ATRIO HEALTH PLANS

Alpha-1 Proteinase Inhibitor
Prolastin-C (Human) J0256
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

- ☐ Individual has a diagnosis of congenital alpha-1 antitrypsin deficiency (alpha-1 proteinase inhibitor deficiency); AND
- ☐ Documentation of patient's alpha-1 antitrypsin level less than or equal to 11 µmol/L (approximately equivalent to 80 mg/dL measured by radial immunodiffusion or 57 mg/dL measured by nephelometry); AND
- ☐ Individual has clinically evident emphysema (or chronic obstructive pulmonary disease [COPD]); AND
- ☐ Individual is currently a non-smoker; AND
- ☐ One of the following:
  - ☐ Documentation patient has moderate airflow obstruction evidenced by a forced expiratory volume (FEV1) of 30-65% of predicted value prior to initiation of therapy; OR
  - ☐ Documentation patient has a rapid decline in lung function. measured by a change in FEV1 greater than 120 ml/year.

If not, please provide **clinical rationale** for formulary exception: _____
_____

- **Alpha-1 proteinase inhibitor therapy may NOT be approved for individuals who are IGA deficient and have IgA antibodies;**

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FEV1 decline, preservation of CT scan lung density or improvement in symptom burden); AND

☐ Individual remains a non-smoker.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Alpha-1 Proteinase Inhibitor PA

Drug Name(s):
PROLASTIN-C
Alpha-1 Proteinase Inhibitor (Human)

Criteria for approval of Non-Formulary/Preferred Drug:
MCG Criteria
Alpha-1 proteinase inhibitor[A] may be indicated when ALL of the following are present:

- Age 18 to 65 years
- Alpha-1 antitrypsin deficiency with proteinase inhibitor ZZ phenotype
- Alpha-1 proteinase inhibitor serum level less than 11 micromoles/L (59 mg/dL)
- Chronic obstructive pulmonary disease with pulmonary function impairment, as indicated by 1 or more of the following:
    - Baseline FEV1 between 30% and 65% of predicted value
    - FEV1 below 30% of predicted value in patient on chronic maintenance alpha-1 proteinase inhibitor therapy
    - FEV1 greater than 65% and accelerated FEV1 decline (eg, greater than 100 mL) over previous 12 months
- Continued optimal conventional treatment for chronic obstructive pulmonary disease (eg, bronchodilators, supplemental oxygen, if necessary)
- Current nonsmoker for 6 or more months
- Normal C-reactive protein level
- No selective IgA deficiency with accompanying anti-IgA antibodie

Exclusion Criteria:
N/A

Prescriber Restrictions:
N/A

Coverage Duration:
Approval will be for 6 months

FDA Indications:
Prolastin-C

1. Chronic replacement therapy in adults with congenital deficiency of alpha-1 antitrypsin and clinically evident emphysema

Off-Label Uses:
N/A

Age Restrictions:
Only approved in adults 18 years of age or older

Other Clinical Consideration:
Contraindicated in Immunoglobulin A (IgA)-deficient patients with antibodies against IgA

Resources:
https://careweb.careguidelines.com/ed24/ac/ac04_084.htm#ClinicalIndications_ac04_084