

Aralast® NP, Glassia®, Prolastin-C® and Zemaira® (alpha-1 proteinase inhibitor human)

When requesting Aralast® NP, Glassia®, Prolastin-C®, and Zemaira® (alpha-1 proteinase inhibitor human), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

- For chronic augmentation and maintenance therapy in individuals with clinically evident emphysema due to severe congenital deficiency of alpha-1 proteinase inhibitor (alpha-1 antitrypsin deficiency)¹⁻⁴

Approved Off-label Compendial uses⁵

- No off-label uses meet evidence standards

Coverage Guidelines

Congenital alpha-1 antitrypsin deficiency with clinically evident emphysema

The individual must meet **all** of the following criteria for approval:

- Clinically evident emphysema due to severe congenital alpha-1 antitrypsin deficiency^{1-4,6}
- Individual does **not** have immunoglobulin A (IgA) deficiency with antibodies against IgA¹⁻⁴
- Plasma alpha-1 antitrypsin (AAT) levels <11 micromol/L (80 mg/dL)⁷
- Airflow obstruction evidenced by forced expiratory volume in 1 second (FEV1) <80% of predicted⁷
- Nonsmoker or ex-smoker⁷

Approval duration: 12 months

Additional Information for Prescribers¹⁻⁴

- These therapies may carry a risk of transmitting infectious agents such as viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite manufacturing steps designed to minimize the risk of viral transmission.
- All infections thought by a physician possibly to have been transmitted by this product should be reported to the manufacturer or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References

1. Aralast® NP prescribing information. Westlake Village, CA: Baxalta US Inc.: Revised September 2016. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a9a5b46e-04da-41bd-bb5f-c4936b664fef>. Accessed February 6, 2017.
2. Glassia® prescribing information. Negev, Israel: Kamada Limited.: Revised June 2016. http://www.shirecontent.com/PI/PDFs/GLASSIA_USA_ENG.pdf. Accessed February 6, 2017.
3. Prolastin-C® prescribing information. Research Triangle Park, NC: Grifols Therapeutics Inc.: Revised August 2016. <http://www.prolastin.com/documents/5103363/0/prolastinPI/b436e646-0787-4aad-a3d5-b5e004cc92c6>. Accessed February 6, 2017.
4. Zemaira® prescribing information. Kankakee, IL: CSL Behring LLC.: Revised September 2015. <http://labeling.cslbehring.com/PI/US/Zemaira/EN/Zemaira-Prescribing-Information.pdf>. Accessed February 6, 2017.
5. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 6, 2017. <https://www.micromedexsolutions.com>.
6. Balduyck M, Odou MF, Zerimech F, et al. Diagnosis of alpha-1 antitrypsin deficiency: modalities, indications and diagnosis strategy. *Rev Mal Respir*. 2014;8:729-745. <https://www.ncbi.nlm.nih.gov/pubmed/25391508>. Accessed February 6, 2017.
7. Anon. 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. <http://www.atsjournals.org/doi/pdf/10.1164/rccm.168.7.818>. Accessed February 6, 2017.