PROLASTIN-C LIQUID
Enrollment Form

PROLASTIN DIRECT® Your partner in alpha-1

READY-TO-INFUSE PROLASTIN® C LIQUID alpha$_1$-proteinase inhibitor (human)

Fax completed form to the PROLASTIN DIRECT Hub at 1-888-817-2098.
To reach the PROLASTIN DIRECT care team, call 1-833-746-6321.
Hours of Operation: 8 AM to 8 PM EST.

INFUSION LOCATION

☐ **Home infusion provided by Accredo**

- Fill out all sections except section 4.
- **To avoid delays, please ensure all required sections are completed**
- Give pages 5-8 to the patient to complete and sign
- Fax the completed and signed enrollment form pages 1 & 3, a copy of front and back of patient medical and prescription insurance cards, clinical documentation, and signed patient consents pages 5-8 to PROLASTIN DIRECT Hub at 1-888-817-2098

☐ **Buy and Bill Location: Hospital/Infusion Center Provider/Healthcare Provider's Office**

- Fill out Sections 1,2,3 & 4
- Give pages 5-8 to the patient to complete and sign
- Fax the completed enrollment form page 1 and signed patient consent pages 5-8 to the PROLASTIN DIRECT Hub at 1-888-817-2098
- Contact CuraScript SD for ordering at prolastindirectwholesale@curascript.com or 1-833-746-6321, follow the prompts for Service Provider

NAIVE TO PROLASTIN-C LIQUID ☐ Yes ☐ No

1 PATIENT INFORMATION

Patient full name _____ SSN (last 4 digits only) _____ DOB _____ Gender ☐ M ☐ F
Home address _____ City _____ State _____ Zip _____
Best contact number _____ ☐ Home ☐ Mobile ☐ Work Email address _____

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

2 INSURANCE INFORMATION *Please attach a copy of both sides of all patient's medical and prescription card(s)*

☐ **Check if the patient is uninsured**

Pharmacy plan name _____ Pharmacy plan phone number _____
Policy ID # _____ Group ID # _____
RX BIN # _____ RX PCN # _____

Primary insurance _____ Secondary insurance _____
Insurance contact number _____ Insurance contact number _____
Policy ID# _____ Policy ID# _____
Group ID# _____ Group ID# _____
Policy holder full name _____ Policy holder full name _____
Relationship to patient _____ Relationship to patient _____

3 PRESCRIBER INFORMATION

Prescriber's full name _____ NPI # _____ Tax ID # _____
Street address _____ City _____ State _____ Zip _____
Office contact name _____ Office contact phone _____ Office contact fax _____
Office contact email address _____

4 INFUSION LOCATION INFORMATION *For buy and bill customers only*

Facility name _____ Address _____
Contact name _____ Best contact number _____

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PRIOR AUTHORIZATION CHECKLIST

Please note: The information below is typically required for insurance to review the patient's eligibility. Missing information may delay approval or result in 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
- ✓ 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, including smoking history
- ✓ Diagnostic imaging-chest X-ray, CT scan
- ✓ Evidence of lung function decline, forced expiratory volume (FEV), and pulmonary function test (PFT)

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

- ✓ Letter of medical necessity
- ✓ IgA antibody results (may be required for certain insurance plan approvals)

QUICK START PROGRAM ELIGIBILITY REQUIREMENTS

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 diagnosis of alpha$_1$-antitrypsin deficiency and valid prescription for PROLASTIN-C LIQUID. The patient must also be new to PROLASTIN-C LIQUID.

To qualify for enrollment, all of the following criteria must be met:

- ✓ The patient meets all clinical criteria outlined in their commercial insurance plan's medical policy
- ✓ The patient has experienced a delay of five (5) or more business days in securing a benefits investigation or prior authorization for PROLASTIN-C LIQUID
- ✓ The patient has commercial insurance that covers medication costs for treatment with PROLASTIN-C LIQUID
- ✓ The patient is not covered, in whole or in part, by Medicaid, Medicare, Medigap, VA, DoD, TRICARE, or any other federal or state healthcare program
- ✓ The patient is a resident of the United States, including the District of Columbia, Puerto Rico, or other US territories
- ✓ The Quick Start Program enrollment box on the next page—labeled "Yes, enroll my patient in the Quick Start Program"—must be checked to initiate enrollment

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Accredo By EVERNORTH

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Patient full name _____ **Patient date of birth:** _____

5 MEDICAL INFORMATION

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 _____ mg/dL or _____ µM

Smoking history ☐ Yes ☐ No If yes, date stopped? _____ **Allergies** ☐ NKDA ☐ Yes, specify _____

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

Medical history ☐ COPD ☐ Asthma ☐ Emphysema ☐ Other _____

Concurrent medications _____

6 PRESCRIPTION INFORMATION

Dose

☐ 60 mg/kg (+/- 10%) IV once weekly

☐ Other dose/frequency

Patient weight ____ lbs / kg recorded on _____

Where clinically appropriate to avoid waste of product, round to the nearest vial size.

Directions

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

☐ Other rate _____

Quantity/Refills

☐ 28-day supply, refill x1 year

☐ Other _____

7 MEDICATION 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

PRN Medications:

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

Premedications

☐ Other _____

8 INFUSION INFORMATION

Vascular Access ☐ Peripheral ☐ Central ☐ Port

Infusion method *Use gravity unless pump is specified* ☐ Gravity ☐ Pump

Normal saline

☐ Normal saline 5 mL intravenous (peripheral line) or 10 mL intravenous (central line) before and after infusion, or as needed for line patency

Heparin flush

☐ 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

Home infusion nursing orders:

- Skilled nursing visit as needed to establish venous access, administer medication, and assess general status and response to therapy
- Supplies: (please strike through if not required)
  Dispense needles, syringes, ancillary supplies, and home medical equipment necessary to administer medication.

9 QUICK START PROGRAM

☐ **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. **See additional eligibility requirements on the previous page*

10 PRESCRIBER SIGNATURE BLOCK

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 Name (*please print*) _____

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.

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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 alpha1-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 any health plan (including my health insurance company) and my healthcare providers (including pharmacy providers) (respectively, "HEALTH PLAN", "PROVIDER" and "PHARMACY") to use and disclose my protected health information (as defined under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Technology for Economic and Clinical Health Act), including but not limited to my name, social security number, contact information, birth date, medical and pharmacy records, information relating to my medical condition, treatment, and health insurance, as well as all information provided on any prescription and information relevant to my enrollment participation, or receipt of assistance under the PROLASTIN DIRECT Program (collectively, "Information"), including to Grifols, AlphaNet, Inc. ("AlphaNet") if consented, and any other third parties engaged to assist in administering the PROLASTIN DIRECT Program ("PROLASTIN DIRECT Partners") for the following purposes:

- To establish my benefit eligibility
- 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 communicate with my healthcare providers and health plans about my benefit and coverage status and/or medical care
- To evaluate the effectiveness of the PROLASTIN DIRECT Program
- To administer, evaluate, and improve the PROLASTIN DIRECT Program, including by analyzing usage patterns and effectiveness of Grifols' products, services, and programs and helping to develop new products, services and programs and for other Grifols general business and administrative purposes
- To assist me in obtaining payment for PROLASTIN-C LIQUID or other medications from my health plan or other programs
- To refer me to additional support services, if needed

I further authorize PROLASTIN DIRECT Partners to obtain, review, use, and disclose my information for the foregoing purposes. 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 and/or other healthcare providers may 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 I sign this Authorization and my 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 the PROLASTIN DIRECT Program. Canceling this Authorization will end further use and disclosure of my Information as authorized above after the date that the PROLASTIN DIRECT Program receives my letter but will not affect 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 Signature (if applicable) Date

Personal Representative's Printed Name

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

Address of Patient or Personal Representative

Telephone Number of Patient or Personal Representative

□ **Marketing Communications Opt-In** *(OPTIONAL)*: I would like to receive marketing and informational communications from Grifols related to my medical condition, treatment, and/or my prescription medication, including offers, marketing and promotional information, and educational materials, via one or more of the communications methods I agreed to above. I understand that opting in to the marketing and informational communications is not required as a condition of (i) eligibility for health plan benefits or ability to obtain treatment from my healthcare providers, (ii) enrollment in the PROLASTIN DIRECT Program, or (iii) purchasing any goods or receiving a co-pay or other support from Grifols.

□ By checking this box, I consent to receive marketing and informational communications from Grifols (as described above) to my phone number provided, including text messages, prerecorded messages and phone calls, which may be sent via auto dialer. Text and data rates may apply. I may opt out at any time by texting "STOP.

CONSENT FOR ENROLLMENT

I understand that by signing this consent form, that I authorize Grifols and its agents, contractors, and other partners responsible for supporting the PROLASTIN DIRECT Program, including my pharmacy provider ("PHARMACY") and AlphaNet, Inc. ("AlphaNet"), (collectively "PROLASTIN DIRECT Partners"), to provide product support to me in connection with my Prolastin treatment. I also understand that my treatment is under the control of my physician, and that none of Grifols, PHARMACY, AlphaNet, nor PROLASTIN DIRECT is acting as my case manager nor is Grifols, AlphaNet or PROLASTIN DIRECT acting as my healthcare provider.

AlphaNet is a not-for-profit organization supported by Grifols to provide disease management and related support activities for the PROLASTIN DIRECT Program. I understand that: (1) I may be contacted by AlphaNet or other PROLASTIN DIRECT Partners on a regular basis for such services; (2) PHARMACY, AlphaNet, or other PROLASTIN DIRECT Partners may exchange with each other information which may be necessary in order to assist in the performance of these functions; and (3) PHARMACY, AlphaNet, and other PROLASTIN DIRECT Partners may recruit the assistance of, and share my information with, each other to help address payer issues, assist in educating my provider, and perform other functions in order to support the access to my treatment with PROLASTIN.

I understand that although the PROLASTIN DIRECT Program is designed to utilize services of AlphaNet and other PROLASTIN DIRECT Partners and such services will be provided to me without cost, I have the option to decline this service by checking the box below. I understand that completing this form does not ensure that I will receive support through PROLASTIN DIRECT. I understand that, by making this selection, some of the support described in this information packet related to AlphaNet's services may not be available to me. If I receive free product through PROLASTIN DIRECT, I will not seek reimbursement or credit for the medication from any insurer, health plan or government program.

I understand that I may cancel this consent at any time by mailing a letter requesting such cancellation to AlphaNet Inc., Attn: Privacy Officer, 3300 Ponce de Leon, Coral Gables, FL 33134. Canceling this consent will end my enrollment in the PROLASTIN DIRECT Program after the date upon which my cancellation is received and will not affect information or support that has already been provided in reliance upon this consent.

- □ I am declining to have AlphaNet provide the above services to me.

My signature certifies that I have read this agreement, and that I consent to participate in the PROLASTIN DIRECT Program and to receive support from PHARMACY, AlphaNet, and other PROLASTIN DIRECT Partners (unless otherwise declined) as described above.

For patients with Veterans Affairs benefits by signing below, disclosure and use of my information provided to PROLASTIN DIRECT/PHARMACY/AlphaNet and/or its Agents is not a part of, endorsed by, or administered by the U.S. Department of Veterans Affairs.

Patient Signature Date

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