Medical Policy

Alpha-1 Proteinase Inhibitors Infusion Therapy Aralast NP™ Glassia™ Prolastin®-C Zemaira®	
MEDICAL POLICY NUMBER	Med_Clin_Ops_081
ORIGINAL EFFECTIVE DATE	January 1, 2021
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan (no policy revisions made) policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Alpha-1-Proteinase Inhibitors infusion therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Aralast NP, Glassia, Prolastin-C, and Zemaira will be provided for 12 months and may be renewed.
Dosing Limitation: 60 mg/kg by intravenous (IV) infusion administered once every 7 days

A. Patient has a documented diagnosis of emphysema confirmed with pulmonary function

testing; **AND**

B. Patient has a documented diagnosis of alpha-1-antitrypsin (ATT) deficiency confirmed by **all** of the following:
    a. Presence AAT deficiency with PiZZ, PiZ (null) or Pi (null,null) phenotypes
    b. Presence of AAT deficiency and clinical evidence of panacinar emphysema
    c. Low serum AAT concentration (≤ 11 uM/L [35% of normal] or ≤ 80 mg/dL [measured by radial immunodiffusion] or ≤ 0.8 g/L [measured by nephelometry]; **AND**
C. Patient is a current non-smoker; **AND**
D. Patient will continue optimal conventional treatment for emphysema (e.g., bronchodilators, supplemental oxygen if necessary).

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Immunoglobulin A (IgA) deficient patients with antibodies against IgA
3. Patients with a history of anaphylaxis or other severe systemic reaction to Alpha1-PI products

BACKGROUND

Alpha1-proteinase inhibitors (Aralast NP™, Glassia™, Prolastin®-C, and Zemaira®) are proven for chronic augmentation and maintenance therapy of patients with emphysema due to congenital deficiency of alpha1-proteinase inhibitor (A1-PI), also known as alpha1-antitrypsin (AAT) deficiency.

DEFINITIONS

1. PROLASTIN -C (Alpha -Proteinase Inhibitor [Human]) Lyophilized Powder for Solution for Intravenous Injection. Initial U.S. Approval: 1987
2. ARALAST NP [Alpha1-Proteinase Inhibitor (Human)] For Intravenous Use. Lyophilized Powder for Solution for Injection. Initial U.S. Approval: 2002
3. ZEMAIRA (alpha -proteinase inhibitor (human)) lyophilized powder for reconstitution for intravenous use. Initial U.S. Approval: 2003
4. GLASSIA [Alpha -Proteinase Inhibitor (Human)] Injection Solution - For Intravenous Use Only. Initial U.S. Approval: 2010

CODING

Applicable NDC Codes	
00944-2814-01	ARALAST NP, alpha-1 proteinase inhibitor human 1 mg
00944-2815-01	ARALAST NP, alpha-1 proteinase inhibitor human 1 mg
00944-2884-01	GLASSIA, alpha-1 proteinase inhibitor human 1 mg
13533-0701-01	PROLASTIN-C, alpha-1 proteinase inhibitor human 1 mg

13533-0703-10	PROLASTIN-C, alpha-1 proteinase inhibitor human 1 mg
13533-0705-01	PROLASTIN-C, alpha-1 proteinase inhibitor human 1 mg
13533-0700-11	PROLASTIN-C, alpha-1 proteinase inhibitor human 1 mg
13533-0700-02	PROLASTIN-C, alpha-1 proteinase inhibitor human 1 mg
13533-0702-11	PROLASTIN-C, alpha-1 proteinase inhibitor human 1 mg
00053-7201-02	ZEMAIRA, alpha-1 proteinase inhibitor human 1 mg

Applicable Procedure Code	
J0256	Injection, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg
J0257	Injection, alpha 1 proteinase inhibitor (human), (glassia), 10 mg

Applicable ICD-10 Codes	
E88.01	Alpha-1-antitrypsin deficiency
J43.0	Unilateral pulmonary emphysema [MacLeod's syndrome]
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified

EVIDENCE BASED REFERENCES

1. Product Information: ARALAST NP intravenous injection, alpha1-proteinase inhibitor (human) intravenous injection. Baxalta US Inc (per manufacturer), Westlake Village, CA, 2015.
2. Product Information: GLASSIA intravenous injection, alpha1-proteinase inhibitor (human) intravenous injection. Baxalta US Inc (per manufacturer), Lexington, MA, 2017
3. Product Information: PROLASTIN(R)-C IV injection, alpha1-proteinase inhibitor (human) IV injection. Talecris Biotherapeutics, Inc, Research Triangle Park, NC, 2009.
4. Product Information: Zemaira(R) IV powder for solution, Alpha1-Proteinase Inhibitor (Human) IV powder for solution. CSL Behring LLC (per manufacturer), Kankakee, IL, 2019.

POLICY HISTORY

Original Effective Date	January 1, 2021
Revised Date	November 8, 2022 – Annual Review and approval (no policy revisions made); P&T Approved March 1, 2023 – Adopted by MA UMC January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee