Takeda Patient Support

US-XMP-2756v2.0 07/24

Glassia [Alpha$_1$-Proteinase Inhibitor (Human)]

Aralast NP [Alpha$_1$-Proteinase Inhibitor (Human)]

GLASSIA and ARALAST NP Start Form

Red indicates required information

Steps for Prescribing Physician

1. Complete sections 1-5 below and give pages 3 and 4 to your patient to complete. **Any missing information may delay enrollment.**
2. Submit the completed form below to Takeda Patient Support by fax at **1-844-755-5751**. **Sections 1-3 must be completed in full.**
   - Including copies of both sides of the patient's insurance card(s) is preferred but not mandatory.
   - Do not submit to Takeda any documentation of labs, clinical history, or other documents supporting the prior authorization process.
3. Look on the back of this form for next steps in getting your patient started on treatment with the help of Takeda Patient Support services. You or your patient may call Takeda Patient Support at **1-866-888-0660**.

ENTIRE SECTIONS 1–3 ARE REQUIRED TO AVOID DELAYS

ITEMS IN RED REQUIRED FOR SECTIONS 4-5

1 Prescribing Physician

Name (First, Last): _____ Tax ID #: _____ NPI #: _____

Street Address: _____ City: _____ State: _____ ZIP: _____

Office Contact: _____ Email: _____ Telephone: _____ Fax: _____

2 Patient Information

Patient Name (First, Middle Initial, Last): _____ DOB (MM/DD/YYYY): _____

Gender*: ☐ Male ☐ Female Email: _____ Preferred Language: _____

Street Address: _____ City: _____ State: _____ ZIP: _____

Preferred Phone #: _____ ☐ Home ☐ Mobile ☐ Work ☐ Do not contact patient until Prescribing Physician has instructed to do so.

Caregiver Name: _____ Caregiver Email: _____

*Takeda and its partners recognize that patients may not identify as male or female. However, many insurance companies still require that one of these two fields be used for each of their members. Please indicate the gender on file with the patient's insurance company.

3 Insurance Information

Including copies of both sides of the patient's insurance card(s) is preferred but not mandatory.

☐ Check if patient does not have insurance.

Primary Insurance: _____ Secondary Insurance: _____

Insurance Telephone: _____ Insurance Telephone: _____

Policy ID #: _____ Policy ID #: _____

Group ID #: _____ Group ID #: _____

Policy Holder Name (First, Last): _____ Policy Holder Name (First, Last): _____

Policy Holder Relationship to Patient: _____ Policy Holder Relationship to Patient: _____

Pharmacy Plan Name: _____ Pharmacy Plan Telephone: _____

Policy ID #: _____ Group ID #: _____ Rx BIN #: _____ Rx PCN #: _____

Medicare Part D: ☐ Yes ☐ No Medicare Part D Plan Name: _____

Subscriber: _____ DOB: _____ Subscriber ID #: _____ Policy Group #: _____

4 Diagnosis/ Medical Assessment

Diagnosis code: ☐ **ICD-10 E.88 01 (AATD)** ☐ **Other Diagnosis Codes:** _____

Serum AAT Level: _____ mg/dL or _____ µm Date: _____

PFT: FEV, % Pred. _____ Date: _____ O_2 Therapy: _____ L/min Date: _____

Phenotype: _____ Genetic Testing Results: _____

Current or former smoker?
☐ Yes ☐ No
If former smoker, date stopped: _____

5 Therapy

Select only one therapy. ☐ **GLASSIA® [Alpha$_1$-Proteinase Inhibitor (Human)]** ☐ **ARALAST® NP [Alpha$_1$-Proteinase Inhibitor (Human)]**

Infusion Location: ☐ Self-Administration (GLASSIA Only) ☐ Home Health ☐ Hospital/Infusion Center ☐ Healthcare Provider's Office

Preferred Specialty Pharmacy: _____ Preferred Hospital Outpatient/Infusion Center: _____

☐ Please provide my patient and/or his/her caregiver with training on the proper self-administration of GLASSIA.

By signing this form, I certify that therapy with GLASSIA or ARALAST NP is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current GLASSIA or ARALAST NP Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to GLASSIA or ARALAST NP therapy to Takeda Pharmaceutical Company Limited, including its agents or contractors, for the purpose of seeking information related to coverage and/or assisting in initiating or continuing GLASSIA or ARALAST NP therapy. I authorize Takeda Patient Support to transmit this prescription to the appropriate pharmacy designated by me, Patient, or Patient's plan. I agree that product provided through the Program shall only be used for Patient, must not be resold, offered for sale or trade or returned for credit.

Prescriber Signature (Required): _____ **Date:** _____

stamps not acceptable

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 delay.

THIS PAGE IS FOR PRESCRIBING PHYSICIANS

What happens next?

- Once the completed form has been submitted to Takeda Patient Support, a dedicated Patient Support Specialist will be assigned to your eligible patient
- The Patient Support Specialist will contact the patient directly to inform him or her of the services available through Takeda Patient Support and to begin the insurance verification process
- The Patient Support Specialist will work with the insurance company to determine insurance benefits
- The Patient Support Specialist will assess the patient's eligibility for co-pay support (when applicable) and provide information about third-party financial assistance programs, as necessary
- If requested, the Patient Support Specialist will set up Takeda-provided self-administration training services (GLASSIA only)

INDICATION AND LIMITATIONS OF USE:

GLASSIA and **ARALAST NP** are Alpha$_1$-Proteinase Inhibitors (Human) (Alpha$_1$-PI) indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha$_1$-PI (alpha$_1$-antitrypsin deficiency). **ARALAST NP** increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha$_1$-PI.

- The effect of augmentation therapy with **GLASSIA**, **ARALAST NP**, or any Alpha$_1$-PI product 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 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 Alpha$_1$-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 Alpha$_1$-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.

GLASSIA and ARALAST NP Start Form

Red indicates required information

Patient Authorization

Review this page and call Takeda Patient Support at **1-866-888-0660** or fax page 3 to **1-844-755-5751**.

Patient Name (First, Middle Initial, Last): _____ **DOB (MM/DD/YYYY):** _____

Patient Authorization to Share Protected Health Information

I authorize any health plan, physician, health care professional, hospital, clinic, pharmacy provider or other health care provider (collectively, "Providers") to disclose my protected health information, including personal information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription ("Information"), to Takeda Pharmaceutical Company Limited, its affiliates and their representatives, agents, and contractors (collectively, the "Company" or "Takeda") in connection with the Company's provision of products, supplies, or services. I understand the Company will provide this Information to a specialty pharmacy to fulfill the prescription. This Information may also be used for internal uses by the Company, including data analysis. Further, I understand that my physician, health insurance, and pharmacy providers may receive financial remuneration from the Companies for providing Protected Health Information, which may be used for marketing purposes.

Further, the Company may use this Information for Takeda Patient Support Services ("Services") (if I agree below) such as verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician by mail, email, or telephone about my medical condition, treatment, care management, product information and health insurance.

I understand that once disclosed to the Company, my Personal Health Information disclosed under this Authorization may no longer be protected by federal privacy law, including HIPAA. I understand that I am entitled to a copy of this Authorization. I understand that I may cancel this Authorization at any time by sending written notice of revocation to Takeda Patient Support, 300 Shire Way, Lexington, MA, 02421. I understand that such revocation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from today's date, unless a shorter period is provided for by state law.

I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my physician, health insurance, and pharmacy providers treat me. I also understand that if I do not sign this Authorization, I will not be able to receive Services from Takeda.

Signature of Patient: _____ **Date:** _____

Legal Representative Signature*: _____ **Date:** _____

Legal Representative Name*: _____ **Relationship to Patient*:** _____

*Required only if applicable.

REQUIRED: Takeda Patient Support Enrollment (must check box below to be enrolled in Services)

☐ I am electing to enroll in the Services and direct all disclosures of my Information in connection with such Services (which may include, but is not limited to, verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician by mail, email, or telephone about my medical condition, treatment, care management, product information and health insurance).

Patient Consent for Marketing Communications

☐ By checking this box, I authorize the use of my Information for Takeda marketing activities and consent to receiving marketing and promotional communications from Takeda. I hereby give consent to Takeda, its affiliates, and their agents and representatives to send communications and information to me via the contact information I have provided above. I understand that this consent will be in effect until I cancel such authorization.

Please see Important Safety Information on page 2 and click for Full Prescribing Information for GLASSIA and ARALAST NP.

Tailored support for you throughout your Alpha-1 augmentation therapy

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

We know that living with Alpha-1 antitrypsin deficiency looks different for everyone. We get to know you, understand who you are, and learn what's important to you—so we can help provide the support you need when it comes to your treatment.

*Takeda Patient Support is a product support program for people who have been prescribed **GLASSIA** or **ARALAST NP**. Our support specialists are here to address your questions and concerns and help get you the answers, resources, and tools you need. Some of the ways we can help include:*

- **Enrolling** you in the **Takeda Patient Support Co-Pay Assistance Program**, if you qualify*†
- **Working** with your specialty pharmacy (or site of care) to **help you receive GLASSIA or ARALAST NP**
- **Arranging** for a **trained nursing professional to teach you or a caregiver how to infuse your treatment at home**, if requested by your healthcare provider (GLASSIA only)
- **Navigating** the **health insurance** process
- **Directing** you to **community support resources and education**
- **Providing** you with **tips and timely information** throughout your **GLASSIA or ARALAST NP** treatment

Want to connect?

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.

If English is not your preferred language, we may be able to assist you in a language of your choosing.

Enroll in Takeda Patient Support Now.

1. Sign the Patient Authorization section on page 3 of this Start Form and call us directly **1-866-888-0660** or fax it to **1-844-755-5751**
2. Your dedicated support specialist will contact you. Keep the Takeda Patient Support number **(1-866-888-0660)** in your phone, and please call us back if you miss a call from us

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

What happens next?

Once you have filled out the Patient Authorization Form (back of this page) and enrolled in Takeda Patient Support, your Takeda Patient Support team can begin providing personalized product support. This includes working with your physician's office, insurance company, and specialty pharmacy to access your prescribed therapy.

†**IMPORTANT NOTICE:** The Takeda Patient Support Co-Pay 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.

Please see Important Safety Information on page 2 and click for Full Prescribing Information for GLASSIA and ARALAST NP.

SHARE THIS PAGE WITH YOUR PATIENT OR THEIR CAREGIVER