Mass General Brigham
Health Plan

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

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
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 alpha$_1$-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
2. US Inc; January 2019.
3. Prolastin-C (alpha$_1$-proteinase inhibitor, human) [prescribing information]. Research Triangle Park,
4. NC: Grifols Therapeutics, Inc; August 2016.
5. Zemaira (alpha$_1$-proteinase inhibitor, human) [prescribing information]. Kankakee, IL: CSL Behring;
6. April 2019.
7. Glassia (alpha$_1$-proteinase inhibitor, human) [prescribing information]. Westlake Village, CA: Baxalta
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.