

This guide contains the following information necessary to bill payers for CUVITRU™ [Immune Globulin Subcutaneous (Human)] 20%:

- Healthcare Common Procedure Coding System (HCPCS) codes
- National Drug Code (NDC) numbers
- Current Procedural Terminology (CPT) codes<sup>a</sup>

The provider is responsible for ensuring accurate and appropriate diagnostic coding to obtain reimbursement.

## Applicable HCPCS Codes<sup>1</sup>

HCPCS Code	Description
J1555	Injection, immune globulin (CUVITRU), 100 mg

### DME and Supply Codes<sup>1</sup>

HCPCS Code	Description
<b>External Infusion Pump</b>	
E0779	Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater
E0780	Ambulatory infusion pump, mechanical, for infusion less than 8 hours
E0781	Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
E0791	Parenteral infusion pump, stationary, single, or multichannel
<b>External Infusion Pump Supplies</b>	
A4221	Supplies for maintenance of drug infusion catheter, per week (list drugs separately)
A4222	Infusion supplies for external drug infusion pump, per cassette or bag
K0552	Supplies for external drug infusion pump, syringe type cartridge, sterile, each

The information contained in this Coding Reference Guide is provided for informational purposes only. Every reasonable effort has been made to verify the accuracy of the information; however, this guide is not intended to provide specific guidance on how to utilize, code, bill, or charge for any product or service. Healthcare providers should make the ultimate determination as to when to use a specific product based on clinical appropriateness for a particular patient. Third-party payment for medical products and services is affected by numerous factors, and Shire cannot guarantee success in obtaining insurance payments. This Coding Reference Guide is current as of December 2017.

## 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.**

## Important Safety 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.**

Please scroll for additional Important Safety Information and [click here](#) for Full Prescribing Information.

**MyIGSource may offer additional assistance and resources.**

**Call 1-855-217-1615, Monday through Friday, 8:30 AM to 5:30 PM ET**

## CUVITRU NDC Numbers<sup>2</sup>

NDC Number	Volume	Grams Protein [Immune Globulin Subcutaneous (Human) 20%]	J1555-Billing Units [Injection, immune globulin (CUVITRU), 100mg] <sup>1</sup>
0944-2850-01	5 mL	1.0	10 units
0944-2850-03	10 mL	2.0	20 units
0944-2850-05	20 mL	4.0	40 units
0944-2850-07	40 mL	8.0	80 units

## CPT Codes

### Subcutaneous Administration<sup>3</sup>

The following CPT codes apply to administration services performed by a healthcare provider concurrent with infusion.

CPT Code	Description
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
96370	Each additional hour (list separately in addition to code for primary procedure)

<sup>a</sup>CPT codes copyright 1995-2017 American Medical Association (AMA). All rights reserved.

## Important Safety Information (continued)

### 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  $\geq 5\%$  of patients were: local adverse reactions, systemic adverse reactions including headache, nausea, fatigue, diarrhea, and vomiting.

Please [click here](#) for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

### REFERENCES

- Centers for Medicare and Medicaid Services. 2018 Alpha-Numeric HCPCS. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2018-Alpha-Numeric-HCPCS-File-.html>. Accessed November 27, 2017.
- CUVITRU [Prescribing Information]. Westlake Village, CA: Baxalta US Inc.
- American Medical Association. Code manager. <https://ocm.ama-assn.org/OCM/CPTRelativeValueSearchResults.do?locality=1&keyword=96369>. Accessed November 27, 2017.