



**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.

<input type="checkbox"/> Standard Request– (72 Hours)	<input type="checkbox"/> 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)

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)

Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.

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 antibodies

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