Takeda Patient Support

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

GAMMAGARD LIQUID 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.

1 Prescribing Physician Information

Name (First, Last):

State License #: | NPI #: | Tax ID #: | PTAN #:

Street Address: | City: | State: | ZIP:

Office Contact: | Telephone: | Fax: | Email:

2 Patient Information

☐ Male ☐ Female

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

Last 4 Digits of Social Security #: | Email: | Mobile Telephone: | Home Telephone:

Street Address: | City: | State: | ZIP:

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:	Pharmacy Plan Name:	Secondary Insurance:
Insurance Telephone:	Pharmacy Plan Telephone:	Insurance Telephone:
Policy ID #:	Policy ID #:	Policy ID #:
Group ID #:	Group ID #:	Group ID #:
Policy Holder Name:	RX BIN #:	Policy Holder Name:
Policy Holder DOB:	RX PCN #:	Policy Holder DOB:

4 Diagnosis/Medical Assessment

PI

Diagnosis (ICD-10): | IgA Level (mg/dL):

IgG Level (mg/dL): | IgG Level (mg/dL):

Pre-Titer Level (mcg/mL): | Post-Titer Level (mcg/mL):

CIDP

EMG/NCS/Nerve Ultrasound (m/sec):

[NF155 Levels:] | MRI results :

[CNTN1 Levels:]

MMN

EMG/NCS/Nerve Ultrasound (m/sec): | MRI results :

IgM Anti-GM1 Titer (mg/mL):

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:

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

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

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.

Name (First, Middle Initial, Last):

DOB (MM/DD/YYYY):

Patient weight (kg):

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

☐ **Patient is already on GAMMAGARD LIQUID**

☐ **Intravenous immune globulin (IVIG) administration** (for PI, MMN, and CIDP patients)[1]

For patients with primary immunodeficiency (PI), administer IVIG doses of 300 to 600 mg/kg every 3 or 4 weeks based on clinical response. See the Infusion Rates for IV Administration table on page 5 for calculation of infusion rate.

For patients with multifocal motor neuropathy (MMN), administer IVIG doses of 0.5 to 2.4 grams/kg per month based on clinical response.

For patients with chronic inflammatory demyelinating polyneuropathy (CIDP), induction dose is 2 g/kg in divided doses over 2 to 5 consecutive days, followed by maintenance infusions. The maintenance dose is 1 g/kg in divided doses over 1 to 4 consecutive days, every 3 weeks. The maintenance dose and dosing interval may be adjusted according to clinical response.

Refills (as allowed by state or payer requirement)

Ordered dose (grams):

every (weeks):

Route:

☐ Central IV ☐ Peripheral IV ☐ SC needle

length: (mm)

☐ **Subcutaneous immune globulin (SCIG) administration** (for PI patients only)[1]

For patients with PI 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.

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:

Additional services

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

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

☐ Pharmacy to provide anaphylactic kit:

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 healthcare professional. Takeda Patient Support provides free infusion training services to enrolled GAMMAGARD LIQUID SCIG patients.

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

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

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

☐ 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 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.

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

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, 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.

Signature of Patient (Required) Date

*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.

6 Takeda Patient Support Enrollment

Patient Name (First, Middle Initial, Last):

DOB (MM/DD/YYYY):

REQUIRED:

Takeda Patient Support 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).

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

Date

OPTIONAL:

Text Communication Agreement Terms & Conditions

By agreeing to these Takeda Patient Support ("Program") text message terms and conditions, you agree to receive text messages on your mobile device subject to the Terms & Conditions described below. You also 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.

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 STOP to any message or by calling 1-866-861-1750.

Consent for Marketing Information: By signing below, 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.

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

Date

*Required only if applicable.

Takeda Patient Support

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Instructions for Completion of Form

- Complete sections 1-6 and **FAX PAGES 1-4 to 1-866-861-1752** and attach a copy of the patient's insurance card (front and back)
- Do not submit to Takeda 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 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

6 Patient HIPAA Authorization and Takeda Patient Support 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 Takeda Patient Support 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 Takeda Patient Support, Patient Support Manager assignment and product support services

	Infusion Rates for IV Administration (PI)[1]	Infusion Rates for IV Administration (MMN)[1]	Infusion Rates for IV Administration (CIDP)[1]
Initial	0.5 mL/kg/hr (0.8 mg/kg/min) for 30 minutes	Increasing rates of infusion starting at 0.5 mL/kg/hr (0.8 mg/kg/min)	0.5 mL/kg/hr (0.8 mg/kg/min)
Subsequent	Increase every 30 minutes (if tolerated) up to 5 mL/kg/hr (8 mg/kg/min)	Increase to a maximum rate of 5.4 mL/kg/hr if tolerated (9 mg/kg/min)	Increase to a maximum rate of 5.4 mL/kg/hr if tolerated (9 mg/kg/min)

	Infusion Rates for SC Administration (PI)[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

What happens next?

- Once the completed form has been submitted to Takeda Patient Support, 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 Takeda Patient Support and to begin the insurance verification process
- The Patient Support Manager will work with the insurance company to determine insurance benefits
- The Patient Support Manager 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

Takeda Patient Support

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INDICATIONS

GAMMAGARD LIQUID is indicated as a replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older, as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN), and as a therapy to improve neuromuscular disability and impairment in adult patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

LIMITATIONS OF USE (CIDP): GAMMAGARD LIQUID has not been studied in immunoglobulin-naive patients with CIDP. GAMMAGARD LIQUID maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with GAMMAGARD LIQUID in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

GAMMAGARD LIQUID for PI is for intravenous or subcutaneous use.
GAMMAGARD LIQUID for MMN and CIDP is for intravenous use only.

IMPORTANT SAFETY INFORMATION

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

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with IV use of IG products, especially those containing sucrose. Acute renal dysfunction/failure has been reported in association with infusions of GAMMAGARD LIQUID. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and use the minimum infusion rate practicable for IV administration. If renal function deteriorates, consider discontinuation.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur. It is critical to distinguish true hyponatremia from a pseudohyponatremia because certain treatments may lead to volume depletion, a further increase in serum viscosity, and a predisposition to thromboembolic events.

Thrombosis: May occur following treatment with IG products and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Aseptic Meningitis Syndrome: Has been reported with use of IG and may occur more frequently in females. 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: GAMMAGARD LIQUID contains 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: Non-cardiogenic pulmonary edema has been reported with IV-administered IG, including GAMMAGARD LIQUID. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Transmittable Infectious Agents: Because GAMMAGARD LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents (e.g., viruses, other pathogens). No confirmed cases of viral transmission or variant Creutzfeldt-Jakob disease (vCJD) have been associated with GAMMAGARD LIQUID.

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

Adverse Reactions

The most serious adverse reactions observed in clinical studies in PI was aseptic meningitis, and in MMN were pulmonary embolism and blurred vision.

The most common adverse reactions observed in ≥5% of patients were:

IV administration for PI: 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: 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.

IV administration for MMN: Headache, chest discomfort, muscle spasms, muscular weakness, nausea, oropharyngeal pain, and pain in extremity.

IV administration for CIDP: Headache, pyrexia, anemia, leukopenia, neutropenia, illness, blood creatinine increased, dizziness, migraine, somnolence, tremor, nasal dryness, abdominal pain upper, vomiting, chills, nasopharyngitis, 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 [prescribing information]. Westlake Village, CA: Baxalta US Inc.

US-GGL-0312v3.0 02/24

Takeda