Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Alpha$_1$-Proteinase Inhibitors

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink^{SM} – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Aralast NP (alpha1-Proteinase Inhibitor (Human)) is an Alpha1-Proteinase Inhibitor (Human) (Alpha1-PI) indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha1-PI. Aralast NP increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. The effect of augmentation therapy with any Alpha1-PI, including Aralast NP, on pulmonary exacerbations and on the progression of emphysema in alpha1-antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with Aralast NP are not available. Aralast NP is not indicated as therapy for lung disease in patients whom severe Alpha1-PI deficiency has not been established.

Glassia (alpha1-Proteinase Inhibitor (Human)) is an Alpha1-Proteinase Inhibitor (Human) (Alpha1-PI) indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). The effect of augmentation therapy with any Alpha -PI, including Glassia, on pulmonary exacerbations and on the progression of emphysema in alpha -antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with Glassia are not available. Glassia is not indicated as therapy for lung disease in patients in whom severe Alpha -PI deficiency has not been established.

Prolastin-C (alpha1-proteinase inhibitor [human]) is an Alpha1-Proteinase Inhibitor (Human) (Alpha1-PI) indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Prolastin-C increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha -PI. The effect of augmentation therapy with any Alpha-PI, including Prolastin-C, on pulmonary exacerbations and on the progression of emphysema in Alpha -PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with Prolastin-C are not available. Prolastin-C is not indicated as therapy for lung disease in patients in whom severe Alpha-PI deficiency has not been established.

Zemaira (alpha1-proteinase inhibitor [human]) is an alpha1-proteinase inhibitor (A1-PI) indicated for chronic augmentation and maintenance therapy in adults with A1-PI deficiency and clinical evidence of emphysema. The effect of augmentation therapy with Zemaira or any A1-PI product on pulmonary exacerbations and on the progression of emphysema in A1-PI deficiency has not been demonstrated in randomized, controlled clinical studies. Zemaira is not indicated as therapy for lung disease patients in whom severe A1-PI deficiency has not been established.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Alpha1-proteinase Inhibitors for Members when the following criteria are met:

Initial Authorization Criteria

1. Patient is 18 years of age or older

AND

2. Documented diagnosis of congenital alpha1-antitrypsin deficiency

AND

3. Documentation of obstructive lung disease as defined by either of the following:
    a. A forced expiratory volume in one second (FEV1) of 30 to 65% of predicted value prior to initiation of therapy
    b. Forced expiratory volume in one second (FEV1) greater than 65% of predicted, but declines by greater than 100 mL/year

AND

4. Prescribed by or in consultation with a pulmonologist

AND

5. Documentation of pretreatment circulating serum concentration of alpha1-antitrypsin level <11 µmol/L (which corresponds to <80 mg/dl if measured by radial immunodiffusion or <57 mg/dl if measured by nephelometry)

Reauthorization Criteria

1. Patient is 18 years of age or older

AND

2. Documented diagnosis of congenital alpha1-antitrypsin deficiency

AND

3. Prescribed by or in consultation with a pulmonologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
    a. Slowed progression of emphysema as evidenced by annual spirometry testing
    b. Decrease in frequency, duration or severity of pulmonary exacerbations

Limitations

- Authorizations will be provided in 12-month intervals.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0256	Injection, alpha 1-proteinase inhibitor, human, 10 mg, not otherwise specified
J0257	Injection, alpha 1 proteinase inhibitor (human), (Glassia), 10 mg

References

1. Aralast NP [package insert]. Westlake Village, CA: Baxalta US Inc.; May 2025.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; February 2025.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2022.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; January 2024.
5. 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.
6. Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. Chronic Obstr Pulm Dis. 2016;3(3):668-82.

7. Stoller JK. Treatment of alpha-1 antitrypsin deficiency. UpToDate. September 19, 2023. Accessed online October 25, 2023.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 21, 2022, year: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Add Reauthorization Criteria. Authorizations will be approved in 12-month intervals. Added provider specialty requirements. Removed the requirement for confirming a diagnosis of congenital alpha1-antitrypsin deficiency by phenotype. Updated the definition of obstructive lung disease by requiring the FEV1 to be greater than 65% of predicted and declines by greater than 100 mL/year (eff 2/1/2024).
- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- November 12, 2024: Administrative update to the overview section to reflect updated indications and limitations of use.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 2025 E-Vote: Administrative update to the overview section to reflect updated indications and limitations of use. (effective 1/1/2026)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.