



MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
01/18/2013	01/18/2017	01/14/2016
Policy Type		
Medical	Administrative	Payment

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.

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

- I. CareSource will approve the use of alpha-1-proteinase inhibitors, and consider their use as medically necessary with emphysema due to AAT deficiency when ALL of the following criteria are met:



- A. Alpha-1 proteinase inhibitor may be indicated when ALL of the following are present:
 - 1. Age 18 years or older
 - 2. Alpha-1 proteinase inhibitor serum level (ATT) when measured by rocket immunoelectrophoresis, radial immunodiffusion, or nephelometry, with the threshold
 - 3. Continued optimal conventional treatment for chronic obstructive pulmonary disease (eg, bronchodilators, supplemental oxygen if necessary)
 - 4. Current nonsmoker for 6 or more months
 - 5. Alpha-1 antitrypsin deficiency with PiZZ(proteinase inhibitor ZZ), PiZ(null), or Pi (null, null) phenotype
 - 6. Documented chronic obstructive pulmonary disease, as indicated by 1 or more of the following:
 - 6.1 Baseline FEV₁ between 30% and 65% of predicted value
 - 6.2 gi04001 Tw 0.976nFE(n)-12.2(e F)-5.4(E)-9.7(V)]TJ 199.32 5and6848 -0 0 6.48 240.48 523.2 0.28



[ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM217890.pdf](#). Accessed November 2012

18. National Collaborating Centre for Chronic Conditions. Chronic obstructive pulmonary disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. Thorax 2004;59 Suppl 1:1-232. (Reviewed March 2008). Available at: <http://www.guidelines.gov/content.aspx?id=23801> , Accessed November 2012
19. American Thoracic Society/European Respiratory Society Statement: Standards for the Diagnosis and Management of Individuals with Alpha-1 Antitrypsin Deficiency approved by the ATS Board of Directors, December 2002, and by the ERS Executive Committee, February 2003, accessed December 2009
20. ATS (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.

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