Medical Policy:

Alpha-1-Proteinase Inhibitors Infusion Therapy

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.207	August 9. 2023	January 2018

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This 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. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Related Medical Guideline

Off-Label Use of FDA-Approved Drugs and Biologicals

Length of Authorization

Coverage will be provided for twelve months and may be renewed.

Dosing Limits [Medical Benefit]

Indication	Dose
All Indications	60 mg/kg by intravenous (IV) infusion administered once every 7 days

Guideline

Applicable Products

Aralast NP®

Glassia®
Prolastin®
Prolastin®-C
Zemaira®

I. Initial Approval Criteria

Alpha-1-Proteinase Inhibitors are considered medically necessary for **emphysema secondary to alpha-1-antitrypsin (ATT) deficiency** when the following criteria are met; all:

1. Presence AAT deficiency with PiZZ, PiZ (null) or Pi (null,null) phenotypes; **AND**
2. Presence of AAT deficiency and clinical evidence of panacinar emphysema **AND**
3. 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**
4. Patient has an FEV1 in the range of 30-65% of predicted; **AND**
5. Member is a non-smoker

II. Renewal Criteria

Coverage will be given for 12 months and is eligible for renewal when the following criteria is met:

1. Patient continues to meet INITIAL APPROVAL CRITERIA.
2. Positive response to treatment (defined by elevation of AAT levels above baseline and/or substantial reduction in deterioration-rate of lung function, as measured by percent-predicted FEV1)
3. Absence of unacceptable drug-toxicity (i.e., hypersensitivity reactions)

Limitations/Exclusions

1. Alpha-1-Proteinase Inhibitors are considered investigational and not medically necessary for any indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

Code	Description
J0256	Injection, alpha 1-proteinase inhibitor (human), Aralast, Prolastin, Zemaira not otherwise specified, 10 mg
J0257	Injection, alpha 1 proteinase inhibitor (human), (GLASSIA), 10 mg
S9346	Home infusion therapy, alpha-1-proteinase inhibitor (e.g., Prolastin); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

Applicable NDCs

Code	Description
00053-7201-02	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Zemaira)
00944-2815-01	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Aralast)
00944-2814-01	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Aralast)
00944-2803-03	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Aralast)

00944-2804-04	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Aralast)
13533-0705-01	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Prolastin)
13533-0705-11	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Prolastin)
13533-0700-02	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Prolastin)
13533-0703-10	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Prolastin)
13533-0702-11	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified (Prolastin)
00944-2884-02	Injection, alpha 1 proteinase inhibitor (human), (Glassia), 10 mg
00944-2884-01	Injection, alpha 1 proteinase inhibitor (human), (Glassia), 10 mg

ICD-10 Diagnoses

Code	Description
E88.01	Alpha-1-antitrypsin deficiency

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/9/2023	Annual Review: Emphysema secondary to alpha-1-antitrypsin (ATT) deficiency Initial Criteria: Added: "Patient has an FEV1 in the range of 30-65% of predicted; **AND"** Removed ICD- 10 Codes: J43.0, J43.1, J43.2, J43.8 and J43.9
EmblemHealth & ConnectiCare	3/23/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	03/30/2020	Annual Review: MG.MM.PH.C27b updated to MG.MM.PH.207
EmblemHealth & ConnectiCare	04/01/2018	Added dose and administration table, Added length of authorization, Extended length of renewal approval from 6 months to 12 months
EmblemHealth & ConnectiCare	01/12/2018	Added prerequisite that member must be a non-smoker

References

1. Glassia [package insert]. Westlake Village, CA; Baxter Healthcare; March 2014. Accessed May 2015.
2. Zemaira [package insert]. Kankakee, IL; CSL Behring LLC; April 2013. Accessed May 2015.
3. Aralast NP [package insert]. Westlake Village, CA; Baxter Healthcare; March 2014. Accessed May 2015.
4. Prolastin [package insert]. Research Triangle Park, NC; Talecris Biotherapeutics; June 2008. Accessed May 2015.
5. Prolastin-C [package insert]. Research Triangle Park, NC; Grifols Therapeutics, Inc; November 2013. Accessed May 2015.
6. American Thoracic Society/European Respiratory Society Statement: Standards for the Diagnosis and Management of Individuals with Alpha-1 Antitrypsin Deficiency approved by the ATS Board of Directors, December 2002, and by the ERS Executive Committee, February 2003.

http://www.sppneumologia.pt/uploads/files/gruposdeestudo/Grupo%20de%20Estudos%20de%20D%C3%A9fice%20de%20Alfa1%20Antitripsina/ATS_ERS%20guidelines.pdf. Accessed January 18, 2017.

7. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Vancouver, WA: Global Initiative for Chronic Obstructive Lung Disease (GOLD); 2011.
8. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L32013). Centers for Medicare & Medicaid Services, Inc. Updated on 04/21/2015 with effective date 05/01/2015. Accessed May 2015.