

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Alpha ₁ -Proteinase Inhibitor (Aralast NP, Glassia, Prolastin C, Zemaira [human])
BENEFIT TYPE	Medical (Pharmacy allowed for Glassia)
STATUS	Prior Authorization Required

Alpha₁-proteinase inhibitor (alpha₁ antitrypsin) from pooled human plasma donors acts as augmentation therapy for maintenance treatment in adults with clinical evidence of emphysema due to severe alpha₁-antitrypsin deficiency (AATD). The available products are Aralast NP, Glassia, Prolastin C, and Zemaira, with none of them being clinically preferred over the others. Prolastin was the first, approved by the FDA in 1987 (and later replaced by Prolastin C). The goal of this therapy is to restore and maintain alpha₁-antitrypsin to protective levels and slow the progression of lung damage and emphysema by inhibiting proteases such as neutrophil elastase.

Alpha-1 antitrypsin deficiency (AATD) is a hereditary disorder caused by pathogenic mutations in the SERPINA1 gene responsible for producing cts

If all the above requirements are met , the medication will be approved for an additional 12 months .

CareSource considers Alpha ₁-Proteinase Inhibitor (Aralast NP, Glassia, Prolastin C, Zemaira [human]) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off Label policy.

DATE	ACTION/DESCRIPTION
07/14/2020	Transferred to new template; revised and updated content.
06/29/2023	Transferred to new template. Updated and added references. Removed lower FEV limit and rate of decline. Added liver transplant exclusion.

References:

1. 2021 Georgia Code Title 33 Insurance Chapter 20A - Managed Health Care Plans Article 2 - Patient's Right to Independent Review § 33-20A-31 Definitions. Justia US Law. Accessed April 25, 2023. <https://law.justia.com/codes/georgia/2021/title-33/chapter-20a/article-2/section-33-20a-31/>.
2. Stoller JK. Treatment of alpha-1-antitrypsin deficiency. UpToDate. <http://www.uptodate.com>. Updated July 13, 2020. Accessed July 13,2020.
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