HelloCUVITRU

Free Trial Request Form

Fax Page 1 to 1-866-861-1617 I Phone: 1-866-861-1750

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

Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

1 Prescribing Physician

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

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): _____ 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 Infusion Location(s)

Infusion Center/Office Name: _____ Infusion Center/Office Telephone: _____

☐ All Infusions In-Home ☐ First Infusion In-Office; Subsequent In-Home* ☐ All Infusions In-Office

For In-Office (first or recurring) Choose One: ☐ Drug ☐ Drug, Ancillaries, and Pump ☐ Drug, Ancillaries, Pump, and Administration

*All in-home infusions will be provided with drug, ancillaries, pump, and administration support.

4 CUVITRU Prescription and Prescribing Physician Signature

Prescription: CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% Solution **ICD-10:** _____

Administer CUVITRU at regular intervals from daily up to every 2 weeks.[1] Patient Weight (kg): _____

☐ **For patients switching from intravenous immune globulin (human) (IVIG) treatment or adult patients switching from CUVITRU [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution:** Establish the initial weekly dose by converting the monthly IVIG or CUVITRU dose into an equivalent weekly dose and increasing it using a dose adjustment factor.[1] To calculate initial weekly dose = (Previous IVIG or CUVITRU dose [in grams] ÷ No. of weeks between IVIG or CUVITRU doses) x 1.30. See Infusion Volume and Rate table on page 3 for calculation of infusion volume and rate.

☐ **For patients switching from subcutaneous immune globulin (SCIG):** The weekly dose of CUVITRU (in grams) is recommended to be the same as the weekly dose of prior SCIG treatment (in grams).[1]

Prescribed Dose: _____ (in grams) (_____ in mL†) every ____ day(s)

For calculating alternative dosing (2-7 times per week or biweekly), please see Full Prescribing Information.

†To convert the dose (in grams) to mL, multiply the calculated dose (in grams) by 5.

See Infusion Volume and Rate table on page 3 for calculation of infusion volume and rate.

☐ Prescriber additional instruction: _____

_____

_____

Infusion Parameters:

First 2 infusions infuse at _____ mL/hr/site

Subsequently may infuse up to _____ mL/hr/site

SC needle length (mm) (check one): ☐ 4 ☐ 6 ☐ 9 ☐ 12 ☐ 14

Infuse into: ☐ 1 ☐ 2 ☐ 3 ☐ 4 subcutaneous site(s)

Confirmation of Epinephrine Prescription

☐ I certify that my patient has a) confirmed having either a separate prescription for epinephrine injection that they are required to fill prior to their initial CUVITRU infusion or b) I have given my patient a separate prescription for epinephrine injection and have instructed my patient to fill the prescription at their cost prior to their initial CUVITRU infusion.

Allergies

☐ No known drug allergies

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

☐ Special instructions: _____

By signing this document, I certify that the patient is capable of self-infusing in the home, where applicable, the patient meets the eligibility requirements, and I have read and agree to the Program Terms. I understand that this program is intended for the evaluation of CUVITRU with my eligible patient to determine whether CUVITRU is right for them. I authorize the agents of Takeda to use the above information to provide the HelloCUVITRU Free Trial Program to my patient. I understand that the agents of Takeda will keep this information confidential and will use it only for the HelloCUVITRU program. This usage may include a follow-up survey about my patient's and/or my experiences with the HelloCUVITRU program and CUVITRU. Neither I nor my agents will submit any portion of the free trial CUVITRU, supplies, pump, or administration services for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly. I understand Takeda may confirm with a third-party infusion provider that it will not submit any portion of the free trial CUVITRU, supplies, pump, or administration services for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly. Provider verifies that they will not bill for products/services, particularly if the first infusion is in office and subsequent infusions are in home.

I acknowledge that by signing this document, I have discussed with my eligible patient about CUVITRU. I have informed my patient that Takeda will contact them via phone or text to coordinate and start a free trial for CUVITRU.

Prescriber Signature (Required): _____ Date: _____

Stamps not acceptable DISPENSE AS WRITTEN

The prescriber is required to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in delay.

5 Patient Authorization and Program Terms Confirmation

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 back 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.

_____ _____ _____ _____

Patient/Legal Representative Signature | Date | Patient Name | Legal Representative Name and Relationship

☐ **I have read, reviewed, and agree to the Program Terms on page 3.**

6 Patient HIPAA Authorization

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

By signing the Patient Authorization section on the second 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 CUVITRU, 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 Signature‡: _____ Date: _____

Legal Representative Name‡: _____

Relationship to Patient‡: _____

‡Required only if applicable.

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Instructions for Completion of Form

1. Prescribing Physician **2. Patient Information** **3. Infusion Location(s)**

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

4. CUVITRU Prescription and Prescribing Physician Signature

- This is a prescription; a physician's signature and date are required

Infusion Volume and Rate[1§]				
Infusion Parameters	First 2 Infusions		Subsequent Infusions	
	Patients <40 kg	Patients ≥40 kg	Patients <40 kg	Patients ≥40 kg
Volume (mL/site)	≤20	≤60	≤60	
Rate (mL/hr/site)	10-20		≤60	

§If the initial infusions are well tolerated, then subsequent infusions can begin at the maximum tolerated rate.

5. Patient Authorization and Program Terms Confirmation

- The patient signature is required to allow personal health information to be shared by third parties to Takeda to facilitate access to CUVITRU (fulfilling and coordinating delivery of medication, etc)

6. Fax page 1 to 1-866-861-1617

Program Terms

- **For In-Home Administration:** The HelloCUVITRU Free Trial Program provides, at no cost, eligible patients with primary immunodeficiency (PI) with four (4) infusions of CUVITRU, ancillary supplies, pump, and administration (in-home infusion nursing services) by a Takeda contractor.
- **For First Infusion In-Office/Remaining Infusions at Home:** The HelloCUVITRU program provides eligible patients with PI with one (1) in-office dose of CUVITRU, followed by three (3) doses of CUVITRU, ancillary supplies, pump, and administration (in-home infusion nursing services) by a Takeda contractor, at no cost.
  - Where ancillaries are requested, office will be provided ancillary supplies and pump.
  - Where administration services are requested, infusion nursing services provided by a Takeda contractor will be provided.
- **For In-Office Administration:** The HelloCUVITRU program provides, at no cost, eligible patients with PI with four (4) doses of CUVITRU.
  - Where ancillaries, pump, and administration are requested, infusion services will be provided by a Takeda contractor.
- This free trial offer is solely intended to allow new patients to try CUVITRU and to determine with their healthcare provider whether CUVITRU is right for them. There is no obligation to continue use of CUVITRU after the free trial has been completed.
- This free trial prescription is valid for one time only with no refills. For any future use, the patient must obtain a new prescription for CUVITRU.
- To be eligible: 1) patient must be ≥2 years of age with an ICD-10 code verifying diagnosis of PI; 2) be a new patient not currently using CUVITRU and who has not previously enrolled in the HelloCUVITRU program; and 3) for in-home administration, physician has determined patient is capable of administering free trial CUVITRU.
- Free trial CUVITRU cannot be exported or transferred in exchange for money, other property, and services.
- **No portion of the free trial CUVITRU, supplies, pump, or administration services may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly.**
- This program is only valid for residents of the United States, excluding Puerto Rico and other US territories.
- Takeda Pharmaceuticals, Inc. reserves the right to change or discontinue this program at any time without notice.
- This is not a financial assistance nor cost savings program.

INDICATION AND IMPORTANT SAFETY INFORMATION

CUVITRU is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients ≥2 years. CUVITRU is for subcutaneous use only.

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin (IG) products, including CUVITRU. 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.**
- **For patients at risk of thrombosis, administer CUVITRU 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 subcutaneous administration of human IG.
- IgA-deficient patients with antibodies against IgA and a history of hypersensitivity to human IG.

Warnings and Precautions See Full Prescribing Information for Warnings and Precautions for: Hypersensitivity, Renal Dysfunction/Failure, Thrombosis, Aseptic Meningitis Syndrome, Hemolysis, Transfusion-Related Acute Lung Injury, Transmittable Infectious Agents, and Interference with Lab Tests.

Adverse Reactions

The most common adverse reactions observed in the clinical trials in ≥5% of patients were: local adverse reactions including mild or moderate pain, erythema, and pruritus, and systemic adverse reactions including headache, nausea, fatigue, diarrhea, and vomiting.

Drug Interactions

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

Please click for Full Prescribing Information.

Reference: 1. CUVITRU [prescribing information]. Lexington, MA: Baxalta US Inc.

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Takeda