

**ARALAST NP (alpha1-proteinase inhibitor [human])**  
**GLASSIA (alpha1-proteinase inhibitor [human])**  
**PROLASTIN-C (alpha1-proteinase inhibitor [human])**  
**ZEMAIRA (alpha1-proteinase inhibitor [human])**  
**Effective 01/01/2021**

|                              |   |                     |  |
|------------------------------|---|---------------------|--|
| <b>Plan</b>                  | <input checked="" type="checkbox"/> MassHealth<br><input type="checkbox"/> Commercial/Exchange                    | <b>Program Type</b> | <input checked="" type="checkbox"/> Prior Authorization                          |
| <b>Benefit</b>               | <input checked="" type="checkbox"/> Pharmacy Benefit<br><input checked="" type="checkbox"/> Medical Benefit (NLX) |                     | <input type="checkbox"/> Quantity Limit<br><input type="checkbox"/> Step Therapy |
| <b>Specialty Limitations</b> | This medication has been designated specialty and must be filled at a contracted specialty pharmacy.              |                     |  |
| <b>Contact Information</b>   | <b>Specialty Medications</b>  |                     |  |
|                              | All Plans   | Phone: 866-814-5506 | Fax: 866-249-6155  |
|                              | <b>Non-Specialty Medications</b>  |                     |  |
|                              | MassHealth  | Phone: 877-433-7643 | Fax: 866-255-7569  |
|                              | Commercial  | Phone: 800-294-5979 | Fax: 888-836-0730  |
|                              | Exchange  | Phone: 855-582-2022 | Fax: 855-245-2134  |
|                              | <b>Medical Specialty Medications (NLX)</b>  |                     |  |
|                              | All Plans   | Phone: 844-345-2803 | Fax: 844-851-0882  |
| <b>Exceptions</b>            | N/A   |                     |  |

**Overview**

Aralast NP, Glassia, Prolastin-C and Zemaira are human plasma alpha-1 antitrypsin (AAT) products used to elevate AAT levels in the blood and lung interstitial tissue in the lungs, AAT deficiency causes chronic obstructive pulmonary disease (i.e., emphysema and bronchiectasis). These products are indicated for long-term augmentation and maintenance therapy in adults with severe hereditary deficiency of alpha<sub>1</sub>-antitrypsin (AAT) with clinically evident emphysema.

**Coverage Guidelines**

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Aralast NP, Glassia, Prolastin-C or Zemaira, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

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.

**Continuation of Therapy**



All members requesting authorization for continuation of therapy must meet all initial authorization criteria.

### **Limitations**

Authorizations will be granted for 36 months

### **References**

1. Aralast NP [package insert]. Westlake Village, CA: Baxalta US Inc.; September 2015.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; June 2017.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; September 2017.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; September 2015.
5. 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.
6. Marciniuk DD, Hernandez P, Balter M, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: a Canadian Thoracic Society clinical practice guideline. *Can Respir J.* 2012;19:109-116.
7. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed (May 2020).

### **Review History**

11/18/2020 – Transitioned from SGM to Custom Criteria; split out MH vs. Commercial.

### **Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.