PHARMACY POLICY STATEMENT

Original Effective Date | Next Annual Review | Last Revision
---|---|---
01/18/2013 | 01/18/2018 | 11/29/2016

Policy Name | Policy Number
---|---
Alpha-1 Proteinase Inhibitors | SRx-0002

Policy Type
Medical | Administrative | PHARMACY | Reimbursement

Pharmacy Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Pharmacy Policy Statement. If there is a conflict between the Pharmacy Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

Contents of Policy

PHARMACY POLICY STATEMENT ................................................................. 1
A. INTRODUCTION .................................................................................. 2
B. DEFINITIONS .................................................................................... 2
C. POLICY COVERAGE CRITERIA ............................................................. 2
   1. Site of Service ............................................................................. 2
   2. Coverage Criteria ................................................................. 3
   3. Dosage and Quantity Limits (listed if applicable) ................. 4
   4. Authorization Period ............................................................. 4
   5. Coding .................................................................................. 4
D. RELATED POLICIES ................................................................. 4
E. REVIEW/REVISION HISTORY ............................................................. 4
F. REFERENCES ................................................................................ 5
A. INTRODUCTION

Alpha-1 Antitrypsin Deficiency is an inherited condition passed from parents to children that can lead to serious lung disease in adults and/or liver disease at any age. Alpha-1 proteinase inhibitors, also called alpha 1-PI, are used to treat the lung disease (emphysema) caused by the lack of alpha 1-antitrypsin (AAT), which is a protein in the body. Alpha-1 proteinase inhibitors replace the protein when the body does not produce enough.

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.

B. DEFINITIONS

1. None applicable.

C. POLICY COVERAGE CRITERIA

1. Site of Service

<table>
<thead>
<tr>
<th>Site of Service Administration</th>
<th>Coverage Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office, Outpatient, Home</td>
<td>Preferred place of service is in the home.</td>
</tr>
</tbody>
</table>

CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings that are supportive of the patient's medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member’s current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.
2. Coverage Criteria

CareSource will approve the use of Aralast NP, Glassia, Prolastin-C, and Zemaira and consider its use medically necessary when the criteria have been met for each drug/condition listed below. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Aralast NP, Glassia, Prolastin-C, or Zemaira coverage criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emphysema due to alpha-1 proteinase inhibitor deficiency</td>
<td>1) Member is age 18 years or older</td>
</tr>
<tr>
<td></td>
<td>2) Diagnosis of emphysema due to alpha-1 antitrypsin deficiency. <em>Include chart notes and imaging studies.</em></td>
</tr>
<tr>
<td></td>
<td>3) Member has one of the high risk phenotypes (PI<em>ZZ, PI</em>[null], or PI*[null][null].)</td>
</tr>
<tr>
<td></td>
<td>4) Serum plasma levels of alpha-1 antitrypsin (ATT) less than 80 mg/dL (11 micromol/L) measured via radial immunodiffusion</td>
</tr>
<tr>
<td></td>
<td>5) Member is currently a non-smoker for 6 or more months</td>
</tr>
<tr>
<td></td>
<td>6) One or more of the following:</td>
</tr>
<tr>
<td></td>
<td>a) Prior to initiation of therapy: Airflow obstruction as evidenced by forced expiratory volume (FEV1) of 30-65% of predicted value</td>
</tr>
<tr>
<td></td>
<td>b) Rapid decline in lung function as measured by a change in FEV1 greater than 120 mL/year</td>
</tr>
</tbody>
</table>

All other uses of Aralast NP, Glassia, Prolastin-C, and Zemaira are considered experimental/investigational; and therefore, will follow CareSource’s off-label policy.

*Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.*

Notes:

- Documented diagnosis must be confirmed by portions of the individual’s medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider’s office, or hospital admission notes.
- Member is required to have completed the trial(s) listed in the above criteria unless the member is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.
3. Dosage and Quantity Limits (listed if applicable)

Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Dosage and Quantity Limit of Aralast NP, Glassia, Prolastin-C, or Zemaira</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emphysema due to alpha-1 proteinase inhibitor deficiency</td>
<td>60 mg/kg once weekly</td>
</tr>
</tbody>
</table>

4. Authorization Period

<table>
<thead>
<tr>
<th>Condition</th>
<th>Approval Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emphysema due to alpha-1 proteinase inhibitor deficiency</td>
<td>The initial authorization for Aralast NP, Glassia, Prolastin-C, or Zemaira is valid for 12 months. Continued treatment may be considered when documentation confirms the diagnosis of emphysema due to ATT deficiency, continued non-smoking status, and efficacy of prior treatment (e.g., plasma ATT levels within the normal/protective range. A reauthorization after successful initiation period will be placed for 12 months. ALL authorizations are subject to continued eligibility.</td>
</tr>
</tbody>
</table>

5. Coding

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0256</td>
<td>Injection, alpha 1-proteinase inhibitor (human), not otherwise specified, 10 mg</td>
</tr>
<tr>
<td>J0257</td>
<td>Injection, alpha 1 - proteinase inhibitor (human), (Glassia), 10 mg</td>
</tr>
</tbody>
</table>

D. RELATED POLICIES

AD-0004: Medical Necessity - Off-Label, Approved Orphan and Compassionate Use Drugs

E. REVIEW/REVISION HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/18/2013</td>
<td>Issued, reviewed</td>
</tr>
<tr>
<td>02/14/2014</td>
<td>Revised authorization period</td>
</tr>
<tr>
<td>01/18/2015</td>
<td>Alpha 1 serum level &amp; FEV value changed</td>
</tr>
<tr>
<td>01/13/2016</td>
<td>Revised phenotypes and modified ATT level</td>
</tr>
<tr>
<td>11/29/2016</td>
<td>Updated policy format, separated by line of business, updated criteria.</td>
</tr>
</tbody>
</table>
F. REFERENCES

5. Zemaira (alpha1-proteinase inhibitor (Human)) [prescribing information]. Kankakee, IL: CSL Behring LLC; September 2015.

The Pharmacy Policy detailed above has received due consideration and is approved.

*Independent medical review – 11/15/2012*