# Aralast-NP, Zemaira, Glassia, Prolastin-C

## CareFirst 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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

**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*

What is the ICD-10 code? _____

What drug is being prescribed?
❑ Aralast NP, *Skip to Site of Service Questions*
❑ Glassia, *Skip to Site of Service Questions*
❑ Prolastin-C, *Continue to Exception Criteria Questions*
❑ Zemaira, *Skip to Site of Service Questions*
❑ Other _____, *Skip to Site of Service Questions*

**Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720**



**CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062**
**Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com**

**Exception Criteria Questions:**

A. The preferred products for you patient's health plan are Aralast NP, Glassia and Zemaira. Can the patient's treatment be switched to one of the preferred products?
- ❑ Yes, Aralast NP *Skip to Site of Service Questions.*
- ❑ Yes, Glassia *Skip to Site of Service Questions.*
- ❑ Yes, Zemaira *Skip to Site of Service Questions.*
- ❑ No, *Continue to B*

B. Did the patient have an inadequate response, contraindication or intolerable adverse event to all of the preferred products (Aralast NP, Glassia and Zemaira)? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s).*** ❑ Yes ❑ No *If Yes or No, Continue to Site of Service Questions*

**Site of Service Questions:**

A. Where will this drug be administered?
- ❑ Ambulatory surgical, *skip to Clinical Criteria Questions*
- ❑ Home infusion, *skip to Clinical Criteria Questions*
- ❑ Off-campus Outpatient Hospital, *Continue to B*
- ❑ On-campus Outpatient Hospital, *Continue to B*
- ❑ Physician office, *skip to Clinical Criteria Questions*
- ❑ Pharmacy, *skip to Clinical Criteria Questions*

B. Is the patient less than 14 years of age?
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to C*

C. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes – This is a continuation of an existing treatment, *Continue to D*
- ❑ No – This is a new therapy request (patient has not received requested medication in the last 6 months), ***ACTION REQUIRED: Please attach supporting clinical documentation.*** *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, ***ACTION REQUIRED: Please attach supporting clinical documentation.*** *Skip to Clinical Criteria Questions*

D. 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, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to E*

E. Does the patient have laboratory confirmed IgA antibodies? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to F*

F. 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, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to G*

G. 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, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to H*

H. 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, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to I*

I. Are ***all*** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? ***ACTION REQUIRED: If Yes, please attach supporting documentation.***
❑ Yes, *Continue to Clinical Criteria Questions*
❑ No, *Continue to Clinical Criteria Questions*

**Criteria Questions:**

1. What is the diagnosis?

❒ Alpha1-proteinase Inhibitor (alpha1-antitrypsin) Deficiency, *Continue to 2*

❒ Acute Graft-Versus-Host Disease (GVHD), *Continue to 10*

❒ Other, please specify. _____, *No further questions*

2. Does the patient have emphysema due to alpha1-antitrypsin (AAT) deficiency?
❒ Yes, *Continue to 3*
❒ No, *Continue to 3*

3. Is this a request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 4*
❒ No, *Continue to 6*

4. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

❒ Yes, *Continue to 6*

❒ No, *Continue to 5*

❒ Unknown, *Continue to 6*

5. Is the patient experiencing beneficial clinical response from therapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

6. Is the patient's pretreatment post-bronchodilation forced expiratory volume in 1 second (FEV1) greater than or equal to 25 percent and less than or equal to 80 percent of the predicted value? ***ACTION REQUIRED***: If Yes, please attach pretreatment post-bronchodilation forced expiratory volume in 1 second (FEV1) results. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 7*
❒ No, *Continue to 7*

7. What is the patient's pretreatment serum alpha1-antitrypsin (AAT) level? ***ACTION REQUIRED***: Please attach supporting pretreatment serum alpha1-antitrypsin (AAT) level.
❒ Less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 8*
❒ Greater than or equal to 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 8*
❒ No serum AAT level, *Continue to 8*

8. Has testing been done to establish the patient's alpha1-antitrypsin protein phenotype or genotype? ***ACTION REQUIRED***: If Yes, attach alpha1-antitrypsin protein phenotype or genotype results. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 9*
❒ No, *Continue to 9*

9. What is the patient's alpha1-antitrypsin protein phenotype?

❒ PiZZ, *No further questions*

❒ PiZ (null), *No further questions*

❒ Pi (null, null) (homozygous) AAT deficiency, *No further questions*

❒ PiMZ, *No further questions*

❒ PiMS AAT deficiency, *No further questions*

❒ 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), *No further questions*

❒ Unknown, *No further questions*

10. Is this a request for treatment of steroid-refractory acute graft-versus-host disease (GVHD) following hematopoietic stem cell transplantation?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

| **Step Therapy Override: Complete if Applicable for the state of Maryland.** | 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 |

| **Step Therapy Override: Complete if Applicable for the state of Virginia.** | Please Circle | |
|---|---|---|
| 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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