Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

# HelloCUVITRU
## FREE TRIAL PROGRAM REQUEST FORM

**For more information, call MyIgSource at 855-217-1615**

### SECTION A
**PATIENT INFORMATION (REQUIRED)**

Patient name: _____ Date of birth: _____ Sex: ☐ Male ☐ Female

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

Telephone: _____ Email: _____ **DIAGNOSIS CODE(S)** (primary diagnosis first): _____

Parent/Guardian name: _____ **CURRENT TREATMENT:** _____
REQUIRED IF PATIENT IS YOUNGER THAN 18 YEARS

☐ English is 2nd language Primary language: _____ **CURRENT/PREFERRED SPP:** _____

### SECTION B
**INFUSION LOCATION(S)**

☐ **HOME (ALL INFUSIONS)**

☐ **PHYSICIAN'S OFFICE (ALL INFUSIONS)**
*For any of the in-office infusions, only drug will be supplied*

☐ **1ST INFUSION IN OFFICE/REMAINING INFUSIONS AT HOME**
*For any of the in-office infusions, only drug will be supplied*

### SECTION C
**PRESCRIPTION & MEDICAL ORDERS**

**Administer CUVITRU™ [Immune Globulin Subcutaneous (Human)] 20% at regular intervals from daily up to every 2 weeks. For patients switching from Immune Globulin Intravenous (Human) treatment (IGIV) or adult patients switching from HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase][1]:**

- **Begin treatment one week after the patient's last IGIV or HYQVIA infusion.**
- **Establish the initial weekly dose by converting the monthly IGIV or HYQVIA dose into an equivalent weekly dose and increasing it using a dose adjustment factor.[1]**

To calculate dose: Initial weekly dose = $\frac{\text{Previous IGIV or HYQVIA dose (in grams)}}{\text{No. of weeks between IGIV or HYQVIA doses}}$ x 1.30

- **For patients switching from Immune Globulin Subcutaneous (Human) treatment (IGSC), the weekly dose of CUVITRU (in grams) is recommended to be the same as the weekly dose of prior IGSC treatment (in grams)[1]**

Prescribed dose: ____(in grams) (_____ in mL*) every _____ day(s)

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

For calculating alternative dosing (2-7 times per week or biweekly), see the Prescribing Information[1].

☐ Pharmacy to calculate infusion parameters and/or nursing to determine number of sites and infusion rate per Prescribing Information recommendation (provide body weight above)

Patient weight: _____ (kg)

**Infusion parameters and additional services:**

First 2 infusions infuse at _____ mL/hr/site‡

Subsequently may infuse up to _____ mL/hr/site‡

Number of infusion site(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4

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

☐ Prescriber alternate instruction: _____

☐ Drug allergies: _____

☐ Other medications (if 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.

‡For the first two infusions of CUVITRU, the recommended infusion rate is 10-20 mL/hr/site. For subsequent infusions, the infusion rate may be increased to 60 mL/hr/site as tolerated.

### SECTION D
**PRESCRIBER INFORMATION (REQUIRED)**

Prescriber name: _____ Office contact: _____

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

Telephone: _____ Fax: _____ Email: _____

Facility or prescriber tax ID #: _____ DEA #: _____ NPI #: _____

### SECTION E
**PROGRAM TERMS**

- **For In-Home Administration:** HelloCUVITRU 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 Shire contractor.
- **For In-Office Administration:** HelloCUVITRU provides, at no cost, eligible patients with PI with four (4) doses of CUVITRU (product only).
- **For 1st Infusion in Office/Remaining Infusions at Home:** HelloCUVITRU provides eligible patients with PI with one (1) in-office dose of CUVITRU (product only), followed by three (3) doses of CUVITRU, ancillary supplies, pump, and administration (in-home infusion nursing services) by a Shire contractor, at no cost.
- 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.
- No-cost nursing administration services may only be provided in patient's home.
- 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.
- Shire US Inc. reserves the right to change or discontinue this program at any time without notice.
- This is not a financial assistance or cost savings program.

## PRESCRIBER INSTRUCTIONS:

1. Complete this enrollment form with patient and provider information
2. Sign the authorization and release below
3. **Fax the completed form to MyIgSource at 855-217-1619**

**PHYSICIAN/PRESCRIBER AUTHORIZATION AND RELEASE (REQUIRED)**

**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 authorize the agents of Shire to use the above information to provide the HelloCUVITRU Program to my patient. I have obtained consent from this patient to release this information to the mail order pharmacy, infusion provider, and program call center. I understand that the agents of Shire 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 HelloCUVITRU 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 Shire 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.

**PRESCRIBER SIGNATURE (REQUIRED):** _____ Date: _____

**Fax the completed form to MyIgSource at 855-217-1619**

**Please see the Indication and Important Risk Information on reverse side of this form and the accompanying Full Prescribing Information, including Boxed Warning regarding Thrombosis.**

Shire

## Indication and Important Risk Information

### Indication

CUVITRU is an Immune Globulin Subcutaneous (Human) (IGSC), 20% Solution indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older.

**CUVITRU is for subcutaneous infusion only.**

### Detailed Important Risk Information

### BOXED WARNING: THROMBOSIS

**Thrombosis may occur with immune globulin 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

CUVITRU is contraindicated in patients who have had an anaphylactic or severe systemic hypersensitivity reaction to the subcutaneous administration of human immune globulin and in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity to human immune globulin treatment.

### WARNINGS and PRECAUTIONS

**Hypersensitivity:** Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human immune globulin. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

**Renal Dysfunction/Failure:** Monitor renal function and urine output and consider lower, more frequent dosing in patients who are at risk of developing renal dysfunction because of pre-existing renal insufficiency or predisposition to acute renal failure.

**Thrombosis:** Monitor for signs and symptoms of thrombosis and assess blood viscosity for those at risk for hyperviscosity.

**Aseptic Meningitis Syndrome (AMS):** Monitor for clinical signs and symptoms of AMS.

**Hemolysis:** Monitor for clinical signs and symptoms of hemolysis and delayed hemolytic anemia.

**Transfusion-Related Acute Lung Injury (TRALI):** Monitor for pulmonary adverse reactions associated with TRALI.

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

**Interference with Laboratory Tests:** False positive serological test results, with the potential for misleading interpretation, may occur as the result of passively transferred antibodies.

### ADVERSE REACTIONS

The most common adverse reactions observed in clinical trials in ≥5% of patients were: local adverse reactions, systemic adverse reactions including headache, nausea, fatigue, diarrhea, and vomiting.

**Please see the accompanying Full Prescribing Information, including Boxed Warning regarding Thrombosis.**

**Reference: 1.** CUVITRU [prescribing information]. Westlake Village, CA: Baxalta US Inc.


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