PROLASTIN-C LIQUID Enrollment Form with Quick Start

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



*See additional eligibility requirements on the next page

Accredo

By EVERNORTH



PATIENT INFORMAT	ΓΙΟΝ				
First name	Middle in	nitialLast name		SSN (last 4 digits only)	DOB// Gender
Home address		C	ty	State	Zip
Best contact number		Home	mail address	S	
	Please attach copies of	the front and back of the patient's	medical	and prescription insurance	cards.
MEDICAL INFORMA	TION Please include a	copy of patient's clinical notes			
ICD-10 Diagnosis	☐ Alpha₁-Antitrypsin Deficiency E88	3.01 Panlobular Emphysema	J43.1	Other	
AAT Phenotype/Genotyp	pe PiZZ PiZ (null) Pi	(null, null) PiSZ Other		FEV ₁ % predicted	d DLCO% predicted
Serum AAT Level	mg/dL or	μM Allergies None or S	pecify		
Treatment History Has	s patient ever received augmentation	n therapy? Yes No If yes, which t	nerapy?		Smoking Yes No
Medical History C	OPD Asthma Emphysema	Other	r		If yes, date stopped/
Concurrent medications		Vascula	ar access [Peripheral Central Port	i yes, date stopped:/
PROLASTIN-C LIQU	IID PRESCRIPTION INFORMA	TION			
Dose		Directions		Quantity/Refills	
60 mg/kg (+/- 10%) N	·	Rate: As tolerated by patient up to 0.08 n			y. Refill x1 year unless otherwise noted
Other dose/frequency	y bs/kg recorded on//	Other rate			
	<u> </u>				
Medications to be used		and a linearity of the linear	:		
=		eedle insertion as needed for intravenous s	ite pain		
Premedication/other	orders:				
Adverse reaction medi	ications: (keep on hand at all times))			
Epinephrine 0.3 mg	auto-injector 2-pk for patients weighi	ng greater than or equal to 30 kg. Administ	er intramuso	cularly as needed for severe anaph	ylactic reaction; may repeat one time.
Epinephrine 0.15 mg	auto-injector 2-pk for patients weigl	ning less than 30 kg. Administer intramuscu	ılarly as nee	eded for severe anaphylactic reaction	on; may repeat one time.
Diphenhydramine 25	mg by mouth for mild allergic reacti	ons and 50 mg for moderate-severe.			
	Saline flushing		Heparir	n flushing	
Flush orders:		(peripheral line) or 10 mL intravenous	Hepa	rin 10 units per mL 3 mL intravenou	us (peripheral line) as final flush
	(central line) before and after info	usion, or as needed for line patency	Hepar	rin 100 units per mL 5 mL intravend	ous (central line) as final flush
First infusion location	preference: Home or Me	dical facility (name, phone of preferred faci	lity, if any):_		
First infusion in home	nursing orders:				
Establish primary IV li	ine with 250 to 500 mL of normal sal	ine or Other a	t KVO rate	prior to infusion	Provide infusion supplies,
Monitor patient includ	ing VS before, Q15 during, and 30 r	ninutes post infusion			including syringes and needles, to safely administer
Skilled nursing visit as	s needed to establish venous access	s, administer medication and assess gener	al status and	d response to therapy	prescribed medication.
PRESCRIBER INFO	RMATION				
Prescriber first name		Prescriber last name			NPI#
		City			
		Office contact phone			
Office contact email add					
	-	that the therapy described above is medica	Ilv necessar	ry and that the information provided	d is accurate to the best of my
knowledge. I authoriz	e PROLASTIN DIRECT to act on m	y behalf for the limited purpose of transmitt st that I have obtained permission from the	ing this pres	scription by any means allowed und	
Prescriber Sigr				Date	
	Dispense as omply with his/her state specific presoculd result in outreach to the presocult in outreach	scription requirements such as e-prescribir	Substitution Pe		e, etc. Non-compliance with state
ENROLL PATIENT IN	N QUICK START PROGRAM				
The PROLASTIN-C LIG	QUID Quick Start Program provides	s eligible patients new to PROLASTIN-C		Yes Fligible patients can rece	nive an initial fourteen (1/1) day supply
LIQUID with up to eight process. Eligible patien	(8) weeks of no-cost therapy during ts must have a confirmed alpha,-al	ng the commercial insurance approval ntitrypsin deficiency diagnosis and valid to be new to PROLASTIN-C LIQUID.	En pat Qu	Patients continuing to see	eive an initial fourteen (14) day supply. ek or appeal coverage determination from are eligible to receive up to a maximum of ASTIN-C LIQUID dispensed in a two (2)- reen (14) days.

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

(Δ)	Iа	ho	rate	orv	wo	rl

if measured by nephelometry
Phenotype or Genotype: Pi77_Pi7 (null) Pi (null) PiS7 or other in which case a one-on-one discussion may be required with the insurance plan medical

Thenotype or Genotype: PIZZ, PIZ (null), PI (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

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	I etter	of r	nedical	l 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,-proteinase inhibitor (human) (alpha,-PI) indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha,-PI (alpha,-antitrypsin deficiency).

Limitations of Use

- The effect of augmentation therapy with any alpha₁-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in alpha₂-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, -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%).

Sample PROLASTIN-C LIQUID Prescription and Enrollment Form

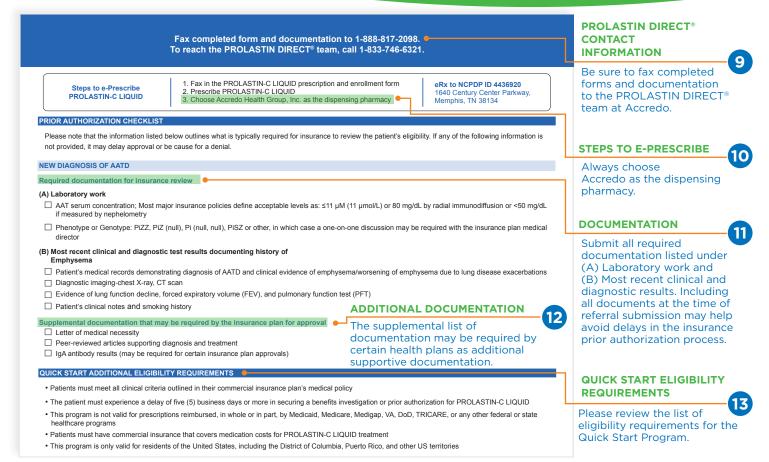


_	'ROLASTIN-C	LIQUID Enrollmer	nt Form with Quid	k Start	INSURANCE CARDS
PROLAS DIREC	STIN. CT	Fax completed form to: 1-86 Accre	38-817-2098 DO	PROLASTIN C LIQUID delta-proteinze irribtor (nuran)	Attach a copy of the front and back of the patient's medical and
Your partner in	<u> </u>	By EVERNORT	H		prescription card(s) to
TIENT INFORMAT					assist with verifying plan
name	Middle	initialLast name			benefit eligibility.
ne address		City		Zip	
t contact number		Home Mobile Work Email			
	•	of the front and back of the patient's r	nedical and prescription insurance	cards.	LICD-10 DIAGNOSIS
DICAL INFORMA	TION Please include a	a copy of patient's clinical notes			These are common
-10 Diagnosis [Alpha,-Antitrypsin Deficiency E8	88.01 Panlobular Emphysema J43	3.1 Other		ICD-10 diagnosis codes
Phenotype/Genotyp	e PiZZ PiZ (null) P	Pi (null, null) PiSZ Other	FEV ₁ % predicted	DLCO% predicted	for alpha-1. All appropria
ım AAT Level	mg/dL or	μM Allergies None or Spec	sify		codes should be selected
tment History Has	patient ever received augmentation	on therapy? Yes No If yes, which ther	apy?	Smoking Yes No	written in.
ical History Co	OPD Asthma Emphysema	Other		If yes, date stopped/	
current medications		Vascular a	access Peripheral Central Port	in yes, date stopped.	
DLASTIN-C LIQU	ID PRESCRIPTION INFORMA	ATION			PHENOTYPE/GENOTYPE
е		Directions	Quantity/Refills		The appropriate
0 mg/kg (+/- 10%) I\	*	Rate: As tolerated by patient up to 0.08 mL/l		. Refill x1 year unless otherwise noted	phenotype/genotype bo
other dose/frequency		Other rate	Other		must be selected/writter
nt weightl	bs/kg recorded on//	-			in.
ications to be used	d as needed:				
idocaine 4% applied	d topically to insertion site prior to r	needle insertion as needed for intravenous site	pain		
remedication/other	orders:				
	cations: (keep on hand at all time				SMOKING HISTORY
iphenhydramine 25	mg by mouth for mild allergic read	ctions and 50 mg for moderate-severe.			insurance plans.
h orders:	Saline flushing Normal saline 3 mL intravenous	s (peripheral line) or 10 mL intravenous	Heparin flushing Heparin 10 units per mL 3 mL intravenou	s (peripheral line) as final flush	EIRST DOSE LOCATION
h orders:	Normal saline 3 mL intravenous	s (peripheral line) or 10 mL intravenous flusion, or as needed for line patency	-		FIRST DOSE LOCATION
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on the DAW line.

Sample PROLASTIN-C LIQUID Prescription and Enrollment Form





To help minimize delays in processing approvals, please fill out this form completely and submit all required documentation.

IMPORTANT SAFETY INFORMATION

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

Limitations of Use

- The effect of augmentation therapy with any alpha,-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in alpha,-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, -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.