# HelloCUVITRU

## FREE TRIAL REQUEST FORM

FAX PAGE 1 TO 1-866-861-1752 PHONE: 1-866-861-1750

Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

### 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. INFUSION LOCATION(S)

☐ All Infusions In-Home: Drug, Ancillaries, Pump, and Administration

First Infusion In-Office; Subsequent In-Home (choose one):
- ☐ Drug
- ☐ Drug, Ancillaries, and Pump
- ☐ Drug, Ancillaries, Pump, and Administration

All Infusions In-Office (choose one):
- ☐ Drug
- ☐ Drug, Ancillaries, Pump, and Administration

### 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 HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution:** Establish the initial weekly dose by converting the monthly IVIG or HYQVIA dose into an equivalent weekly dose and increasing it using a dose adjustment factor.[1] To calculate initial weekly dose = (Previous IVIG or HYQVIA dose [in grams] ÷ No. of weeks between IVIG or HYQVIA doses) x 1.30
See Infusion Volume and Rate table on page 2 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 the 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 2 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)

**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.

**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.

**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.**

### 5. PATIENT AUTHORIZATION AND PROGRAM TERMS CONFIRMATION

By signing this Authorization, I authorize my healthcare providers and pharmacy to disclose my protected health information, including, but not limited to, personal information related to my medical condition, treatment, and care management, as well as all information provided on this form including contact and any prescription information ("Personal Health Information"), to Takeda Pharmaceutical Company Limited, its affiliates, and their representatives, agents and contractors ("Company") in connection with the Company's provision of product, supplies, and/or services under this free trial program. I understand that Company may communicate with me by mail, email, or telephone about my medical condition, treatment, and care management. I understand I may be contacted to participate in a follow-up survey about my experience in this free trial program. 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. 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 revoke this Authorization at any time by sending written notice of revocation to Takeda Patient Support, 300 Shire Way, Lexington, MA 02421, except to the extent that action already has been taken in reliance on this Authorization.

Signature of Patient (Required): _____ Date: _____

Legal Representative (if applicable): _____ Date: _____

☐ I have read, understand, and agree to the Program Terms at the top of page 2.

### 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 In-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, the 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.

## INSTRUCTIONS FOR COMPLETION OF FORM

### 1. Prescribing Physician 2. Patient Information 3. and 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[†] | | | | |
|---|---|---|---|---|
| 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 1-866-861-1752

## 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 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.

***Please click for Full Prescribing Information.***

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