### PHARMACY POLICY STATEMENT

**Ohio Medicaid**

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Aralast NP, Glassia, Prolastin C, Zemaira (alpha-1-proteinase inhibitor [human])</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J0256 (J0257 for Glassia)</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home/Office/Outpatient</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Products) QUANTITY LIMIT—See “Dosage allowed”</td>
</tr>
<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td>Click Here</td>
</tr>
</tbody>
</table>

Aralast NP, Glassia, Prolastin C, and Zemaira are **non-preferred** products and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

**ALPHA\textsubscript{1}-ANTITRYPSIN DEFICIENCY (AATD)**

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist; AND
3. Member has a diagnosis of clinically evident emphysema due to severe AATD; AND
4. Member is a never-smoker or has been a non-smoker for at least 3 months; AND
5. Member is in compliance with any prescribed supportive therapy (at least one)\textsuperscript{1,4} (e.g., bronchodilators, pulmonary rehabilitation, oxygen); AND
6. Chart notes must include lab reports showing ALL of the following\textsuperscript{1}:
   a) Pre-treatment alpha\textsubscript{1}-antitrypsin (AAT) serum level less than 11micromol/L or equivalent;
   b) High risk genotype (e.g. P\textsuperscript{i}ZZ, P\textsuperscript{i}ZNull, P\textsuperscript{i}NullNull);
   c) Pre-treatment FEV\textsubscript{1} is 30-65\%\textsubscript{5} of predicted or has declined at a rate of 100mL/yr or more.
7. **Dosage allowed**: 60mg/kg IV once weekly.

**If member meets all the requirements listed above, the medication will be approved for 6 months.**

For **reauthorization**:

1. Member continues to abstain from smoking; AND
2. At least ONE of the following:
   a) AAT level at or above protective threshold (11 micromol/L);  
   b) Slowed rate of FEV\textsubscript{1} decline per spirometry results;  
   c) CT densitometry report or high resolution computed tomography (HRCT) demonstrates slowed progression of anatomic lung disease.\textsuperscript{3,4}

**If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.**

CareSource considers alpha\textsubscript{1}-proteinase inhibitor not medically necessary for the treatment of the diseases that are not listed in this document.
References:


Effective date: 10/20/2020
Revised date: 07/14/2020