



ISSUE DATE November 30, 2015	EFFECTIVE DATE December 1, 2015	NUMBER *See below
SUBJECT Prior Authorization of Alpha-1 Proteinase Inhibitors - Pharmacy Service		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

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:

1. Inform providers about new requirements for prior authorization of Alpha-1 Proteinase Inhibitors.
2. Issue handbook pages that include instructions on how to request prior authorization of Alpha-1 Proteinase Inhibitors, 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 Service's (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing

*01-15-38	09-15-36	27-15-30	
02-15-30	11-15-29	30-15-29	
03-15-30	14-15-31	31-15-37	
08-15-36	24-15-31	32-15-30	33-15-35

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>

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.

DISCUSSION:

During the September 10, 2015 meeting, the DUR Board recommended that the Department require prior authorization of Alpha-1 Proteinase Inhibitors and proposed guidelines to determine medical necessity to ensure appropriate patient selection and drug utilization of Alpha-1 Proteinase Inhibitors. The requirement for prior authorization and 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 Alpha-1 Proteinase Inhibitors are included in the attached updated provider handbook pages.

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. 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 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

SECTION II

Alpha-1 Proteinase Inhibitors

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 recipient:

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 µmol/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 phenotype [Pi*ZZ, Pi*Z(null), or Pi*(null,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

7. Is a non-smoker or ex-smoker

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

OR

8. Does not meet the 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

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 recipient:

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

OR

6. Does not meet the clinical guidelines listed above, but in the professional judgment of the physician reviewer, the therapy is medically necessary to meet the needs of the recipient.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines listed B. above, to assess the medical necessity of the request for a prescription for an Alpha-1 Proteinase

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

Inhibitor. If the guidelines listed above are met, the reviewer will prior authorize the prescription.

When the Alpha-1 Proteinase Inhibitor being prescribed is therapeutically equivalent to other Alpha-1 Proteinase Inhibitors, the reviewer will take into account the cost of the drug, including the Federal Drug Rebate Program rebate. The reviewer will prior authorize a prescription for the least costly therapeutically equivalent Alpha-1 Proteinase Inhibitor. If the guidelines are not met, or if the prescriber does not agree to the therapeutically equivalent Alpha-1 Proteinase Inhibitor authorized by the reviewer, 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

1. Zemaira (alpha-1 proteinase inhibitor [human]) package insert. Kankakee, IL: CSL Behring LLC; April 2013.
2. Glassia (alpha-1 proteinase inhibitor [human]) package insert. Westlake Village, CA: Baxter Healthcare Corporation; March 2014.
3. Aralast NP (alpha-1 proteinase inhibitor [human]) package insert. Westlake Village, CA: Baxter Healthcare Corporation; April 2010.
4. Prolastin-C (alpha-1 proteinase inhibitor [human]) package insert. Research Triangle Park, NC: Grifols Therapeutics, Inc.; November 2013.
5. Alpha-1 Proteinase Inhibitor Human. In: Micromedex [online database]. Greenwood Village, CO: Truven Health Analytics (accessed 2015 Aug 18).
6. American Thoracic Society/European Respiratory Society statement: standards for the diagnosis and management of individuals with alpha-1 antitrypsin deficiency. *Am J Respir Crit Care Med.* 2003;168:818-900.
7. Stoller JK. Clinical manifestations, diagnosis, and natural history of alpha-1 antitrypsin deficiency. In: UpToDate [internet database]. Barnes PN, Hollingsworth H eds. Waltham, MA: UpToDate. Updated 2014 Sep 08 (accessed 2015 Aug 18).
8. Stoller JK. Treatment of alpha-1 antitrypsin deficiency. In: UpToDate [internet database]. Barnes PJ, Hollingsworth H eds. Waltham, MA: UpToDate. Updated 2015 Jul 02 (accessed 2015 Aug 18).
9. Izaguirre DE. Alpha1-antitrypsin deficiency. In: Medscape [internet database]. Byrd RP ed. New York, NY: WebMD LLC. Updated 2014 Sep 24 (accessed 10 Aug 2015).