MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
01/18/2013	01/18/2016	01/08/2015

Policy Name	Policy Number
Alpha 1-Proteinase Inhibitor Injection	SRx-0002

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

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

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 FEV_1 between 30% and 65% of predicted value
    - FEV_1 below 30% of predicted value in patient on chronic maintenance alpha-1 proteinase inhibitor therapy(6)
    - FEV_1 greater than 65% of predicted value and FEV_1 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

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"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