

ISSUE DATE January 18, 2019	EFFECTIVE DATE January 28, 2019	NUMBER *See below
SUBJECT Prior Authorization of Alpha-1 Proteinase Inhibitors – 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 Alpha-1 Proteinase Inhibitors 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 Alpha-1 Proteinase Inhibitors to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Drug Utilization Review 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 DHS

*01-19-08	09-19-08	27-19-08	33-19-08
02-19-07	11-19-07	30-19-07	
03-19-07	14-19-07	31-19-08	
08-19-10	24-19-07	32-19-07	

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>

Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

DHS is updating the medical necessity guidelines for Alpha-1 Proteinase Inhibitors to clarify that the phenotypes listed for high-risk alpha-1 antitrypsin deficiency are examples of high-risk genetic variants and are not intended to be a complete list. Pi*SZ was added to this list of examples as this genetic variant may also be associated with high-risk disease. There are no other changes to the medical necessity guidelines.

PROCEDURE:

The procedures for prescribers to request prior authorization of Alpha-1 Proteinase Inhibitors are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS 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 Alpha-1 Proteinase Inhibitors) 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Alpha-1 Proteinase Inhibitors

A. Prescriptions That Require Prior Authorization

All prescriptions for an Alpha-1 Proteinase Inhibitor must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Alpha-1 Proteinase Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a diagnosis of clinically evident emphysema secondary to severe alpha-1 antitrypsin deficiency (AATD) documented by a baseline (pre-treatment) alpha-1 antitrypsin plasma serum level less than 11 $\mu\text{mol/L}$ using rocket immunoelectrophoresis, less than 80 mg/dL using radial immunodiffusion, or less than 57 mg/dL using nephelometry,

AND

2. Has a high-risk AATD genetic variant [e.g., Pi^*SZ , Pi^*ZZ , $\text{Pi}^*\text{Z}(\text{null})$, or $\text{Pi}^*(\text{null},\text{null})$],

AND

3. Is prescribed a dose that is consistent with package labeling,

AND

4. Is age-appropriate according to package labeling,

AND

5. Does not have a contraindication to the prescribed Alpha-1 Proteinase Inhibitor,

AND

6. Is being prescribed the requested agent by or in consultation with a pulmonologist,

AND

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7. Is a non-smoker or ex-smoker.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS for an Alpha-1 Proteinase Inhibitor: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Alpha-1 Proteinase Inhibitors that were previously approved will take into account whether the beneficiary:

1. Has documentation of improvement or stabilization of the signs and symptoms of emphysema associated with alpha-1 antitrypsin deficiency, including slowed progression of emphysema as evidenced by annual spirometry testing or a decrease in frequency, duration, or severity of pulmonary exacerbations,

AND

2. Is being prescribed the requested agent by, or in consultation with, a pulmonologist,

AND

3. Is a non-smoker or ex-smoker,

AND

4. Does not have a contraindication to the prescribed Alpha-1 Proteinase Inhibitor,

AND

5. Is prescribed a dose that is consistent with package labeling.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

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C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines listed Section B. above to assess the medical necessity of a prescription for an Alpha-1 Proteinase Inhibitor. 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, the services are medically necessary to meet the medical needs of the beneficiary.

D. REFERENCES

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4. Prolastin-C (alpha-1 proteinase inhibitor [human]) package insert. Research Triangle Park, NC: Grifols Therapeutics, Inc.; November 2013.
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