Alpha1-Proteinase Inhibitors

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Alpha1-Proteinase Inhibitors drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Prolastin-C is the preferred product. The criteria will require the use of the health plan’s preferred product before the use of targeted products (Aralast NP, Glassia, Zemaira), unless there are clinical circumstances that exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a non-preferred product.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Aralast NP
   Chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of alpha1-proteinase inhibitor (alpha1-antitrypsin deficiency)

2. Glassia
   Chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of alpha1-proteinase inhibitor (alpha1-antitrypsin deficiency)

3. Prolastin-C
   Chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha1-proteinase inhibitor (alpha1-antitrypsin deficiency)

4. Zemaira
   Chronic augmentation and maintenance therapy in adults with alpha1-proteinase inhibitor deficiency and clinical evidence of emphysema

All other indications are considered experimental/investigational and are not a covered benefit.
Table. Alpha1-Proteinase Inhibitor Products

<table>
<thead>
<tr>
<th>Medication</th>
<th>Generic Name</th>
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</thead>
<tbody>
<tr>
<td><strong>Preferred Products:</strong></td>
<td></td>
</tr>
<tr>
<td>Prolastin-C</td>
<td>alpha1-proteinase inhibitor [human]</td>
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<tr>
<td><strong>Targeted Products:</strong></td>
<td></td>
</tr>
<tr>
<td>Aralast NP</td>
<td>alpha1-proteinase inhibitor [human]</td>
</tr>
<tr>
<td>Glassia</td>
<td>alpha1-proteinase inhibitor [human]</td>
</tr>
<tr>
<td>Zemaira</td>
<td>alpha1-proteinase inhibitor [human]</td>
</tr>
</tbody>
</table>

**POLICY**

Criteria for Initial Approval

I. Indefinite authorization of Prolastin-C may be granted for treatment of alpha1-antitrypsin (AAT) deficiency when ALL of the following criteria are met:
   - The member has clinically evident emphysema.
   - 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).
   - 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 predicted.

II. Indefinite authorization of Aralast-NP, Glassia, and Zemaira may be granted for treatment of alpha1-antitrypsin (AAT) deficiency when ALL of the following criteria are met:
   - The member has clinically evident emphysema.
   - 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).
   - 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 predicted.
   - The member has experienced an intolerable adverse event with the preferred product, Prolastin-C.

Continuation of Therapy

I. All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Prior approval is required. Submit a prior approval/treatment request now.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**PROCEDURES AND BILLING CODES**

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0256 – Inj, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg (Prolastin-C, Aralast NP, Zemaira)
- J0257 – Inj, alpha 1 proteinase inhibitor (human), 10 mg (Glassia)
REFERENCES


POLICY HISTORY

Policy #: 05.02.39
Policy Creation: January 2018
Reviewed: April 2019
Revised:
Current Effective Date: February 15, 2018