE inhibitor, or an Angiotensin Modulator Combination in DHS' Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).~~

~~5. An angiotensin receptor-neprilysin inhibitor (ARNI).~~

B. Revisions to Exemptions from Prior Authorization

The following are exempt from prior authorization:

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

2. Epaned (enalapril oral solution) when prescribed for a child under ~~6~~ **9 (nine)** years of age.

C. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for ~~a non-preferred~~ **an** Angiotensin Modulator, the determination of whether the requested prescription is medically necessary will take into account ~~the following~~ **whether the beneficiary**:

1. For ~~an initial request for approval of~~ an aliskiren agent, ~~whether the beneficiary~~ **both of the following**:

a. Is age-appropriate according to FDA-approved package labeling**,** ~~or~~ nationally recognized compendia**, or peer-reviewed medical literature**

~~AND~~

b. 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 ARBs**;**

~~AND~~

c. ~~Is not taking an ACE inhibitor or an ARB~~**;**

AND

~~2. For a request for a renewal of a prescription for an Aliskiren Agent, whether the beneficiary:~~

~~a. is not taking an ACE Inhibitor or an ARB~~

~~**AND**~~

~~2. For an initial request for approval of an angiotensin receptor-neprilysin inhibitor (ARNI), whether the beneficiary **all of the following**:~~

~~a. Is prescribed the requested ARNI for treatment of a condition **an indication** that is a **included in the** U.S. Food and Drug Administration (FDA)-approved **package labeling** OR a medically accepted indication**,**~~

~~AND~~

~~b. Is prescribed the medication by or in consultation with a cardiologist**,**~~

~~AND~~

~~c. Is age-appropriate according to FDA-approved package labeling**,** or nationally recognized compendia**, or peer-reviewed medical literature,**~~

~~AND~~

~~d. Has no contraindication to the prescribed ARNI~~

~~AND~~

~~e. Does not have severe hepatic impairment~~

~~AND~~

~~f. Is prescribed a dose that is consistent with FDA-approved package labeling~~**~~,~~** ~~or nationally recognized compendia~~**~~, or peer-reviewed medical literature,~~**

~~AND~~

~~g. Has evidence of tolerability to an ACE inhibitor or an ARB~~

~~AND~~

~~**h. One of the following:**~~

~~i. Is currently receiving optimally tolerated doses of **all** of the following:~~

~~a) Beta blocker (carvedilol, metoprolol succinate sustained release, bisoprolol)~~
~~b) Mineralocorticoid receptor blocker~~
~~c) Diuretic~~

~~OR~~

~~ii. Has a contraindication or intolerance to optimally titrated doses of **all** of the following:~~

~~a) Beta blocker (carvedilol, metoprolol succinate sustained release, bisoprolol)~~
~~b) Mineralocorticoid receptor blocker~~
~~c) Diuretic~~**~~;~~**

~~**AND**~~

~~3. For a request for a renewal of a prescription for an ARNI, whether the beneficiary:~~

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

~~AND~~

~~b. Has no contraindication to the prescribed ARNI~~

~~AND~~

~~c. Does not have severe hepatic impairment~~

~~AND~~

~~d. Is prescribed a dose that is consistent with FDA-approved package labeling or nationally recognized compendia~~

~~**AND**~~

2. For all other non-preferred Angiotensin Modulators, ~~whether the beneficiary~~ has a history of therapeutic failure**, contraindication,** or intolerance of the preferred Angiotensin Modulators**; AND**

~~AND~~

3. For therapeutic duplication, ~~whether~~ **one of the following**:

   a. ~~For an ACE inhibitor, the beneficiary~~ Is being titrated to or tapered from another ~~ACE inhibitor, an ARB,~~ **Angiotensin Modulator** or an Angiotensin Modulator Combination

   b. **Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;**

      ~~AND~~

   ~~c. For an ARB, the beneficiary is being titrated to or tapered from another ARB, an ACE inhibitor, or an Angiotensin Modulator Combination~~

      ~~OR~~

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

   AND

4. If a prescription for an 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.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

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 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 beneficiary.

E. References

1. Colucci, W.S. Overview of the therapy of heart failure with reduced ejection fraction. UpToDate, accessed August 23, 2018.
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6. Practice Changing Updates. Cardiovascular Medicine (July 2015) Angiotensin receptor-neprilysin inhibitor for heart failure. UpToDate, accessed August 7, 2015.
7. Stiles, S. After Sinking in, PARADIGM-HF Critiqued at HFSA Sessions. Medscape September 25, 2014.
8. Tekturna package insert. Novartis Pharmaceuticals Corporation, East Hanover, NJ. November 2017.
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10. Yancy C.W., et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol 2017; Volume 70, Issue 6:776-803.