Alpha-1 Proteinase Inhibitors (Prolastin-C®, Zemaira®)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2016
Revision Date: September 27, 2023
Review Date: September 20, 2023
Line of Business: Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Zemaira intravenous solution
Prolastin-C intravenous powder for solution
Prolastin-C intravenous solution

Listed Indications

Congenital Alpha1-antitrypsin Deficiency

Congenital Alpha1-antitrypsin Deficiency

Does the member meet all of the following criteria?	
Criteria #1	The member has a diagnosis of congenital alpha1-antitrypsin deficiency with clinically evident emphysema and chronic replacement therapy is needed.
Criteria #2	The member has an alpha1-antitrypsin phenotype of PiZZ, PiZ(null), or Pi (null, null) or phenotypes associated with serum alpha 1-antitrypsin concentrations of less than 57mg/dL if/when measured by laboratories using nephelometry instead of radial immunodiffusion.Otherwise, a deficiency is shown at 80mg/dL. (These products should not be used in individuals with the PiMZ or PiMS phenotypes of alpha1-antitrypsin deficiency because these individuals appear to be at small risk of developing clinically evident emphysema.)
Criteria #3	Member has had previous treatment, contraindication, or intolerance to both of the following: Aralast NP AND Glassia.
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	IgA deficient members or presence of antibodies against IgA.
Approval Duration	
Initial	Alpha-1 Proteinase Inhibitors (Prolastin-C, Zemaira) will be approved in plan year durations.

Back to top

Background

This is a prior authorization policy about Alpha-1 Proteinase Inhibitors (Prolastin-C, Zemaira).

Alpha-1 antitrypsin (a1-PI) deficiency is a chronic and hereditary disorder. It usually manifests in the third or fourth decades of life. The panacinar emphysema that develops is usually worse in the lower areas of the lung. The pathogenesis of emphysema in patients with this deficiency is not well understood. Alpha-1 Proteinase Inhibitors (Prolastin-C, Zemaira) are products that work to replace the anti-elastase activity that is missing in patients with a1-PI deficiency.

Some other key points include: Alpha1-PI is not indicated as therapy for lung disease patient in whom congenital alpha1-PI is not established. In some adults, alpha1-antitrypsin deficiency is complicated by cirrhosis or panniculitis.

Alpha-1 Proteinase inhibitors are contraindicated in IgA deficient patients with antibodies against IgA, since these products may contain trace amounts of IgA and cause an increased risk for severe hypersensitivity.

The long-term effects of chronic replacement therapy with alpha1-PI in individuals having emphysema due to alpha1-antitrypsin deficiency are not known because of inadequate clinical data (the number of patients is small and the course of disease is variable and slowly progressive).

	PROLASTIN-C	ARALAST NP	ZEMAIRA	GLASSIA
Entered market	February 1988	May 2003	July 2003	October 2010
Marketed by	Talecris Biotherapeutics	Baxter Healthcare	CSL Behring	Kamada Ltd.
Recommended dose	60mg/kg IV weekly	60mg/kg IV weekly	60mg/kg IV weekly	60 mg/kg IV weekly
How Supplied	1G/50ml and 0.5G/50ml	1G/50ml and 0.5G/50ml	1G/20ml vial	1G/50ml vial
Quantity needed for 28 Day Supply (90kg male)	1200ml (24 vials) or 2160ml (44 vials)	1200ml (24 vials) or 2160ml (44 vials)	480 ml or 24 vials	1200 ml or 24 vials
Storage	Refrigerated 2-8° C/36–46° F or at temperatures not to exceed 25° C or 77° F Do not freeze	Refrigerated 2–8° C/35–46° F or at temperatures not to exceed 25° C or 77° F Use product removed from refrigeration within one month Do not freeze	Up to 25°C or 77°F Do not freeze	Refrigerated 2-8° C/36–46° F Do not freeze Brief excursions to room temperature are acceptable
Dilutant (sterile water)	20ml for 1000mg vial	25ml 500mg vial 50ml 1,000mg vial	20ml 1,000mg vial	None (comes as a liquid ready to use). Volume of product 50ml for 1000mg vial
Infusion rate	0.08 ml/kg per min	0.08 ml/kg per min	0.08 ml/kg per min	0.2 ml/kg per min
Infusion time (approximate)	15 minutes	15 minutes	15 minutes	15 minutes
Contraindications	Individuals with known selective IgA deficiency with antibodies against IgA	Individuals with known selective IgA deficiency (< 15mg/dl) with antibodies against IgA	Individuals with known selective IgA deficiency with antibodies against IgA	Individuals with known selective IgA deficiency with antibodies against IgA
Common side effects	Chills, malaise, headache, rash, hot flush, pruritis	Headache, somnolence, chills, fever, vasodilation, pruritus, (itching) rash, abnormal vision, chest pain, increased cough, dyspnea	Asthenia (weakness) injection site pain, dizziness, headache, paresthesia (abnormal skin sensations) and Pruritis (itching)	Headache, dizziness
Viral inactivation processes	Solvent detergent Nanofiltration	Solvent detergent Nanofiltration	Pasteurization Dual ultra-filtration	Solvent detergent Nanofiltration
Number for reporting adverse events	800-520-2807	888-675-2762	800-504-5434	866-GLASSIA

Alpha-1 Proteinase Inhibitors (Prolastin-C, Zemaira) are lyophilized preparations of purified human alpha1-proteinase inhibitors (a1-PI), also known as alpha1-antitrypsin.

These products inhibit neutrophil elastase (NE) which degrades protein components of the alveolar walls. Patients with a1-PI deficiency have little protection from the harmful effects of NE. Severe forms of this deficiency lead to panacinar emphysema which significantly shortens life expectancy.

Alpha-1 Proteinase Inhibitors (Prolastin-C, Zemaira) are indicated for chronic augmentation and maintenance therapy of individuals having

congenital deficiency of a1-PI with clinically demonstrable panacinar emphysema.

Alpha-1 Proteinase Inhibitors (Prolastin-C, Zemaira) are available in vials containing the labeled amount of functionally active a1-PI, usually 0.5gm or 1.0gm in powder form that must be reconstituted before use.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Prolastin-C; Zemaira; infusion; Alpha-1 Proteinase inhibitors; antitrypsin; chronic augmentation therapy; chronic replacement therapy; pharmacy

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; URL: http://www.clinicalpharmacology.com Updated Periodically
2. Lexi-Comp [database online]. Hudson, OH Lexi-comp, Inc.: URL http://online.lexi.com Updated Periodically
3. Micromedex Healthcare Series: DRUGDEX. Thomson Micromedex, Greenwood Village, CO. Updated Periodically
4. Prolastin-C [package insert] Talecris Biotherapeutics, Inc.; Research Triangle Park, NC. 27709 January 2022.
5. Zemaira [package insert] CSL Behring LLC. Kankakee, IL 60901. Revised April 2013.

Disclaimer	State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.