A. SUBJECT

Alpha 1-Proteinase Inhibitor Injection
- Aralast
- Glassia
- Prolastin
- Zemaira

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member’s specific benefit plan.

The intent of the Alpha 1-proteinase inhibitor injection program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines, and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A
D. POLICY
CareSource will approve the use of alpha-1-proteinase inhibitor, and consider their use as medically necessary with emphysema due to AAT deficiency when ALL of the following criteria are met:

Alpha-1 proteinase inhibitor may be indicated when ALL of the following are present:

- Age 18 years or older
- Alpha-1 proteinase inhibitor serum level less than 11 micromoles/L (59 mg/dL)
- Continued optimal conventional treatment for chronic obstructive pulmonary disease (eg, bronchodilators, supplemental oxygen if necessary)
- Current nonsmoker for 6 or more months
- Alpha-1 antitrypsin deficiency with proteinase inhibitor ZZ phenotype
- Documented chronic obstructive pulmonary disease, as indicated by 1 or more of the following:
  - Baseline FEV₁ between 30% and 65% of predicted value
  - FEV₁ below 30% of predicted value in patient on chronic maintenance alpha-1 proteinase inhibitor therapy(8)
  - FEV₁ greater than 65% of predicted value and FEV₁ decline of 100 mL in 1 year
- Normal C-reactive protein level
- No selective IgA deficiency with accompanying anti-IgA antibodies

NOTE: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider’s office or hospital admission notes.

Refer to the product package insert for dosing, administration and safety guidelines.

All other uses of Alpha 1-proteinase inhibitor injections are considered experimental/investigational and therefore, will follow CareSource's off-label policy.

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE
HCPCS  
J0256 - Injection, alpha 1-proteinase inhibitor (human), not otherwise specified, 10 mg
J0257 - Injection, alpha 1 - proteinase inhibitor (human), (Glassia), 10 mg

CPT

PLACE OF SERVICE
Office, Outpatient, Home

**Preferred place of service is in the home

Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient’s medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member’s current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.
AUTHORIZATION PERIOD
Approved authorizations are valid for 1 year. Continued treatment may be considered when the member has shown biological response to treatment. ALL authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY
Date Issued: 01/18/2013
Date Reviewed: 01/18/2013, 02/14/2014
Date Revised: 02/14/2014 – Revised auth period
01/08/2015 – Alpha 1 serum level & FEV value changed

F. REFERENCES


“This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.”

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 11/15/2012