POLICY Document for Aralast-NP

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

**Site of Care Criteria**

**Administration of Intravenous Alpha-1-Antitrypsin**

Aralast-NP, Glassia, Prolastin-C, Zemaira

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of alpha-1-antitrypsin drugs in an outpatient hospital setting for up to 2 doses when a member is new to therapy.

This policy provides coverage for administration of alpha-1-antitrypsin in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.

B. The member has developed IgA antibodies which increases the risk for infusion related reactions.

C. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).

D. The member has severe venous access issues that require the use of a special intervention.

E. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.

F. Alternative infusion sites are not available.

G. The member is less than 21 years of age or 65 years of age or older.

For situations where administration of alpha-1-antitrypsin does not meet the criteria for outpatient hospital infusion, coverage for alpha-1-antitrypsin is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion.
Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT
Alpha₁-Proteinase Inhibitors

ARALAST NP (alpha₁-proteinase inhibitor [human])
GLASSIA (alpha₁-proteinase inhibitor [human])
PROLASTIN-C (alpha₁-proteinase inhibitor [human])
ZEMAIRA (alpha₁-proteinase inhibitor [human])

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Aralast NP
   Chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of alpha₁-proteinase inhibitor (alpha₁-antitrypsin deficiency)

2. Glassia
   Chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of alpha₁-proteinase inhibitor (alpha₁-antitrypsin deficiency)

3. Prolastin-C
   Chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha₁-proteinase inhibitor (alpha₁-antitrypsin deficiency)

4. Zemaira
   Chronic augmentation and maintenance therapy in adults with alpha₁-proteinase inhibitor deficiency and clinical evidence of emphysema

All other indications are considered experimental/investigational and are not a covered benefit.
II. CRITERIA FOR INITIAL APPROVAL

Indefinite authorization may be granted for treatment of alpha1-antitrypsin (AAT) deficiency when all of the following criteria are met:

1. The member has clinically evident emphysema.
2. The member’s pretreatment serum AAT level is less than 11 micromol/L (80 mg/dl by radial immunodiffusion or 50 mg/dl by nephelometry).
3. The member’s pretreatment post-bronchodilation forced expiratory volume in 1 second (FEV₁) is greater than or equal to 25% and less than or equal to 80% of the predicted value.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

REFERENCES:

SECTION 1

SECTION 2