ATRIO HEALTH PLANS

Alpha-1 Proteinase Inhibitor

Prolastin-C (Human) J0256 is non-preferred. The preferred product is Part D covered Prolastin-C. (May require PA)

Prior Authorization Step Therapy 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)**

☐ **Patient has tried / failed Humira under Medicare Part D - Billing Date: _____**

If not, please provide clinical rationale why member cannot Self-Administer

_____

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

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

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

☐ Patient had an adequate response or significant improvement while on this medication.

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