

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). **ARALAST NP** increases 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 during 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 occurring in ≥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 May 2024, that may be potential options for use with **GLASSIA** and **ARALAST NP**.

Alpha₁-Proteinase Inhibitors (Alpha₁-PIs) 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, 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](#).

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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	An International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code is a diagnostic code 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). The CPT® Editorial Panel, appointed by the American Medical Association (AMA) Board of Trustees, is responsible for maintaining and updating the CPT code set. 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	Healthcare Common Procedure Coding System (HCPCS) codes are used primarily to identify products, supplies, and services not covered by the CPT code. ⁴ J-codes The most common HCPCS codes are called J-codes, which are used primarily to identify an injectable drug product or biologic. ⁵

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Product Codes



ICD-10-CM Diagnostic Codes⁶

The following table lists the possible 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

The following table lists the possible commonly used CPT codes for diagnosing Alpha₁-antitrypsin deficiency.

CPT CODES	CODE DESCRIPTION
82103	Alpha-1-antitrypsin total level
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 medical supplies, medications, special trays, or medical devices but excluding eyeglasses
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, due to respiratory-transmitted infectious disease

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Product Codes



HCPCS CODES

J-codes^{8,9}

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*

NDC⁸⁻¹⁰

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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Aralast NP
[Alpha₁-Proteinase Inhibitor (Human)]

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
0260	IV therapy
0261	IV therapy, infusion pump
0262	IV therapy, pharmacy services
0263	IV therapeutic drug, supply, and delivery
0264	IV therapy, supplies
0269	IV therapy, other

CMS=Centers for Medicare & Medicaid Services.

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Product Codes



Recommended Dosing Regimen

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

GLASSIA¹⁰

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

ARALAST NP⁹

- 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	5	≥68 minutes through 82 minutes
2	≥23 minutes through 37 minutes	6	≥83 minutes through 97 minutes
3	≥38 minutes through 52 minutes	7	≥98 minutes through 112 minutes
4	≥53 minutes through 67 minutes	8	≥113 minutes through 127 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. Four callouts are present:

- A**: Points to the Revenue Codes and Descriptions section (lines 42-43).
- B**: Points to the Product and Procedure Codes section (lines 44-45).
- C**: Points to the Total Charges section (line 47).
- D**: Points to the Admit Diagnosis section (line 69).

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 the 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® (ESI/Cigna)
- Advanced Infusion Services (AIS)
- Amerita
- AvevoRx®
- BioPlus®
- CVS® (Caremark/Coram)
- CenterWell (Humana Specialty) Specialty Pharmacy™
- OptionCare Health®
- Optum® (BriovaRx/United)
- Walgreens Specialty Pharmacy

ORDERING INFORMATION:

GLASSIA NDC0944-2884-01

GLASSIA J-codeJ0257

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

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

ARALAST NP J-codeJ0256

The SPPs listed above are national distributors of GLASSIA and ARALAST NP. You can also inquire with a regional SPP about acquiring Takeda Alpha₁-PI treatments. Work with your patients to determine which SPP is appropriate for their circumstances.

In-Suite Infusion Can Be Purchased Directly From Takeda

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

1-800-423-2090, Monday through Thursday, 9:00 AM to 6:00 PM ET | Friday, 9:00 AM to 3:30 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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Tailored support for your patient's prescribed Alpha₁ augmentation therapy



After you and your patient choose a treatment path, Takeda Patient Support is here with a range of personalized services for them.

We know living with Alpha₁-antitrypsin deficiency looks different for everyone. Whether they've just been diagnosed or have been on treatment for a long time, we get to know your patient. We work to understand who they are, and we learn what's most important to them—so we can help provide the support they need when it comes to their treatment.

From the moment they enroll, dedicated support specialists will work with them.

*When you prescribe **GLASSIA® [Alpha₁-Proteinase Inhibitor (Human)]** or **ARALAST® NP [Alpha₁-Proteinase Inhibitor (Human)]** for your patient, Takeda Patient Support is here for them. Our support specialists can address your patient's questions and concerns and help get them the information they need.*

For onboarding, access, and reimbursement assistance, our services include:

- 🔄 **Benefits investigation** to help determine your patient's insurance benefits and eligibility for certain services
- 🔄 **Prior authorization (PA), reauthorization, and appeals information**
- 🔄 **Enrollment in the Takeda Patient Support Co-Pay Assistance Program**, if they qualify*
- 🔄 **Information about financial assistance options**, if they're eligible

Our additional services include:

- 🔄 **Specialty pharmacy (or site of care) triage** and coordination
- 🔄 **Takeda product infusion training** for healthcare providers, as well as **home treatment support and education** for your patient
- 🔄 **Arranging** for a trained nursing professional to teach your patient or their caregiver how to infuse treatment at home, if requested by your office (GLASSIA only)
- 🔄 **Directing your patient** to community support resources

*To be eligible, your patient must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Call us for more details.

Need assistance?

Our support specialists are never more than a tap or a call away—
1-866-888-0660,
Monday through Friday, 8:30 AM to 8 PM ET.

Need to enroll your patient?

Visit our convenient online enrollment portal at TakedaPatientSupport.com/HCP.
You can also enroll your patient by faxing the completed Start Form to **1-844-755-5751**.

References



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