



## AAT Deficiency

### Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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**Patient's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
**Patient's ID:** \_\_\_\_\_ **Patient's Date of Birth:** \_\_\_\_\_  
**Physician's Name:** \_\_\_\_\_  
**Specialty:** \_\_\_\_\_ **NPI#:** \_\_\_\_\_  
**Physician Office Telephone:** \_\_\_\_\_ **Physician Office Fax:** \_\_\_\_\_

**Referring Provider Info:**  Same as Requesting Provider

**Name:** \_\_\_\_\_ **NPI#:** \_\_\_\_\_  
**Fax:** \_\_\_\_\_ **Phone:** \_\_\_\_\_

**Rendering Provider Info:**  Same as Referring Provider  Same as Requesting Provider

**Name:** \_\_\_\_\_ **NPI#:** \_\_\_\_\_  
**Fax:** \_\_\_\_\_ **Phone:** \_\_\_\_\_

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

**Required Demographic Information:**

*Patient Weight:* \_\_\_\_\_ kg

*Patient Height:* \_\_\_\_\_ cm

**Exception Criteria Questions:**

- A. What is the ICD-10 code? \_\_\_\_\_
- B. What product is being prescribed?
  - Aralast NP       Glassia       Prolastin-C, *Skip to Site of Service Questions*
  - Zemaira       Other \_\_\_\_\_
- C. Is the product being requested for the treatment of Alpha1-antitrypsin (AAT) deficiency?
  - Yes     No    *If No, skip to Site of Service Questions*
- D. The preferred product for you patient's health plan is Prolastin-C. Can the patient's treatment be switched to the preferred product?
  - Yes    *Skip to Site of Service Questions.*
  - No
- E. Does the patient have a documented intolerable adverse event to the preferred product (Prolastin-C)?  
**ACTION REQUIRED: If Yes, please attach supporting chart note(s).**     Yes     No

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- F. Was the documented intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information? **ACTION REQUIRED: If Yes, please attach supporting chart note(s).**  
 Yes  No

**Site of Service Questions:**

- A. Where will this drug be administered?  
 Ambulatory surgical, *skip to Clinical Questions*  Home infusion, *skip to Clinical Questions*  
 Off-campus Outpatient Hospital  On-campus Outpatient Hospital  
 Physician office, *skip to Clinical Questions*  Pharmacy, *skip to Clinical Questions*
- B. Is this request to continue previously established treatment with the requested medication?  
 Yes → This is a continuation of an existing treatment.  
 No → This is a new therapy request (patient has not received requested medication in the last 6 months), *skip to Clinical Criteria Questions*  
 No → This is a request for a different brand of alpha-1-antitrypsin product that the patient has not received previously, *skip to Clinical Criteria Questions*
- C. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? **ACTION REQUIRED: If Yes, Attach supporting clinical documentation**  Yes, *skip to Clinical Criteria Questions*  No
- D. Does the patient have laboratory confirmed IgA antibodies? **ACTION REQUIRED: If Yes, Attach supporting clinical documentation**  Yes, *skip to Clinical Criteria Questions*  No
- E. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? **ACTION REQUIRED: If Yes, Attach supporting clinical documentation**  Yes, *skip to Clinical Criteria Questions*  No
- F. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? **ACTION REQUIRED: If Yes, Attach supporting clinical documentation**  
 Yes, *skip to Clinical Criteria Questions*  No
- G. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? **ACTION REQUIRED: If Yes, Attach supporting clinical documentation**  Yes, *skip to Clinical Criteria Questions*  No

**Clinical Criteria Questions:**

- What drug is being prescribed?  Aralast NP  Glassia  Prolastin-C  Zemaira  Other \_\_\_\_\_
- What is the diagnosis?  
 Alpha<sub>1</sub>-antitrypsin (AAT) deficiency (also known as alpha<sub>1</sub>-proteinase inhibitor deficiency)  
 Other (please specify) \_\_\_\_\_
- What is the ICD-10 code? \_\_\_\_\_
- Does the patient have emphysema due to alpha1-antitrypsin (AAT) deficiency?  Yes  No
- Is this a request for continuation of therapy with the requested drug?  Yes  No *If No, skip to #8*
- Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?  Yes  No  Unknown *If Yes or Unknown skip to #8*
- Is the patient experiencing beneficial clinical response from therapy?  Yes  No *No further questions*

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8. Is the patient's pretreatment post-bronchodilation FEV<sub>1</sub> (forced expiratory volume in 1 second) greater than or equal to 25 percent and less than or equal to 80 percent of the predicted value? **ACTION REQUIRED: If Yes, attach supporting test results.**  Yes  No
9. What is the patient's pretreatment serum alpha<sub>1</sub>-antitrypsin (AAT) level? **ACTION REQUIRED: If Yes, attach supporting test results.** \_\_\_\_\_ micromol/L OR mg/dL (*circle units*)  No serum AAT level
10. Has testing been done to establish the patient's alpha<sub>1</sub>-antitrypsin protein phenotype or genotype? **ACTION REQUIRED: If Yes, attach alpha1-antitrypsin phenotyping test result.**  Yes  No
11. What is the patient's alpha<sub>1</sub>-antitrypsin protein phenotype?  
 PiZZ  PiZ (null)  Pi (null, null)  PiMZ  PiMS  
 Other phenotype or genotype associated with serum AAT concentrations of less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry)  
 Unknown

<b>Step Therapy Override: Complete if Applicable for the state of Maryland.</b>	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

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<b>Step Therapy Override: Complete if Applicable for the state of Virginia.</b>	<b>Please Circle</b>	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

*I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.*

**X** \_\_\_\_\_

**Prescriber or Authorized Signature**

**Date (mm/dd/yy)**

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