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

<table>
<thead>
<tr>
<th>Plan</th>
<th>Benefit</th>
<th>Program Type</th>
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<tr>
<td>☐ MassHealth</td>
<td>☑ Pharmacy Benefit</td>
<td>☑ Prior Authorization</td>
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<td>☒ Commercial/Exchange</td>
<td>☑ Medical Benefit (NLX)</td>
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<td>☐ Step Therapy</td>
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Specialty Limitations
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

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<tr>
<td></td>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
<td>Fax: 866-249-6155</td>
</tr>
<tr>
<td></td>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
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<tr>
<td></td>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
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<td></td>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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<tr>
<td></td>
<td>All Plans</td>
<td>Phone: 844-345-2803</td>
<td>Fax: 844-851-0882</td>
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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 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 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
5. Glassia (alpha1-proteinase inhibitor, human) [prescribing information]. Westlake Village, CA: Baxalta
6. 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

**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.