



Medicare Part C Medical Coverage Policy

Immunoglobulin Therapy (Intravenous and Subcutaneous) in the Home

Origination: June 17, 2009
Review Date: September 21, 2023
Next Review: September 2024

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Intravenous Immunoglobulin (IVIG) is a solution of human immunoglobulins specifically prepared for intravenous infusion for the treatment of primary immune deficiency disease. It is considered medically necessary for use as replacement therapy in patients with primary immunodeficiency in which severe impairment of antibody capacity is present. Covered diseases include congenital hypogammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked immunodeficiency with hyper-IgM, chronic inflammatory demyelinating polyneuropathy, and severe combined immunodeficiency.

POLICY STATEMENT

Coverage will be provided for IVIG when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions for will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

PART B COVERAGE CRITERIA:

A. Preauthorization by the Plan may be required;

1. Intravenous immune globulin (IVIG) is covered if all of the following criteria are met:

- a. It is an approved pooled plasma derivative for the treatment of primary immune deficiency disease; **and**
- b. The member has a diagnosis of primary immune deficiency disease D80.0, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D81.0, D81.1, D81.2, D81.5, D81.6, D81.7, D81.82, D81.89, D81.9, D82.0, D82.1, D82.4, D83.0, D83.1, D83.2, D83.8, D83.9 or G11.3 ; **and**
- c. The IVIG is administered in the home; **and**
- d. The treating physician has determined that administration of the IVIG in the member's home is medically appropriate; **and**
- e. The IVIG is administered with an infusion pump.

2. Subcutaneous immune globulin (SCIg) is covered only if criteria a through c and d or e are met:

- a. The subcutaneous immune globulin preparation is a pooled plasma derivative which is FDA ; **and**
- b. Subcutaneous immune globulin is administered in the home; **and**
- c. The treating practitioner has determined that administration of the SCIg in the member's home is medically necessary and appropriate; **and**
- d. The member has a diagnosis of primary immune deficiency disease (see diagnosis codes in #1b).
- e. The member has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP--ICD 10: G61.81) that has responded to IVIg treatment

WHEN COVERAGE WILL NOT BE APPROVED UNDER PART B BENEFIT

If all of the criteria are not met and the IVIG is not administered with an infusion pump, the IVIG will be denied as noncovered

Coverage under the IVIG benefit is limited to the IVIG itself, not to related supplies and services. If the IVIG is not administered with an infusion pump, related supplies will be denied as noncovered

Codes J1573 (hepatitis B immune globulin, Hepagam B) and J2791 (Rho (D) immune globulin, Rhophylac) are non-covered under Part B. These drugs are not indicated for the treatment of primary immune deficiency disease (Part B #1b above).

PART D COVERAGE CRITERIA:

Preauthorization by the Plan is required;

1. If the above criteria are not met for coverage under the Part B benefit, the medication may be covered under Part D if:
 - a. The medication is administered for an FDA approved use;
 - b. The medication is on a prescription from a physician;
 - c. The medication is used and sold in the United States
 - d. The medication is used for a medically accepted indication and is not for the diagnosis of primary immune deficiency disease as listed above.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: J1459, J1554, J1555, J1556, J1557, J1558, J1559, J1561, J1562, J1566, J1568, J1569, J1572, J1575, J1576, J1599, J7799.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

References:

1. Medicare Local Coverage Determination for Intravenous Immunoglobulin (IVIG) – CGS Administrators (L33610); Effective date: 10/01/2015; Accessed via www.cms.gov/; 08/29/2023.
2. Medicare Local Coverage Determination (L34580) – Palmetto GBA Part A/B; effective 10/01/2015; Viewed via <http://www.palmettogba.com/palmetto/palmetto.nsf/SiteHome?ReadForm>; 5/5/2022. Medicare Local Coverage Determination for External Infusion Pumps—CGS Administrators (L33794); Effective date: 10/01/2015; Accessed via www.cms.gov on 08/29/2023.
3. Medicare Local Coverage Article for Intravenous Immune Globulin—CGS Administrators (A52509); Effective date: 10/01/2015; Accessed via www.cms.gov on 08/29/2023
4. Medicare Local Coverage Article for Billing and Coding: Intravenous Immunoglobulin (IVIG)—Palmetto GBA Part A/B (A56718); Effective date: 07/25/2019; Accessed via www.cms.gov on 08/29/2023
5. Medicare Claims Processing Manual, Chapter 17, Section 80.6; Accessed via Internet site www.cms.gov; viewed on 8/13/2013; Section 50.3 and Section 60.1 assessed online on 08/29/2023.
6. Medicare Benefit Policy Manual; Chapter 15; Covered Medical and Other Health Services; 50.6 Coverage of IVIG for Treatment of Primary Immune Deficiency Diseases in the Home. Viewed online at www.cms.gov on 08/29/2023.
7. Medicare Prescription Drug Benefit, Chapter 6, Part D Drugs and Formulary Requirements, Section 10.2 reviewed online at www.cms.gov on 08/29/2023.
8. CGS: Celerian Group Company News and Publication: Cuvitru-Correct Coding; November 10, 2016. Accessed via internet site <https://cgsmedicare.com/jb/pubs/news/2017/11/cope5337.html> viewed on 08/29/2023

Policy Implementation/Update Information:

Revision Date: New policy June 17, 2009, Reviewed March 2010-Formatting and minor wording changes. August 2012-no criteria changes, updated applicable codes.

Revision Date: Revised December 18, 2013. Policy edited to include coverage for IVIG under Part B if it meets the local jurisdiction criteria.

Revision Date: April 16, 2014 updated code.

Revision Date: November 18, 2015. Annual Review, updated title to reflect addition of subcutaneous immune globulin criteria added to the policy. Updated Description of Procedure or Service per CMS guidance; Indications For Coverage: removed ICD-9 diagnosis codes for item #1 and added item #2 coverage criteria for Subcutaneous Immune Globulin for policy consistency and clarity; added subcutaneous immune globulin codes to Code section; updated reference section. 12/16/15 Added code J1579.

Revision Date: January 18, 2017. Staff clarification update: Added Under Subcutaneous Immune Globulin- Added “

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NOTE: There is now a newly covered, FDA approved subcutaneous immune globulin drug called Cuvitru (Shire) that is administered subcutaneously via an infusion pump. Coverage is available when the following criteria are met: The criteria for subcutaneous immune globulin via external infusion pump are met (See Medical Coverage Policy External Infusion Pump)

Revision Date: February 21, 2018 Added Code J1555 to coding section.

Revision Date: January 16, 2019: Annual Review, Staff Clarification; Removed Note Under Indications for Coverage Part B-A-2-

“NOTE: There is now a newly covered, FDA approved subcutaneous immune globulin drug called Cuvitru (Shire) that is administered subcutaneously via an infusion pump. Coverage is available when the following criteria are met: The criteria for subcutaneous immune globulin via external infusion pump are met (See Medical Coverage Policy External Infusion Pump)”

Revision Date: 8/21/19; CMS Update per MLN MM1125 with addition of new approved diagnosis codes: G11.3, D80.0, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D81.0, D81.1, D81.2, D81.5, D81.6, D81.7, D81.89, D81.9, D82.0, D82.1, D82.4, D83.0, D83.1, D83.2, D83.8, or D83.9.

Revision Date: May 20, 2020: CMS Update: Addition of newly covered unlisted subcutaneous immunoglobulin therapy (Xembify (J7799)) administered by external infusion pump. Under Indications for Coverage A. 2 Addition of “NOTE: There is now a newly approved subcutaneous immune globulin drug called Xembify (J7799) that is administered subcutaneously via an infusion pump. Coverage is available when the following criteria are met: The criteria for subcutaneous immune globulin via external infusion pump are met (See Medical Coverage Policy External Infusion Pump).”

Revision Date: May 19, 2021-Coding Update-Addition of J1554 per update to LCD.

Revision Date: May 18, 2022: Annual Review; No CMS Updates. Minor Revisions Only.

Revision Date: September 21, 2023: Annual Review. Verbiage added to reflect LCDs/LCAs. Coding Update: Added J1576 and J1558 per LCD. Added additional ICD 10 diagnosis codes under indications for coverage. Added additional LCD and LCAs to the reference section.

Approval Dates:

Medical Coverage Policy Committee: September 21, 2023

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