

Alpha-1 Proteinase Inhibitors (human)
**Aralast NP
 Glassia
 Prolastin-C
 Zemaira**
Effective January 1/1/2021

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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	
	Medical Specialty Medications (NLX)		
All Plans	Phone: 844-345-2803	Fax: 844-851-0882	
Exceptions	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 alpha₁-antitrypsin (AAT) with clinically evident emphysema.

Coverage Guidelines

Authorization may be granted for members new to the plan 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 members when all the following criteria have been met, and documentation is provided:

1. The member has a diagnosis of alpha 1-antitrypsin (AAT) deficiency
2. The member has clinically evident emphysema.
3. 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).
4. 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.

5. **For Aralast, NP, Glassia and Zemaira:** the member has had documented intolerance, inadequate response or contraindication to Prolastin-C.

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition.

Limitations

1. Initial approvals and Reauthorizations will be granted for 36 months

References

1. Aralast NP (alpha1-proteinase inhibitor, human) [prescribing information]. Lexington, MA: Baxalta US Inc; January 2019.
2. US Inc; January 2019.
3. Prolastin-C (alpha₁-proteinase inhibitor, human) [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics, Inc; August 2016.
4. NC: Grifols Therapeutics, Inc; August 2016.
5. Zemaira (alpha₁-proteinase inhibitor, human) [prescribing information]. Kankakee, IL: CSL Behring; April 2019.
6. April 2019.
7. Glassia (alpha₁-proteinase inhibitor, human) [prescribing information]. Westlake Village, CA: Baxalta US Inc; June 2016
8. US Inc; June 2016

Review History

11/18/2020-Updated: per 1/1/2021 strategy Prolastin C is the preferred agent. Changed all other products as non-preferred, changed approval duration from indefinite to 36 months: Nov P+T review.

