

ISSUE DATE July 31, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Angiotensin Modulators – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

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 requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Angiotensin Modulators submitted for prior authorization.

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 delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Angiotensin Modulators to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services’ (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and makes recommendations relating to the following:

*01-19-40	09-19-38	27-19-36	33-19-38
02-19-35	11-19-34	30-19-34	
03-19-34	14-19-34	31-19-40	
08-19-43	24-19-36	32-19-34	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>
--

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the 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;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

DISCUSSION:

During the May 15, 2019, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Angiotensin Modulators:

- Increase the age for exemption from prior authorization for Epaned (enalapril oral solution) from children under 6 (six) years of age to children under 9 (nine) years of age and
- Remove the prior authorization requirement for an angiotensin receptor neprilysin inhibitor.

The revisions to the guidelines to determine medical necessity of Angiotensin Modulators, as recommended by the P&T Committee, 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 chapter 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

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I

Pharmacy Prior Authorization General Requirements

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II

Pharmacy Prior Authorization Guidelines

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Angiotensin Modulators

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

B. 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 9 (nine) years of age.

C. Review of Documentation for Medical Necessity

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

1. For an aliskiren agent, **both** of the following:
 - a. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
 - 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;

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

2. For all other non-preferred Angiotensin Modulators, has a history of therapeutic failure, contraindication, or intolerance of the preferred Angiotensin Modulators;
AND
3. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from another Angiotensin Modulator or 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

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.
2. Drazner, M. Use of angiotensin II receptor blocker and neprilysin inhibitor in heart failure with reduced ejection fraction. UpToDate, accessed August 23, 2018.
3. Entresto prescribing information. Novartis November 2017.
4. <http://www.fda.gov/drugs/drugsafety/ucm300889.htm>, accessed May 2012.
5. Mandrola, J. The Benefits of Slow Medicine Apply to Entresto. Medscape, July 16, 2015.
6. Practice Changing Updates. Cardiovascular Medicine (July 2015) Angiotensin

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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.
 9. Tekturna HCT package insert. Novartis Pharmaceuticals Corporation, East Hanover, NJ. November 2016.
 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.