Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Coding Reference Guide

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[a]

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

If a patient is denied, call MyIgSource to determine what additional assistance may be available.

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

Applicable HCPCS Codes[1]

HCPCS Code	Description
J3590[b]	Unclassified biologics
J3490[b]	Unclassified drugs
J7799[b]	Not otherwise classified (NOC) drugs other than inhalation drugs, administered through durable medical equipment (DME)

DME and Supply Codes[1]

HCPCS Code	Description
External Infusion Pump	
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
External Infusion Pump Supplies	
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

CUVITRU NDC Numbers[2]

NDC Number	Volume	Grams Protein
0944-2850-01	5 mL	1.0
0944-2850-03	10 mL	2.0
0944-2850-05	20 mL	4.0
0944-2850-07	40 mL	8.0

CPT Codes

Subcutaneous Administration[3]

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)

[a]CPT codes copyright 2015 American Medical Association (AMA). All rights reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein.

[b]Reporting drugs with unclassified codes typically requires additional descriptive documentation that may include one or more of the following: Brand and generic names of drug, strength and dose administered, NDC, and method of administration.

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 September 2016.

Please see the Indication and Detailed Important Risk Information on the next page and click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

Shire

Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

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 click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

REFERENCES

1. Centers for Medicare and Medicaid Services. 2016 Alpha-Numeric HCPCS. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2016-Alpha-Numeric-HCPCS-File.html. Accessed June 16, 2016.
2. CUVITRU [Prescribing Information]. Westlake Village, CA: Baxalta US Inc.
3. American Medical Association. Code manager. https://ocm.ama-assn.org/OCM/CPTRelativeValueSearchResults.do?locality=1&keyword=96369. Accessed May 6, 2015.

© 2016 Shire US Inc., Lexington, MA 02421. All rights reserved. 1-800-828-2088.
SHIRE and the Shire Logo are registered trademarks of Shire Pharmaceutical Holdings Ireland Limited or its affiliates.
CUVITRU is a trademark or registered trademark of Baxalta Incorporated, a wholly owned, indirect subsidiary of Shire plc.
CPT is a registered trademark of the American Medical Association.

USBS/MG 223/16-0026a October 2016

Shire
1200 Lakeside Drive
Bannockburn, IL 60015
www.shire.com

Shire