PROLASTIN-C LIQUID Enrollment Form with Quick Start

Fax completed form to: 1-888-817-2098

PROLASTIN DIRECT® Your partner in alpha-1

Accredo By EVERNORTH

READY-TO-INFUSE PROLASTIN® C LIQUID alpha1-proteinase inhibitor (human)

PATIENT INFORMATION

First name _____ Middle initial ____ Last name _____ SSN (last 4 digits only) _____ DOB ___/___/___ Gender ☐ M ☐ F

Home address _____ City _____ State _____ Zip _____

Best contact number _____ ☐ Home ☐ Mobile ☐ Work Email address _____

Please attach copies of the front and back of the patient's medical and prescription insurance cards.

MEDICAL INFORMATION *Please include a copy of patient's clinical notes*

ICD-10 Diagnosis ☐ Alpha$_1$-Antitrypsin Deficiency E88.01 ☐ Panlobular Emphysema J43.1 ☐ Other _____

AAT Phenotype/Genotype ☐ PiZZ ☐ PiZ (null) ☐ Pi (null, null) ☐ PiSZ ☐ Other _____ FEV$_1$ _____ % predicted DLCO _____ % predicted

Serum AAT Level _____ mg/dL or _____ µM Allergies ☐ None or ☐ Specify _____

Treatment History Has patient ever received augmentation therapy? ☐ Yes ☐ No If yes, which therapy? _____

Medical History ☐ COPD ☐ Asthma ☐ Emphysema ☐ Other _____

Concurrent medications _____ Vascular access ☐ Peripheral ☐ Central ☐ Port

Smoking History ☐ Yes ☐ No

If yes, date stopped. ___/____

PROLASTIN-C LIQUID PRESCRIPTION INFORMATION

Dose

☐ 60 mg/kg (+/- 10%) IV once weekly

☐ Other dose/frequency _____

Patient weight _____ lbs / kg recorded on ___/___/___

Directions

Rate: As tolerated by patient up to 0.08 mL/kg/min

☐ Other rate _____

Quantity/Refills

☐ Dispense up to 28-day supply. Refill x1 year unless otherwise noted

☐ Other _____

Medications to be used as needed:

☐ Lidocaine 4% applied topically to insertion site prior to needle insertion as needed for intravenous site pain

☐ Premedication/other orders: _____

Adverse reaction medications: *(keep on hand at all times)*

Epinephrine 0.3 mg auto-injector 2-pk for patients weighing greater than or equal to 30 kg. Administer intramuscularly as needed for severe anaphylactic reaction; may repeat one time.

Epinephrine 0.15 mg auto-injector 2-pk for patients weighing less than 30 kg. Administer intramuscularly as needed for severe anaphylactic reaction; may repeat one time.

Diphenhydramine 25 mg by mouth for mild allergic reactions and 50 mg for moderate-severe.

Flush orders:

Saline flushing

Normal saline 3 mL intravenous (peripheral line) or 10 mL intravenous (central line) before and after infusion, or as needed for line patency

Heparin flushing

Heparin 10 units per mL 3 mL intravenous (peripheral line) as final flush

Heparin 100 units per mL 5 mL intravenous (central line) as final flush

First infusion location preference: ☐ Home or ☐ Medical facility (name, phone of preferred facility, if any): _____

First infusion in home nursing orders:

Establish primary IV line with 250 to 500 mL of normal saline or ☐ Other _____ at KVO rate prior to infusion

Monitor patient including VS before, Q15 during, and 30 minutes post infusion

Skilled nursing visit as needed to establish venous access, administer medication and assess general status and response to therapy

Provide infusion supplies, including syringes and needles, to safely administer prescribed medication.

PRESCRIBER INFORMATION

Prescriber first name _____ Prescriber last name _____ NPI# _____

Street address _____ City _____ State _____ Zip _____

Office contact name _____ Office contact phone _____ Office contact fax _____

Office contact email address _____

By signing below, I authorize this prescription and certify that the therapy described above is medically necessary and that the information provided is accurate to the best of my knowledge. I authorize PROLASTIN DIRECT to act on my behalf for the limited purpose of transmitting this prescription by any means allowed under applicable law to Accredo Health Group, Inc. If the patient is 18 years old or younger, I attest that I have obtained permission from the patient's legal guardian.

Prescriber Signature _____ *Dispense as Written* _____ *Substitution Permitted* Date _____

The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber.

ENROLL PATIENT IN QUICK START PROGRAM

The PROLASTIN-C LIQUID Quick Start Program provides eligible patients new to PROLASTIN-C LIQUID with up to eight (8) weeks of no-cost therapy during the commercial insurance approval process. Eligible patients must have a confirmed alpha$_1$-antitrypsin deficiency diagnosis and valid PROLASTIN-C LIQUID prescription. The patient must also be new to PROLASTIN-C LIQUID.

See additional eligibility requirements on the next page

☐ **Yes Enroll my patient in the Quick Start Program**

Eligible patients can receive an initial fourteen (14) day supply. Patients continuing to seek or appeal coverage determination from their commercial insurer are eligible to receive up to a maximum of eight (8) weeks of PROLASTIN-C LIQUID dispensed in a two (2)-week supply EVERY fourteen (14) days.

To reach the PROLASTIN DIRECT care team, call 1-833-746-6321. Hours of Operation: 8 AM to 8 PM EST.

Please see Important Safety Information on the next page and accompanying full Prescribing Information for PROLASTIN-C LIQUID.

Fax completed form and documentation to 1-888-817-2098.
To reach the PROLASTIN DIRECT® team, call 1-833-746-6321.

Steps to e-Prescribe PROLASTIN-C LIQUID	1. Fax in the PROLASTIN-C LIQUID prescription and enrollment form 2. Prescribe PROLASTIN-C LIQUID 3. Choose Accredo Health Group, Inc. as the dispensing pharmacy	**eRx to NCPDP ID 4436920** 1620 Century Center Parkway, Suite 109, Memphis, TN 38134

PRIOR AUTHORIZATION CHECKLIST

Please note that the information listed below outlines what is typically required for insurance to review the patient's eligibility. If any of the following information is not provided, it may delay approval or be cause for a denial.

NEW DIAGNOSIS OF AATD

Required documentation for insurance review

(A) Laboratory work

- ☐ AAT serum concentration; Most major insurance policies define acceptable levels as: ≤11 µM (11 µmol/L) or 80 mg/dL by radial immunodiffusion or <50 mg/dL if measured by nephelometry
- ☐ Phenotype or Genotype: PiZZ, PiZ (null), Pi (null, null), PiSZ or other, in which case a one-on-one discussion may be required with the insurance plan medical director

(B) Most recent clinical and diagnostic test results documenting history of Emphysema

- ☐ Patient's medical records demonstrating diagnosis of AATD and clinical evidence of emphysema/worsening of emphysema due to lung disease exacerbations
- ☐ Diagnostic imaging-chest X-ray, CT scan
- ☐ Evidence of lung function decline, forced expiratory volume (FEV), and pulmonary function test (PFT)
- ☐ Patient's clinical notes and smoking history

Supplemental documentation that may be required by the insurance plan for approval

- ☐ Letter of medical necessity
- ☐ Peer-reviewed articles supporting diagnosis and treatment
- ☐ IgA antibody results (may be required for certain insurance plan approvals)

QUICK START ADDITIONAL ELIGIBILITY REQUIREMENTS

- Patients must meet all clinical criteria outlined in their commercial insurance plan's medical policy
- The patient must experience a delay of five (5) business days or more in securing a benefits investigation or prior authorization for PROLASTIN-C LIQUID
- This program is not valid for prescriptions reimbursed, in whole or in part, by Medicaid, Medicare, Medigap, VA, DoD, TRICARE, or any other federal or state healthcare programs
- Patients must have commercial insurance that covers medication costs for PROLASTIN-C LIQUID treatment
- This program is only valid for residents of the United States, including the District of Columbia, Puerto Rico, and other US territories

IMPORTANT SAFETY INFORMATION

PROLASTIN®-C LIQUID is an alpha$_1$-proteinase inhibitor (human) (alpha$_1$-PI) indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha$_1$-PI (alpha$_1$-antitrypsin deficiency).

Limitations of Use

- The effect of augmentation therapy with any alpha$_1$-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in alpha$_1$-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials
- Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with PROLASTIN-C LIQUID are not available
- PROLASTIN-C LIQUID is not indicated as therapy for lung disease in patients in whom severe alpha$_1$-PI deficiency has not been established

PROLASTIN-C LIQUID is contraindicated in immunoglobulin A (IgA)-deficient patients with antibodies against IgA or patients with a history of anaphylaxis or other severe systemic reaction to alpha$_1$-PI products.

Hypersensitivity reactions, including anaphylaxis, may occur. Monitor vital signs and observe the patient carefully throughout the infusion. If hypersensitivity symptoms occur, promptly stop PROLASTIN-C LIQUID infusion and begin appropriate therapy.

Because PROLASTIN-C LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents, eg,viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. This also applies to unknown or emerging viruses and other pathogens.

The most common adverse reactions during PROLASTIN-C LIQUID clinical trials in >5% of subjects were diarrhea and fatigue, each of which occurred in 2 subjects (6%).

Please see accompanying full Prescribing Information for PROLASTIN-C LIQUID.

PATIENT HIPAA AUTHORIZATION

By signing this Authorization, I authorize PHARMACY, PROVIDER or HEALTH PLAN to use and disclose my personal health information, including but not limited to my name, medical and pharmacy records, information relating to my medical condition, treatment, and health insurance, as well as all information provided on any prescription for the following purposes:

- To enroll me in the PROLASTIN DIRECT Program
- To provide me with information about PROLASTIN-C LIQUID
- To provide me with other educational information related to my medical condition
- To market products and services to me related to my medical condition
- To assist me in obtaining payment for PROLASTIN-C LIQUID or other medications
- To refer me to additional support services, if needed

PHARMACY, PROVIDER or HEALTH PLAN is authorized to contact me by mail, e-mail, text, telephone, and/or any alternative communication method that I request for such purposes. I understand that PHARMACY, will receive financial remuneration from Grifols to provide some of these communications to me and that the use and disclosure of my information as described in this Authorization may be considered use or disclosure for marketing under HIPAA. I authorize these uses and disclosures to the extent they are directly related to the PROLASTIN DIRECT Program, my prescription, services associated with my prescription, or other specialty pharmacy programs.

Once my health information has been disclosed, I understand that federal privacy laws may no longer protect the information. I understand that I may refuse to sign this Authorization, and that doing so will not affect my ability to receive treatment with PROLASTIN-C LIQUID or obtain insurance or insurance benefits. I understand that I am entitled to a copy of this Authorization, and that I may cancel this Authorization at any time, by mailing a letter requesting cancellation to: PROLASTIN DIRECT Program c/o **1680 Century Center Parkway, Suite 8, Memphis TN 38134.**

I understand that the cancellation shall be effective upon actual receipt of my letter by PHARMACY, PROVIDER or HEALTH PLAN. Canceling this Authorization will end further use and disclosure of my health information as authorized above after the date that PHARMACY, PROVIDER or HEALTH PLAN receive my letter, but will not affect health information that has already been used or disclosed in reliance upon this Authorization.

This Authorization expires ten (10) years from the date this Authorization is signed unless a shorter time period is required under state law.

Patient Signature: _____ Date: _____

Patient Name (print): _____

Personal Representative (if applicable): _____

Personal Representative's Printed Name: _____

Relationship to Patient, including the authority for status as Personal Representative: _____

Address of Patient or Personal Representative: _____

Telephone number: (___)_____

AUTHORIZATION AND NOTICE OF RELEASE OF INFORMATION

Patient Name:

At my request, I hereby authorize the use or release of my protected health information, including all of my medical records, by and between PHARMACY, PROVIDER or HEALTH PLAN and AlphaNet, Inc. ("AlphaNet") as follows: (a) among each other, (b) to or from my physician or representatives of my physician or other health providers involved in my care, and (c) to or from a third party payer. The purpose of such release of information shall be to help assure continuity of treatment including but not limited to: submission of claims to third-party payers for payment, proper communication of information to health care providers and insurance carriers, proper reimbursement of services, and administration of the PROLASTIN DIRECT Program. I also authorize and understand that PHARMACY, PROVIDER or HEALTH PLAN and other health care providers involved in my care may use the aforementioned information for quality assurance purposes, including but not limited to, quality assurance reviews conducted by the Joint Commission on Accreditation of Health Care Organizations.

I understand that neither PHARMACY, PROVIDER or HEALTH PLAN nor AlphaNet will condition its provision of services to me upon my execution of this Authorization, unless the Authorization is required for research purposes or for the creation of health data for disclosure to a third party.

If I am receiving PROLASTIN-C LIQUID through the PROLASTIN DIRECT Program, I also hereby authorize the following: (1) use of my personal information (specifically my name, my contact information, my diagnosis of having Alpha-1, my insurance information and any treatment I am then receiving) by AlphaNet to contact me on a regular basis: (a) for purposes of its provision of disease management services, education and patient support, (b) for purposes of informing me of clinical trials and studies related to my health condition and programs designed to further scientific research related to my health condition, and (c) for other activities associated with the PROLASTIN DIRECT Program; (2) PHARMACY, PROVIDER or HEALTH PLAN may provide AlphaNet with such information as may be necessary in order to assist AlphaNet in the performance of these functions; and (3) PHARMACY, PROVIDER or HEALTH PLAN and AlphaNet may recruit the assistance of, and share my information with each other to help resolve payer issues, assist in education of my nursing provider and other functions in order to help assure the continuity and quality of my treatment.

I understand that this Authorization shall expire upon completion of the services I receive through the PROLASTIN DIRECT Program, unless I revoke it. I may revoke this Authorization at any time by notifying AlphaNet in writing at the following address:

AlphaNet, Inc.

3300 Ponce de Leon

Coral Gables, FL 33134

Attn: Privacy Officer

If I revoke this Authorization, it will not have any effect on the actions taken by AlphaNet or PHARMACY, PROVIDER or HEALTH PLAN before the revocation. I understand that the revocation of this Authorization will not affect the use of my name or other portions of my protected health information described above, by PHARMACY, PROVIDER or HEALTH PLAN or AlphaNet or others, prior to the date of revocation, but that subsequent thereto, neither my name nor any other protected health information pertaining to me will be used or disclosed pursuant to this Authorization.

I understand that the information disclosed pursuant to this Authorization may be subject to redisclosure by the recipient, because it may no longer be protected by federal privacy regulations.

I understand that I may refuse to sign this Authorization. If I sign, I will be given a copy of this Authorization after I sign it.

My signature certifies that I have read this Authorization and release the use of information as described above.

Patient Signature	Date
Patient's Agent/Title (if applicable) Signature	Date