RX.PA.004.CCH ALPHA$_1$ PROTEINASE INHIBITORS (HUMAN)

The purpose of this policy is to define the prior authorization process for Aralast NP, Glassia, Prolastin-C, and Zemaira.

Aralast NP is indicated for chronic augmentation therapy in patients having congenital deficiency of alpha$_1$-proteinase inhibitor (alpha$_1$-PI) with clinically evident emphysema.

Glassia is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to congenital deficiency of alpha1-proteinase inhibitor (alpha$_1$-PI).

Prolastin-C is indicated for chronic replacement therapy of individuals having congenital deficiency of alpha$_1$-PI (alpha$_1$-antitrypsin deficiency) with clinically demonstrable panacinar emphysema.

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

DEFINITIONS

Alpha$_1$- Antitrypsin Deficiency – 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 Medical Policy Committee.

The drugs, Aralast NP, Glassia, Prolastin-C, and Zemaira, are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be prescribed by, or in consultation with, a pulmonologist
- Must be age 18 years or older
- Must have a confirmed diagnosis of congenital alpha$_1$-antitrypsin deficiency with clinically evident emphysema or airflow obstruction
- Must have an alpha$_1$-antitrypsin phenotype of PI*ZZ, PI*ZNull or PI*NullNull
- Must have a baseline (pretreatment) serum alpha$_1$-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 immunoglobulin (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, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J0256	Aralast NP, Prolastin-C, Zemaira	INJECTION, ALPHA 1-PROTEINASE INHIBITOR (HUMAN), NOT OTHERWISE SPECIFIED, 10 MG
J0257	Glassia	Injection, alpha 1 proteinase inhibitor (human), (GLASSIA), 10 mg

References:

1. Silverman EK, Sandhaus RA. Clinical practice. Alpha1-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 (alpha1-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.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	XX/XX

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.

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior

authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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