

Billing and Coding Guide

A useful resource to support reimbursement
of GLASSIA® and ARALAST® NP across
different sites of care



Important Safety Information

INDICATION AND LIMITATIONS OF USE:

GLASSIA and **ARALAST NP** are Alpha₁-Proteinase Inhibitors (Human) (Alpha₁-PI) indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha₁-PI (alpha₁-antitrypsin deficiency). **GLASSIA** and **ARALAST NP** increase antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha₁-PI.

- The effect of augmentation therapy with **GLASSIA**, **ARALAST NP**, or any Alpha₁-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha₁-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials.
- Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with **GLASSIA** or **ARALAST NP** are not available.
- **GLASSIA** and **ARALAST NP** are not indicated as therapies for lung disease in patients in whom severe Alpha₁-PI deficiency has not been established.

IMPORTANT SAFETY INFORMATION

Contraindications

- Immunoglobulin A (IgA) deficient patients with antibodies against IgA
- History of anaphylaxis or other severe systemic reaction to Alpha₁-PI products.

Warnings and Precautions

Hypersensitivity: **GLASSIA** and **ARALAST NP** may contain trace amounts of IgA. Patients with known antibodies to IgA have a greater risk of developing severe hypersensitivity and anaphylactic reactions. Closely follow the recommended infusion rate, monitor vital signs continuously, and observe the patient throughout the infusion. If hypersensitivity symptoms occur, discontinue the infusion and administer appropriate emergency treatment. Have epinephrine and/or other appropriate supportive therapy available for any acute anaphylactic or anaphylactoid reaction.

Transmissible Infectious Agents: Because **GLASSIA** and **ARALAST NP** are made from human plasma, they may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD), and theoretically the Creutzfeldt-Jakob disease (CJD) agent and other pathogens. No seroconversions for hepatitis B or C or human immunodeficiency virus or any other known infectious agent were reported with the use of **GLASSIA** or **ARALAST NP** during the clinical trials.

Adverse Reactions

GLASSIA: The serious adverse reaction observed during clinical trials was exacerbation of chronic obstructive pulmonary disease (COPD). The most common adverse reactions (>0.5% of infusions) in clinical trials were headache and upper respiratory infection.

ARALAST NP: Hypersensitivity reactions have been reported in patients following administration of **ARALAST NP**. The most common adverse reactions (>0.5% of infusions) in clinical trials were headache, musculoskeletal discomfort, vessel puncture site bruise, nausea, and rhinorrhea.

Please click for Full Prescribing Information for [GLASSIA](#) and [ARALAST NP](#).

Introduction



Billing and coding for GLASSIA® and ARALAST® NP might feel complex at first. **Don't worry. We have you covered.**

This resource provides an overview of the current relevant codes, as of [January 2023], that may be potential options for use with **GLASSIA** and **ARALAST NP**.

Alpha-1-antitrypsin (Alpha-1) proteinase inhibitors can be administered in the home setting, hospital, or various medical facilities. This guide will walk you through the information you need to seek reimbursement for the use of these products within these different settings.

Helpful reminders for submitting claims

- Clarify the payer's coding and clinical documentation requirements, as there may be variations in payer requirements
- Keep in touch with a payer representative who may help clarify problems with the original claim and provide information on current claims as they are processed
- Ensure claims are checked for errors and are accurate and complete before submitting

Please see Indication and Important Safety Information on page 2, and click for Full Prescribing Information for [GLASSIA](#) and [ARALAST NP](#).

Coding and coverage policies may change periodically and often without warning. The information provided here should in no way be considered a guarantee of coverage or reimbursement for any product or service.

Glassia
[Alpha₁-Proteinase Inhibitor (Human)]

Aralast NP
[Alpha₁-Proteinase Inhibitor (Human)]

Introduction



An Overview of Reimbursement Codes

Below are general definitions of commonly used reimbursement codes.

CODE TYPE	CODE DESCRIPTION
ICD-10-CM	The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) are diagnostic codes that must be used for all healthcare services provided in the United States. ¹
CPT	A Current Procedural Terminology (CPT®) code is a 5-digit number used to identify medical services and procedures performed by healthcare professionals (HCPs). These codes are maintained by the American Medical Association (AMA). ²
NDC	A National Drug Code (NDC) is a unique 3-segment number that serves as a universal product identifier for a drug. ³
HCPCS	<p>Healthcare Common Procedure Coding System (HCPCS) codes are used primarily to identify products, supplies, and services not covered by the CPT code.⁴</p> <p>J-codes</p> <p>The most common HCPCS codes are called J-codes, which are used to primarily identify an injectable drug product or biologic.⁵</p>

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Product Codes



ICD-10-CM Diagnostic Codes⁶

The following table lists commonly used codes for GLASSIA[®] and ARALAST[®] NP.

ICD-10-CM CODES	CODE DESCRIPTION
E88.01	Alpha-1-antitrypsin deficiency
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified

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Product Codes



CPT Codes for Diagnostic Testing⁷

These CPT codes are commonly used for diagnosing Alpha-1 deficiency.

CPT CODES	CODE DESCRIPTION
82103	Alpha-1-antitrypsin total
82104	Alpha-1-antitrypsin phenotype
81332	The lab analyst performs the technical lab test to detect the presence of common changes in the gene for serpin peptidase inhibitor, clade A, Alpha-1 antiproteinase, antitrypsin, member 1, also known as SERPINA1
82542	Column chromatography/mass spectrometry
81479	Molecular pathology procedure that does not have a specific code

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Product Codes



CPT Administration Codes⁷

The following table lists the possible commonly used CPT codes applicable for GLASSIA® and ARALAST® NP infusion.

CPT CODES	CODE DESCRIPTION
96365	Intravenous (IV) infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)
96367	IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour
96523	Irrigation of implanted venous access device for drug delivery systems
99070	Additional supplies provided over and above those usually included with a specific service, such as drugs, IV catheters, or trays
99072	Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other nonfacility service(s), only when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease

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Product Codes



HCPCS CODES

J-codes⁸⁻¹⁰

The following table lists the possible commonly used J-codes for GLASSIA® and ARALAST® NP.

DRUG	J-CODES	CODE DESCRIPTION
GLASSIA (solution)	J0257	Injection, Alpha-1 proteinase inhibitor (human), (GLASSIA), 10 mg*
ARALAST NP (powder)	J0256	Injection, Alpha-1 proteinase inhibitor (human), not otherwise specified, 10 mg*

NDC^{8,10}

The following table lists the possible commonly used NDCs for GLASSIA and ARALAST NP.

DRUG	NDC	1 BILLABLE UNIT*	SDV SIZE
GLASSIA (solution)	0944-2884-01	10 mg	1 g/50 mL
ARALAST NP (powder)	0944-2814-01	10 mg	0.5 g/25 mL
	0944-2815-01		1 g/50 mL

*To convert the dosage in grams to International Units (IU), 1 g = 1,000 IU. For the billable units above, 10 mg = 10 IU.
SDV=single-dose vial.

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Product Codes



Hospital Revenue Codes¹¹

The following table lists the possible commonly used hospital revenue codes for the CMS-1450 form (hospital outpatient).

REVENUE CODES	CODE DESCRIPTION
260	IV therapy
261	IV therapy, infusion pump
262	IV therapy, pharmacy services
263	IV therapeutic drug, supply, and delivery
264	IV therapy, supplies
269	IV therapy, other

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Product Codes



Recommended Dosing Regimen

The dose prescribed follows the FDA-approved labeling based on the patient's confirmed diagnosis.

GLASSIA®⁸

- 60 mg/kg body weight administered once weekly by IV infusion
- Administer at a rate not to exceed 0.2 mL/kg body weight/minute depending on patient response and comfort

ARALAST® NP¹⁰

- 60 mg/kg body weight administered once weekly by IV infusion
- Administer at a rate not to exceed 0.2 mL/kg body weight/minute and as determined by the response and comfort of the patient

Billing for Home Infusion Therapy Services¹²

The table below shows the 15-minute time increments that HCPs may use to report visit length (15 minutes = 1 unit).

UNIT	TIME INCREMENTS	UNIT	TIME INCREMENTS
1	≥8 minutes through 22 minutes	6	= 83 minutes to <98 minutes
2	= 23 minutes to <38 minutes	7	= 98 minutes to <113 minutes
3	= 38 minutes to <53 minutes	8	= 113 minutes to <128 minutes
4	= 53 minutes to <68 minutes	9	= 128 minutes to <143 minutes
5	= 68 minutes to <83 minutes	10	= 143 minutes to <158 minutes

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Sample Claim Forms



Sample Claim Form CMS-1450 (Hospital Outpatient)

This form, also known as the UB-04, is the standard claim form to bill Medicare Fee-for-Service.

The image shows a sample CMS-1450 Hospital Outpatient Claim Form. Callouts A, B, C, and D highlight specific sections:

- A: REVENUE CODES AND DESCRIPTIONS** - Points to line 42, where revenue codes corresponding to HCPCS or CPT codes are entered.
- B: PRODUCT AND PROCEDURE CODES** - Points to line 44, where CPT codes, HCPCS codes, and modifiers are entered.
- C: TOTAL CHARGES** - Points to line 47, where the total amount charged for each line of service is entered.
- D: ADMIT DIAGNOSIS** - Points to line 69, where the diagnosis is entered using ICD-10-CM codes.

A REVENUE CODES AND DESCRIPTIONS

On line 42, enter the revenue codes that correspond to the HCPCS or CPT codes outlined on line 44. For line 43, enter a revenue descriptor (optional).

B PRODUCT AND PROCEDURE CODES

On line 44, indicate the appropriate CPT codes, HCPCS codes, and modifiers as required by Medicare or other payer.

C TOTAL CHARGES

Use line 47 to enter the total amount charged for each line of service.

D ADMIT DIAGNOSIS

On line 69, indicate diagnosis using appropriate ICD-10-CM codes. Code to the highest level of specificity for the date of service and enter diagnoses in priority order.

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Sample Claim Forms



Sample Claim Form CMS-1500 (Physician's Office)

The CMS-1500 claim form is the standard claim form used to bill many government and private insurers.

A

DIAGNOSIS CODE

In Box 21, indicate the corresponding ICD-10-CM code for the patient's diagnosis.

B

PRODUCT INFORMATION

Box 24 is for supplemental information, such as the NDC. Verify information requirements with the payer.

C

DATE OF SERVICE

When required by payers to provide the NDC in Box 24A, enter the dates of service that correspond to the code.

D

PRODUCT AND PROCEDURE CODES

In Box 24D, document the HCPCS code for the infusion product and the CPT code representing the procedure performed.

E

DIAGNOSIS POINTER

Specify the diagnosis in Box 21 related to each CPT/HCPCS code listed in Box 24D. This may be indicated as a letter or number, depending on the payer.

F

SERVICE UNITS

In Box 24G, indicate the appropriate number of service units that should reflect the actual number of medication doses provided.

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Distribution and Inventory



Select Specialty Pharmacies Are Authorized Distributors for Home Infusion

If you and your patient opt for home infusion, GLASSIA® and ARALAST® NP are available through a specialty pharmacy provider (SPP). The following SPPs are authorized to dispense GLASSIA and ARALAST NP:

- [Accredo® Specialty Pharmacy]
- [AllianceRx Walgreens Pharmacy]
- [AvevoRX®]
- [CVS Health®]
- [CenterWell Pharmacy™]
(formerly Humana RightSource®)
- [Option Care Health®]
- [Optum® Infusion Pharmacy]

ORDERING INFORMATION:

GLASSIA NDC 0944-2884-01

GLASSIA J-code J0257

ARALAST NP NDC (0.5 g/25 mL) 0944-2814-01

ARALAST NP NDC (1 g/50 mL) 0944-2815-01

ARALAST NP J-code J0256

The SPPs listed above are national distributors of GLASSIA and ARALAST NP. You can also inquire with a regional SPP about acquiring Takeda Alpha-1 proteinase inhibitor treatments. Work with your patients to determine which SPP is appropriate for their circumstances.

In-Suite Infusion Can Be Purchased Directly From Takeda

To determine the number of vials needed to fill your patient's weekly dose, please contact Takeda Medical Information at 1-877-TAKEDA-7 or medinfoUS@takeda.com.

For direct ordering information about GLASSIA or ARALAST NP, please contact Takeda Customer Care.

[1-800-423-2090], Monday through Friday, 8:00 AM to 7:00 PM ET

Note that certain ancillary infusion supplies may be needed for infusion but are not available for purchase through Takeda.

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OnePath is **CO-PAY ASSISTANCE.**

The OnePath Co-Pay Assistance Program may help cover certain out-of-pocket treatment costs for eligible commercially insured patients prescribed GLASSIA® [Alpha₁-Proteinase Inhibitor (Human)] or ARALAST® NP [Alpha₁-Proteinase Inhibitor (Human)] who are enrolled in OnePath.*

The following are covered up to the program maximum and may be paid directly to the provider:

- 100% of eligible out-of-pocket costs related to your treatment, which may include deductibles, co-pays, and co-insurance
- Out-of-pocket costs of eligible infusion charges, where applicable by law

At a minimum, to be eligible for the program, a patient must:

- Be enrolled in OnePath
- Have commercial insurance



Other eligibility requirements may apply.

***IMPORTANT NOTICE:** The OnePath Copay Assistance Program (the Program) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), Tricare, Medigap, VA, DoD, or other federal or state programs (including any medical or state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. The Program cannot be combined with any other rebate/coupon, free trial, or similar offer. Copayment assistance under the Program is not transferable. The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your insurance provider. If your insurance situation changes you must notify the Program immediately at 1-866-888-0660. Coverage of certain administration charges will not apply for patients residing in states where it is prohibited by law. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice.



OnePath is **PERSONALIZED PRODUCT SUPPORT FOR YOUR PATIENTS.**

The Takeda OnePath program provides a range of product support services for your patients prescribed GLASSIA® [Alpha₁-Proteinase Inhibitor (Human)] or ARALAST® NP [Alpha₁-Proteinase Inhibitor (Human)].

From the moment your patients enroll in OnePath, a dedicated Patient Support Manager will work with them one-on-one to help them access their prescribed Takeda medication.

Learn more at OnePath.com

OnePath helps your patients and caregivers



Navigate the health insurance process



Enroll in the OnePath Co-Pay Assistance Program (if eligible) or discuss financial assistance options



Coordinate medication delivery with various sites of care such as hospital-owned specialty pharmacies, home care providers, and infusion centers (if applicable)



Receive free self-administration training with a nurse (if applicable)



Learn about additional support, education, and community resources

For more information, please contact OnePath at **1-866-888-0660** Monday through Friday, 8:30 AM to 8:00 PM ET, or visit OnePath.com.

Access the OnePath **Start Form** for GLASSIA and ARALAST NP.

References



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