Premier Health Plan

POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.131.E (B)*
REVISION DATE: *02/18*

POLICY TITLE: ***Alpha$_1$-Proteinase Inhibitors: Aralast NP™, Glassia™, Prolastin®, Prolastin-C®, Zemaira®***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2010 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Alpha$_1$ Proteinase Inhibitors.

Aralast NP is indicated for chronic augmentation therapy in patients having congenital deficiency of alpha1-proteinase inhibitor (alpha1-PI) with clinically evident emphysema.

Glassia is is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to congenital deficiency of alpha1-proteinase inhibitor (alpha1-PI).

Prolastin is indicated for chronic replacement therapy of individuals having congenital deficiency of alpha1-PI (alpha1-antitrypsin deficiency) with clinically demonstrable panacinar emphysema.

Prolastin-C is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to deficiency of alpha1-proteinase inhibitor (alpha1-antitrypsin deficiency).

Zemaira is indicated for chronic augmentation and maintenance therapy in individuals with alpha1-PI deficiency and clinical evidence of emphysema.

The recommendations are based upon the American Thoracic Society/European Respiratory Society Statement.

DEFINITIONS

Alpha1- Antitrypsin Deficiency[1-4] - a rare genetic condition characterized by low levels of serum alpha1-antitrypsin (AAT). AAT is a serine protease inhibitor that inhibits neutrophil elastase (NE). Neutrophil elastase degrades elastin and other extracellular matrix components. The imbalance between the AAT and NE increases the risk of emphysema. AAT deficiency also increases the risk of liver disease and several other conditions.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Aralast NPTM, GlassiaTM, Prolastin®, Prolastin-C®, Zemaira®, are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Aralast NP, Glassia, and Zemaira are subject to the preferred medical drug list program. This program applies to the alpha1-proteinase inhibitor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Alpha1-Proteinase Inhibitor Products

	Product(s)
Preferred	• Prolastin-C (alpha1-proteinase inhibitor [human])
Non-Preferred	• Aralast NP (alpha1-proteinase inhibitor [human]) • Glassia (alpha1-proteinase inhibitor [human]) • Zemaira (alpha1-proteinase inhibitor [human])

Requests for a non-preferred drug must meet one of the following exception criteria in addition to clinical criteria:

II. EXCEPTION CRITERIA (*Use for Aralast NP/Glassia/Zemaira Requests Only*)

Coverage for a non-preferred product is provided when the member has experienced a documented intolerable adverse event to the preferred product.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the clinical criteria listed under the respective diagnosis:

- Must be prescribed by or in consultation with a pulmonologist
- Must be age 18 years or older
- Must have a confirmed diagnosis of congenital alpha1-antitrypsin deficiency with clinically evident emphysema or airflow obstruction
- Must have an alpha1-antitrypsin phenotype of PI*ZZ, PI*ZNull or PI*NullNull
- Must have a baseline (pretreatment) serum alpha1-antitrypsin concentration of less than 11µmol/L as documented by either of the following:
    - Less than 50mg/dL as determined by nephelometry
    - Less than 80mg/dL as determined by radial immunodiffusion
- Must be a non-smoker
- Must not have selective IgA deficiencies with known antibodies against IgA (anti-IgA antibodies)

Reauthorization Criteria:
All prior authorization renewals are reviewed on an annual basis to determine the

Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Silverman EK, Sandhaus RA. Clinical practice. Alpha$_1$-antitrypsin deficiency. N Engl J Med. 2009 Jun 25;360(26):2749-57.
2. 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.
3. Fairbanks KD, Tavill AS. Liver disease in alpha 1-antitrypsin deficiency: a review. Am J Gastroenterol. 2008 Aug;103(8):2136-41
4. Tirado-Conde G, Lara B, Miravitlles M. Augmentation therapy for emphysema due to alpha-1-antitrypsin deficiency. Ther Adv Respir Dis. 2008 Feb;2(1):13-21.
5. Aralast NP (alpha$_1$-proteinase inhibitor [human]) package insert. Westlake Village, CA: Baxter Healthcare Corporation. May 2007.
6. Zemaira (alpha1-proteinase inhibitor, human) package insert. Kankakee, IL: CSL Behring LLC, January 2007.
7. Prolastin (alpha1-proteinase inhibitor [human]) package insert. Research Triangle Park, NC: Talecris Biotherapeutics, Inc. June 2008.
8. Prolastin-C (alpha1-proteinase inhibitor [human]) package insert. Research Triangle Park, NC: Talecris Biotherapeutics, Inc. October 2009.
9. Glassia [package insert]. Westlake Village, CA: Baxter Healthcare; August 2010.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Preferred Product Update (effective 4/1/18)	*02/18*