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.

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*

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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

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:

1. What is the diagnosis?
   ❑ Alpha$_1$-antitrypsin (AAT) deficiency (also known as alpha$_1$-proteinase inhibitor deficiency)
   ❑ Other _____
2. Does the patient have emphysema due to alpha1-antitrypsin (AAT) deficiency? ❑ Yes ❑ No
3. Is this a request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to # 6*
4. 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 #6*
5. Is the patient experiencing beneficial clinical response from therapy? ❑ Yes ❑ No *No Further Questions*
6. Is the patient's pretreatment post-bronchodilation FEV_1 (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
7. What is the patient's pretreatment serum alpha$_1$-antitrypsin (AAT) level? ***Action Required: Attach supporting test results.*** _____ **micromol/L OR mg/dL *(circle units)*** ❑ No serum AAT level
8. Has testing been done to establish the patient's alpha$_1$-antitrypsin protein phenotype? ***Action Required: If 'Yes', Attach alpha1-antitrypsin phenotyping test result.*** ❑ Yes ❑ No
9. What is the patient's alpha$_1$-antitrypsin protein phenotype?
   ❑ PiZZ ❑ PiZ (null) ❑ Pi (null, null) ❑ PiMZ ❑ PiMS ❑ Unknown
   ❑ Other phenotype associated with serum AAT concentrations of less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry)

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

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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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