Takeda Patient Support

GAMMAGARD LIQUID ERC Patient Start Form

Fax pages 1-4 to **1-866-861-1752** | Phone: **1-866-861-1750**

Please ensure patient reads and signs **pages 3 and 4** for appropriate authorizations.

GAMMAGARD LIQUID ERC
[Immune Globulin Infusion (Human)]
≤2 µg/mL IgA in a 10% Solution

1 Prescribing Physician Information

Prescriber Name (First, Last):

Title:

State License #:

NPI #:

Tax ID #:

PTAN #:

Street Address:

City:

State:

Zip Code:

Office Contact:

Email:

Telephone:

Fax:

2 Patient Information

☐ Male ☐ Female

Patient Name (First, Middle Initial, Last):

DOB (MM/DD/YYYY):

Last 4 Digits of Social Security #:

Email:

Street Address:

City:

State:

Zip Code:

Mobile Telephone:

Home Telephone:

Caregiver Name (First, Last):

Relationship to Patient:

Caregiver Telephone:

Caregiver Email:

3 Insurance Information

Please attach copies of both sides of patient's medical and prescription insurance cards.

☐ Check if patient does not have insurance.

Primary Insurance:

Insurance Telephone:

Policy ID #:

Group ID #:

Policy Holder Name:

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:

Policy Holder DOB (MM/DD/YYYY):

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4 Diagnosis/Medical Assessment

Diagnosis (ICD-10):

PI

IgA Level (mg/dL):

IgG Level (mg/dL):

IgM Level (mg/dL):

Pre-Titer Level (mcg/mL):

Post-Titer Level (mcg/mL):

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

Name (First, Middle Initial, Last):

DOB (MM/DD/YYYY):

Patient Weight (kg):

Prescription:

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

☐ **Patient is already on GAMMAGARD LIQUID ERC**

☐ **Refills** (as allowed by state or payer requirement)

☐ **Intravenous immune globulin (IVIG) administration**[1]

Administer IVIG doses of 300 to 600 mg/kg every 3 to 4 weeks based on clinical response. See the Infusion Rates for IV Administration table on page 5 for calculation of infusion rate.

Ordered Dose (grams):

Every (weeks):

Route:

☐ Central IV ☐ Peripheral IV ☐ SC needle

Length (mm):

☐ **Subcutaneous immune globulin (SCIG) administration**[1]

For patients switching from IVIG to SCIG treatment, the formula below is used to calculate the recommended initial dose. See the Infusion Rates for SC Administration table on page 5 for calculation of infusion rate. Maintenance dose is based on clinical response and target IgG trough level.

To calculate SCIG dose = (1.37 x previous IVIG dose) ÷ Number of weeks between IVIG doses

☐ No known drug allergies

☐ Patient allergies (drug and non-drug):

Special Instructions:

Preferred site of care if not self-administered (check one)

☐ Infusion suite ☐ Begin treatment in clinical setting, then transition to home care

Has a referral been sent to site of care? ☐ Yes ☐ No

☐ Prescriber's office ☐ Home infusion ☐ Hospital outpatient

Preferred Specialty Pharmacy:

Preferred Infusion Suite/Hospital Outpatient (if applicable):

Additional services and infusion training are available.

Check the box next to any of the services below. Check the last box if the patient opts out.

☐ Pharmacy to provide needles, syringes, venous access device supplies, and other ancillary supplies needed for infusion

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

☐ Name of pharmacy (to provide anaphylactic kit):

☐ Training available to SCIG patients

GAMMAGARD LIQUID ERC SCIG is intended for self-administration or administration by a caregiver. The patient or caregiver should be trained by a healthcare professional. Takeda Patient Support provides free infusion training services to enrolled patients.

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

By signing this form, I certify that therapy with GAMMAGARD LIQUID ERC is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current GAMMAGARD LIQUID ERC 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 ERC 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 ERC 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) Stamps not acceptable

SIGN

DISPENSE AS WRITTEN Date SUBSTITUTION PERMITTED Date

The prescriber is required 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.

Please see Important Safety Information on page 6 and click for Full Prescribing Information, including Boxed Warning regarding Thrombosis, Renal Dysfunction and Acute Renal Failure.

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6 Patient HIPAA Authorization

Patient Name (First, Middle Initial, Last):

DOB (MM/DD/YYYY):

By signing the Patient Authorization section on the third page of this Takeda Patient Support Ig Enrollment Form, I authorize my physician, health insurance, and pharmacy providers (including any specialty pharmacy that receives my prescription) to disclose my protected health information, including, but not limited to, information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form ("Protected Health Information"), to Takeda Pharmaceuticals U.S.A., Inc. and its present or future affiliates, including the affiliates and service providers that work on Takeda's behalf in connection with the Takeda Patient Support, Ig Patient Support Program (the "Companies"). The Companies will use my Protected Health Information for the purpose of facilitating the provision of the Takeda Patient Support, Ig Patient Support Program products, supplies, or services as selected by me or my physician and may include (but not be limited to) verification of insurance benefits and drug coverage, prior authorization education, financial assistance with co-pays, patient assistance programs, and other related programs. Specifically, I authorize the Companies to 1) receive, use, and disclose my Protected Health Information in order to enroll me in Takeda Patient Support, Ig and contact me, and/or the person legally authorized to sign on my behalf, about Takeda Patient Support, Ig; 2) provide me, and/or the person legally authorized to sign on my behalf, with educational materials, information, and services related to Takeda Patient Support, Ig; 3) verify, investigate, and provide information about my coverage for GAMMAGARD LIQUID ERC, including but not limited to communicating with my insurer, specialty pharmacies, and others involved in processing my pharmacy claims to verify my coverage; 4) coordinate prescription fulfillment; and 5) use my information to conduct internal analyses. I understand that employees of the Companies only use my Protected Health Information for the purposes described herein, to administer the Takeda Patient Support, Ig Patient Support Program or as otherwise required or allowed under the law, unless information that specifically identifies me is removed. 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. I understand that Protected Health Information disclosed under this Authorization may no longer be protected by federal privacy law. I understand that I am entitled to a copy of this Authorization. I understand that I may revoke this Authorization and that instructions for doing so are contained in Takeda's Website Privacy Notice available at www.takeda.com/privacy-notice/ or I may revoke this Authorization at any time by sending written notice of revocation to Takeda Patient Services 610 Crescent Executive Court, Suite 200 Lake Mary, FL 32746. 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 the date it is signed and provided on the first page of this enrollment form, 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 Takeda Patient Support, Ig Patient Support Program products, supplies, or services.

SIGN

Signature of Patient (Required) Date

SIGN

*Legal Representative Name:

***Legal Representative Signature** Date

*Relationship to Patient:

*Required only if applicable.

Please see Important Safety Information on page 6 and click for Full Prescribing Information, including Boxed Warning regarding Thrombosis, Renal Dysfunction and Acute Renal Failure.

Takeda Patient Support

Patient Name: _____

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7 Takeda Patient Support Enrollment (signature required for enrollment)

By signing below, I am electing to enroll in Takeda Patient Support Services ("Services") and direct all disclosures of my Information in connection with such Services (which may include, but are 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).

SIGN

_____

Signature of Patient (Required)/***Legal Representative Signature** Date

*Required only if applicable.

8 Patient Consent for Communications

Marketing Communications

☐ By checking this box, I authorize the use of my Information for Takeda marketing activities and consent to receiving marketing, market research opportunities, 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.

Text Communications

☐ By checking this box, you agree to the Takeda Patient Support ("Program") text message terms and conditions below, and you agree to receive text messages on your mobile device subject to the Terms & Conditions. You consent to receive autodialed and/or prerecorded calls and/or text messages from or on behalf of the Program at the telephone number provided above. You understand that this consent is not a condition of purchase or use of the Program or of any Takeda product or service. Such messages may be nonmarketing messages related to the Patient Support Program. There is no fee payable to Takeda to receive text messages; however, your carrier's message and data rates may apply.

Text Communication Agreement Terms & Conditions

You represent that you are the account holder for the mobile telephone number(s) that you provide to opt in to the Program. You are responsible for notifying Takeda immediately if you change your mobile telephone number. You may notify Takeda of a number change by calling 1-866-861-1750. Data obtained from you in connection with your registration for, and use of, this SMS service may include your phone number and/or email address, related carrier information, and elements of pharmacy claim information and will be used to administer this Program and to provide Program benefits such as information about your prescription, refill reminders, and Program updates and alerts.

Takeda will not be liable for any delays in the receipt of any SMS messages, as delivery is subject to effective transmission from your network operator. This Program is valid with most major US cellular providers.

Takeda may be required to contact the user if an adverse event is reported.

You agree to indemnify Takeda and any third parties texting on its behalf in full for all claims, expenses, and damages related to or caused, in whole or in part, by your failure to immediately notify us if you change your telephone number, including but not limited to all claims, expenses, and damages related to or arising under the Telephone Consumer Protection Act.

Takeda reserves the right to rescind, revoke, or amend the Program without notice at any time.

You can unsubscribe from this Program by texting back STOP to any message or by calling 1-866-861-1750.

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Before you fax this form, confirm you have:

- ☐ Completed **sections 1-8**
- ☐ Attached a copy of the patient's **insurance card (front and back)**
- ☐ Ensured the patient/legal representative has **signed pages 3 and 4**
- ☐ Not submitted any documentation of labs, clinical history, or other documents supporting the prior authorization process

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

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

- Please indicate the number of refills
- This is a prescription; a physician's signature and date are required
- **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

Infusion Rates for IV Administration[1]

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 SC Administration[1]

	Patients ≥40 kg	Patients <40 kg
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 HIPAA Authorization

The patient signature is required to allow personal health information to be shared by third parties to Takeda to facilitate access to GAMMAGARD LIQUID ERC (insurance benefits, self-administration training [available to SCIG patients only], transfer Rx to specialty pharmacy provider, etc).

7 Takeda Patient Support Enrollment

The patient signature is required to enroll in Takeda Patient Support, and allows patients to receive product support and services from Takeda if eligible.

Check additional services and infusion training if needed, or check the last box if patient opts out.

8 Patient Consent for Communications

The patient must check the appropriate boxes to receive Takeda marketing and text communications.

What happens next?

- Once the completed form has been submitted to Takeda Patient Support, a dedicated Support Specialist will be assigned to your eligible patient
- The 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 Support Specialist will work with the insurance company to determine insurance benefits
- The 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
- **Available to SCIG patients only:** If requested, the Support Specialist will set up Takeda-provided self-administration training services

Takeda Patient Support

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INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin (IG) products, including GAMMAGARD LIQUID ERC. 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 ERC does not contain sucrose.**
- **For patients at risk of thrombosis, administer GAMMAGARD LIQUID ERC 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 the administration of GAMMAGARD LIQUID ERC.

Warnings and Precautions

Hypersensitivity Reactions: Severe hypersensitivity reactions may occur with immune globulin (IG) products, including GAMMAGARD LIQUID ERC, even in patients previously treated with IG products. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. In case of severe hypersensitivity, discontinue GAMMAGARD LIQUID ERC infusion immediately and manage with appropriate medications which may include epinephrine for immediate treatment.

Renal Injury: Renal injury, including acute renal failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis may occur with use of IG products, including GAMMAGARD LIQUID ERC. Ensure patients are not volume depleted before administering GAMMAGARD LIQUID ERC. In patients who are at risk of renal injury because of pre-existing renal insufficiency or predisposition to acute renal failure (such as diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs), administer GAMMAGARD LIQUID ERC at the minimum rate of infusion practicable.

Hyperproteinemia, Hyperviscosity, and Hyponatremia: May occur in patients receiving IG products, including GAMMAGARD LIQUID ERC. Distinguish true hyponatremia from pseudohyponatremia that is temporally or causally related to hyperproteinemia with concomitant decreased calculated serum osmolality or elevated osmolar gap. Treatment aimed at decreasing serum free water in patients with pseudohyponatremia may lead to volume depletion and hyperviscosity and a predisposition to thromboembolic events.

Thrombosis: May occur following treatment with IG products, including GAMMAGARD LIQUID ERC. Risk factors include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. Ensure adequate hydration in patients before administration of GAMMAGARD LIQUID ERC. For patients at risk of thrombosis, administer GAMMAGARD LIQUID ERC at the minimum dose and infusion rate practicable. Monitor patients for signs and symptoms of thrombosis. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity.

Aseptic Meningitis Syndrome (AMS): May occur with use of IG products, including GAMMAGARD LIQUID ERC. The risk of AMS may be higher with high doses (2g/kg) and/or rapid infusion. Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

Hemolysis: May occur with IG products, including GAMMAGARD LIQUID ERC due to the presence of blood group antibodies, which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Transfusion-Related Acute Lung Injury (TRALI): May occur following treatment with IG products, including GAMMAGARD LIQUID ERC. Symptoms typically occur within 1 to 6 hours after treatment. Monitor patients for signs and symptoms of TRALI. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. Manage patients using oxygen therapy with ventilatory support as appropriate.

Transmission Infectious Agents: There is risk of transmission of infectious disease or agents including viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and the Creutzfeldt-Jakob disease agent with GAMMAGARD LIQUID ERC administration because it is manufactured using human blood.

Interference with Lab Tests: False positive serological test results and certain assay readings may occur as the result of passively transferred antibodies.

Adverse Reactions

No clinical studies have been conducted using GAMMAGARD LIQUID ERC. The safety of GAMMAGARD LIQUID ERC in patients with primary humoral immunodeficiency (PI) is supported by two clinical studies conducted on GAMMAGARD LIQUID.

IV Administration: The most common adverse reactions observed in ≥5% of patients in study 1 were headache, fatigue, pyrexia, chills, nausea, pain in extremity, diarrhea, migraine, vomiting, dizziness, urticaria, cough, asthma, oropharyngeal pain, infusion site extravasation, arthralgia, rash, myalgia, pruritus, and cardiac murmur.

Subcutaneous administration: The most common adverse reactions observed in ≥5% of patients in study 2 were infusion site (local) event, headache, pyrexia, fatigue, heart rate increased, abdominal pain upper, vomiting, arthralgia, nausea, asthma, blood pressure systolic increased, diarrhea, ear pain, aphthous ulcer, migraine, oropharyngeal pain, and pain in extremity.

Drug Interactions

Passive transfer of antibodies may transiently interfere with immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

Please click for Full Prescribing Information.

Reference: 1. GAMMAGARD LIQUID ERC [prescribing information]. Cambridge, MA: Takeda Pharmaceuticals, U.S.A., Inc.

Takeda