### Market Applicability

<table>
<thead>
<tr>
<th>Market</th>
<th>DC</th>
<th>FL &amp; FHK</th>
<th>FL MMA</th>
<th>FL LTC</th>
<th>GA</th>
<th>KS</th>
<th>KY</th>
<th>MD</th>
<th>NJ</th>
<th>NV</th>
<th>NY</th>
<th>TN</th>
<th>TX</th>
<th>WA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable</td>
<td>X</td>
<td>X</td>
<td>NA</td>
<td>NA</td>
<td>X</td>
<td>NA</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>NA</td>
<td>NA</td>
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</tbody>
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*FHK- Florida Healthy Kids

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**Alpha-1 Proteinase Inhibitors**  
**CG-DRUG-92**

### Override(s) & Approval Duration

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
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<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 Year</td>
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### Medications

- Aralast NP (alpha-1 proteinase inhibitor)
- Glassia (alpha-1 proteinase inhibitor)
- Prolastin-C (alpha-1 proteinase inhibitor)
- Zemaira (alpha-1 proteinase inhibitor)

### APPROVAL CRITERIA

Augmentation therapy with intravenous alpha-1 proteinase inhibitors (Aralast NP, Glassia, Prolastin-C, and Zemaira) may be approved for adults with congenital alpha-1 antitrypsin deficiency when all of the following criteria are met:

I. Confirmation that alpha-1 antitrypsin level is less than or equal to 11 µmol/L*; **AND**

II. Individual is currently a non-smoker; **AND**

III. Individual has clinically evident emphysema; **AND**

IV. One of the following:
   A. Moderate airflow obstruction is evidenced by forced expiratory volume (FEV₁) of 30-65% of predicted value, prior to initiation of therapy; **OR**
   B. Individual has a rapid decline in lung function as measured by a change in FEV₁ greater than 120 ml/year.

*Note: Serum levels of alpha-1 antitrypsin can be assessed by immunodiffusion, immune turbidimetry, rocket immunoelectrophoresis, or nephelometry. Given the variations in testing modalities, it is essential to know the range of normal values for the test used in a given individual. For example, 11 µmol/L is approximately equivalent to a commercial standard level of 80 mg/dL by immunodiffusion or 57 mg/dL by nephelometry.

Use of alpha-1 proteinase inhibitors (Aralast NP, Glassia, Prolastin-C, and Zemaira) may **not** be approved for individuals with IgA antibodies.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.  
CRX-ALL-0290-18
Market Applicability

| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
|--------|----|---------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | NA | NA |

*FHK- Florida Healthy Kids

Use of alpha-1 proteinase inhibitors (Aralast NP, Glassia, Prolastin-C, and Zemaira) is considered investigational and may not be approved when the criteria above are not met and for all other indications including, but not limited to:

I. Bronchopulmonary dysplasia;
II. Cystic fibrosis;
III. Diabetes mellitus;
IV. Graft versus host disease (GVHD);
V. Post-lung transplantation for acute rejection or infection episodes.

State Specific Mandates

<table>
<thead>
<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
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<tbody>
<tr>
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Key References:


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