GAMMAGARD LIQUID
[Immune Globulin Infusion (Human)] 10%

ONEPATH® START FORM: AUTHORIZATION FOR ONEPATH SERVICES

FAX PAGES 1 AND 3 TO 1-833-388-5467 PHONE: 1-866-888-0660

OnePath

THIS START FORM IS INTENDED FOR USE ONLY FOR PATIENTS WITH PRIMARY IMMUNODEFICIENCY.

1 Prescribing Physician

Name (First, Last): _____ State License #: _____ NPI #: _____

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

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

2 Patient Information

Patient Name (First, Middle Initial, Last): _____ ☐ Male ☐ Female

DOB (MM/DD/YYYY): _____ Age (Years): _____ Last 4 Digits of Social Security #: _____ Email: _____

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

Mobile Telephone (M): _____ Work Telephone (W): _____ Home Telephone (H): _____ Preferred #: ☐ M ☐ W ☐ H

Caregiver Name (First, Last): _____ Relationship to Patient: _____ Caregiver Telephone: _____

Caregiver Email: _____

3 Insurance Information

Please attach copies of both sides of patient's insurance card(s). ☐ **Check if patient does not have insurance.**

Primary Insurance: _____ Insurance Telephone: _____

Policy ID #: _____ Group ID #: _____

Policy Holder Name (First, Last) and Relationship to Patient: _____ Policy Holder DOB (MM/DD/YYYY): _____

Pharmacy Plan Name: _____ Pharmacy Plan Telephone: _____

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

Secondary Insurance: _____ Insurance Telephone: _____

Policy ID #: _____ Group ID #: _____

Policy Holder Name (First, Last) and Relationship to Patient: _____ Policy Holder DOB (MM/DD/YYYY): _____

4 Diagnosis/ Medical Assessment

(a) Diagnosis: ICD-10: _____

(b) IgG Level (mg/dL): _____ (c) IgA Level (mg/dL): _____ (d) IgM Level (mg/dL): _____

(e) Pre Titer Level (mcg/mL): _____ (f) Post Titer Level (mcg/mL): _____

5 GAMMAGARD LIQUID Prescription, Training Request/Waiver, and Prescribing Physician Signature

PRESCRIPTION: GAMMAGARD LIQUID® [Immune Globulin Infusion (Human)] 10% Solution

Route of Administration:

☐ **Intravenous Administration (IVIG)**

For patients with primary immunodeficiency (PI), IVIG doses of 300 to 600 mg/kg every 3 weeks or 4 weeks based on clinical response.[1] See IV Administration Rate table on page 2 for calculation of infusion rate.

☐ **Subcutaneous Administration (SCIG)**

For patients with PI switching from IVIG to SCIG treatment, the formula to the right is used to calculate the recommended initial dose.[1] See SC Administration Rate table on page 2 for calculation of infusion rate.

$$\text{SCIG DOSE} = \frac{1.37 \times \text{PREVIOUS IVIG DOSE}}{\text{\# OF WEEKS BETWEEN IVIG DOSES}}$$

Training available to SCIG patients: GAMMAGARD LIQUID SCIG is intended for self-administration or administration by a caregiver. The patient or caregiver should be trained by a health care professional. OnePath provides free infusion training services to enrolled GAMMAGARD LIQUID SCIG patients.

☐ **If you choose to opt out of these services, please check this box.**

Patient Weight (kg): _____ Ordered Dose (Grams): _____ every _____ weeks

_____ Refills (as allowed by state or payer requirement)

Route: ☐ Central IV ☐ Peripheral IV ☐ SC: Needle length, mm: _____

Allergies

☐ No known drug allergies

☐ Patient allergies (drug and non-drug): _____

☐ Special instructions: _____

Additional Services

☐ Provide needles, syringes, venous access device (VAD) supplies, and other ancillary supplies needed for infusion

☐ Durable medical equipment (DME)—infusion pump with supplies

☐ Anaphylaxis kit: _____

Preferred Site of Care If Not Self-Administering (Mark One):

☐ INFUSION SUITE ☐ BEGIN TREATMENT IN CLINICAL SETTING, THEN TRANSITION TO HOME CARE ☐ PRESCRIBER'S OFFICE ☐ HOME INFUSION ☐ HOSPITAL OUTPATIENT

Preferred Specialty Pharmacy: _____

Preferred Infusion Suite/Hospital Outpatient (if applicable): _____

By signing this form, I certify that therapy with GAMMAGARD LIQUID is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current GAMMAGARD LIQUID 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 GAMMAGARD LIQUID 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 GAMMAGARD LIQUID therapy. I authorize OnePath 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.

Please ensure that patient reads and signs page 3 for appropriate authorizations.

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

Stamps not acceptable DISPENSE AS WRITTEN

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.

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INSTRUCTIONS FOR COMPLETION OF FORM

1 Prescribing Physician 2 Patient Information 3 Insurance Information 4 and Diagnosis/Medical Assessment

- Fill out completely
- Do not submit to Takeda any documentation of labs, clinical history, or other documents supporting the prior authorization process

5 GAMMAGARD LIQUID Prescription, Training Request/Waiver, and Prescribing Physician Signature

- Please indicate the number of refills
- **Available to SCIG patients only:** Check the appropriate box to specify whether you would like your patient to be trained by Takeda on self-administration or whether training has already occurred
- This is a prescription; a physician's signature and date are required

Infusion Rates for Intravenous Administration

Initial	0.5 mL/kg/hr (0.8 mg/kg/min) for 30 minutes
Maintenance	Increase every 30 minutes (if tolerated) up to 5 mL/kg/hr (8 mg/kg/min)

Infusion Rates for Subcutaneous Administration

	40 kg BW and greater	Under 40 kg BW
Initial	30 mL/site at a rate of 20 mL/hr/site	20 mL/site at a rate of 15 mL/hr/site
Maintenance	30 mL/site at a rate of 20 to 30 mL/hr/site	20 mL/site at a rate of 15 to 20 mL/hr/site

6 Patient Authorization to Share Personal Health Information and OnePath Enrollment

- The patient signature is required to allow personal health information to be shared by third parties to Takeda to facilitate access to GAMMAGARD LIQUID (insurance benefits, self-administration training [available to SCIG patients only], transfer Rx to specialty pharmacy provider, etc)
- **Checking the OnePath Enrollment box allows patients to receive product support services from Takeda, if eligible**
  - Benefits investigation
  - Infusion training (if applicable, available to SCIG patients only)
  - Co-pay support (when applicable) and information about third-party financial assistance programs, as necessary
  - Enrollment in OnePath—Patient Support Manager assignment and product support services

7 Fax pages 1 and 3 to 1-833-388-5467

- Attach a copy of the patient's insurance card

WHAT HAPPENS NEXT?

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

INDICATION AND IMPORTANT SAFETY INFORMATION

GAMMAGARD LIQUID is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients ≥2 years.

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin (IG) products, including GAMMAGARD LIQUID. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients with immune globulin intravenous (IGIV) products. Patients predisposed to renal dysfunction include those with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. GAMMAGARD LIQUID does not contain sucrose.**
- **For patients at risk of thrombosis, administer GAMMAGARD LIQUID at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.**

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to human IG
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG. Anaphylaxis has been reported with intravenous (IV) use of GAMMAGARD LIQUID.

Warnings and Precautions

See Full Prescribing Information for Warnings and Precautions for:

Hypersensitivity, Renal Dysfunction/Failure, Hyperproteinemia, increased serum viscosity, and hyponatremia, Thrombosis, Aseptic Meningitis Syndrome, Hemolysis, Transfusion-Related Acute Lung Injury, Transmittable Infectious Agents, and Interference with Lab Tests.

Adverse Reactions

IV administration for PI: The serious adverse reaction seen during IV clinical studies was aseptic meningitis. The most common adverse reactions observed in ≥5% of subjects were headache, fatigue, pyrexia, nausea, chills, rigors, pain in extremity, diarrhea, migraine, dizziness, vomiting, cough, urticaria, asthma, pharyngolaryngeal pain, rash, arthralgia, myalgia, oedema peripheral, pruritus, and cardiac murmur.

Subcutaneous administration for PI: The most common adverse reactions observed in ≥5% of subjects were infusion site (local) event (rash, erythema, edema, hemorrhage, and irritation), headache, fatigue, heart rate increased, pyrexia, abdominal pain upper, nausea, vomiting, asthma, blood pressure systolic increased, diarrhea, ear pain, aphthous stomatitis, migraine, oropharyngeal pain, and pain in extremity.

Please click for the Full Prescribing Information.

Reference: 1. GAMMAGARD LIQUID [prescribing information]. Westlake Village, CA: Baxalta US Inc.

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

6 Patient Authorization to Share Personal Health Information and OnePath Enrollment

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, the Company may use this Information for OnePath Product Support 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.

Additionally, if I check the box below regarding marketing communications, I authorize the Company to use and disclose my Information to send marketing materials to me (as described below).

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 OnePath, 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 OnePath Product Support Program products, supplies, or services.

Signature of Patient (Required): _____ Date: _____

Legal Representative Name (if applicable): _____

Relationship to Patient (if applicable): _____

Legal Representative Signature (if applicable): _____ Date: _____

OnePath Enrollment (must check box below to be enrolled in product support services through OnePath)

☐ I am electing to enroll in OnePath Product Support Services ("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).

Signature of Patient (Required): _____ Date: _____

Legal Representative Signature (if applicable): _____ Date: _____

Consent for Future Information

☐ 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.