Immune Globulin

Guideline Number: MPG176.18
Approval Date: February 23, 2024

➲ Terms and Conditions

Table of Contents **Page**

Related Medicare Advantage Coverage Summary

- Medications/Drugs (Outpatient/Part B)

Policy Summary

➲ See Purpose

Overview

Immune serums (immune globulin) provide passive immunity to infectious disease. The protection will be of rapid onset, but of short duration. Immune sera are obtained from pooled human plasma of either general population donors or hyperimmunized donors. It may be administered either by intravenous (IV) or subcutaneous (SC) injection.

Guidelines

Intravenous Immune Globulin (IVIG)

IVIg is a solution of human immunoglobulins specifically prepared for intravenous infusion. Immunoglobulin contains a broad range of antibodies that specifically act against bacterial and viral antigens.

There are several off-label uses for IVIg, especially in neurological disorders. There is good scientific evidence that supports use in a few of the disorders; in others, however, the evidence is either poor or absent. This policy addresses the off-label uses of IVIg in certain neurological conditions. This policy does not address the use of IVIg in any condition covered by a National Coverage Determination (NCD) or CMS manual instruction, refer to NCD 250.3 Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases.

- Idiopathic Thrombocytopenic Purpura (ITP) in Pregnancy
- Neurological Disorders
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Acute Immune thrombocytopenia (ITP)
- Chronic Refractory Immune thrombocytopenia (ITP)
- Symptomatic Human Immunodeficiency Virus (HIV)
- Immunoglobulin Deficiencies
- Other Disorders for treatment may include but are not limited to chronic lymphocytic leukemia with associated hypogammaglobulinemia, bone marrow/stem cell transplantation, Kawasaki disease (mucocutaneous lymph node syndrome), transplantation rejection, kidney, stem cell or heart, antibody-mediated, desensitization for a pre-kidney or pre-heart transplantation, and autoimmune retinopathy (limited to three months unless there is improvement on therapy)

Subcutaneous Immune Globulin (SCIG)

As in IVIG therapy, subcutaneous immune globulin (SCIG) administration should be individualized for each patient. Currently, SCI therapy is FDA-approved for use in the treatment of PI diseases and CIDP only. Many studies have shown that SCIG and IVIG therapy are equivalent for managing PI diseases, and noninferiority has been a standard prerequisite of FDA approval. Outcome measures in patients receiving reduced doses of SCIG contrasted with IVIG are not available, with the exception of hospitalization, which was 30% higher in those receiving the reduced dose.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each

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HCPCS Code	Description
J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1551	Injection, immune globulin (Cutaquig), 100 mg
J1554	Injection, immune globulin (Asceniv), 500 mg
J1555	Injection, Immune Globulin (Cuvitru), 100 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	Injection, immune globulin (Xembify), 100 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1561	Injection, immune globulin, (Gamunex/Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562	Injection, immune globulin (Vivaglobin), 100 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), intravenous, non-lyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immuneglobulin
J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg (Effective 07/01/2023)
J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg
Q2052	Services, supplies and accessories used in the home for the administration of intravenous immune globulin (IVIG)

Coding Clarifications: Diagnosis codes listed below are for SCIG (Subcutaneous Immune Globulin) indications/administration. For IVIG (Intravenous Immune Globulin) indications/administration and/or home use refer to related Local Coverage Determinations (LCD's and Local Coverage Articles).

Diagnosis Code	Description
For HCPCS Codes J1551, J1555, J1558, J1559, J1561, J1562, J1569, and J1575	
D80.0	Hereditary hypogammaglobulinemia
D57.04	Hb-SS disease with dactylitis (Effective 10/01/2023)
D57.214	Sickle-cell/Hb-C disease with dactylitis (Effective 10/01/2023)
D57.414	Sickle-cell thalassemia, unspecified, with dactylitis (Effective 10/01/2023)
D57.434	Sickle-cell thalassemia beta zero with dactylitis (Effective 10/01/2023)
D57.454	Sickle-cell thalassemia beta plus with dactylitis (Effective 10/01/2023)
D57.814	Other sickle-cell disorders with dactylitis (Effective 10/01/2023)
D61.02	Shwachman-Diamond syndrome (Effective 10/01/2023)
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near - normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T - and B - cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B - cell numbers
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
D81.4	Nezelof's syndrome
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.82	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott - Aldrich syndrome
D82.1	Di George's syndrome
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B - cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T - cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B - or T – cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D89.84	IgG4-related disease (Effective 10/01/2023)
G11.3	Cerebellar ataxia with defective DNA repair
G61.81	Chronic inflammatory demyelinating polyneuritis

Diagnosis Code	Description
For HCPCS Codes J1551, J1555, J1558, J1559, J1561, J1562, J1569, and J1575	
M60.80	Other myositis, unspecified site (Effective 10/01/2023)

Questions and Answers

1	Q:	Are there circumstances in which unspecified diagnosis codes must be accompanied by a more specific diagnosis code to further define the underlying condition(s)?
	A:	Yes, per CMS, when unspecified diagnosis codes are reported on the claim line a more specific diagnosis is also required to demonstrate the medical necessity for intravenous immune globulin therapy.
2	Q:	Were there changes to the coverage of HCPCS code Q2052 pertaining to the IVIG demonstration ending on December 31, 2023?
	A:	Yes, per CMS, IVIG (in-home coverage) will become a permanent benefit of Medicare starting January 1, 2024. Suppliers should continue supplying IVIG as usual. Please refer to 'References' section below for additional information located in the references for CMS DME LCD and LCA for Intravenous Immune Globulin and Noridian DME website.

References

CMS National Coverage Determination (NCD)

For coverage criteria of Autoimmune Mucocutaneous Blistering Diseases, refer to CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, § NCD 250.3 Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases.

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L39314 Off-Label Use of Intravenous Immune Globulin (IVIG)	A59105 Billing and Coding: Off-Label Use of Intravenous Immune Globulin (IVIG)	NGS	CT, IL, MA, ME, MN, NH, NY (Entire State), RI, VT, WI	CT, IL, MA, ME, MN, NH, NY (Upstate, Downstate, Queens), RI, VT, WI
L34007 Immune Globulin	A57778 Billing and Coding: Immune Globulin	First Coast	FL, PR, VI	FL, PR, VI
L34580 Intravenous Immunoglobulin (IVIG)	A56718 Billing and Coding: Intravenous Immunoglobulin (IVIG)	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L34771 Immune Globulins	A57554 Billing and Coding: Immune Globulins	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L35093 Immune Globulin	A56786 Billing and Coding: Immune Globulin	Novitas	AR, CO, DC, DE, LA, MD, MS NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS NJ, NM, OK, PA, TX
L35891 Intravenous Immune Globulin	A56779 Billing and Coding: Intravenous Immune Globulin	CGS	KY, OH	KY, OH
L38268 Immune Thrombocytopenia (ITP) Therapy	A57160 Billing and Coding: Immune Thrombocytopenia (ITP) Therapy	CGS	KY, OH	KY, OH

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L34314 Immune Globulin Intravenous (IVIg)	A54641 Billing and Coding: Intravenous Immune Globulin (IVIg) - NCD 250.3	Noridian	AS, CA (Entire State), GU, HI, MP, NV	AS, CA (Entire State), GU, HI, MP, NV
	A54660 Billing and Coding: Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home – Medicare Benefit Policy Manual, Chapter 15, 50.6			
	A57187 Billing and Coding: Immune Globulin Intravenous (IVIg)			
L34074 Immune Globulin Intravenous (IVIg)	A54643 Billing and Coding: Intravenous Immune Globulin (IVIg) - NCD 250.3	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
	A54662 Billing and Coding: Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home – Medicare Benefit Policy Manual, Chapter 15, 50.6			
	A57194 Billing and Coding: Immune Globulin Intravenous (IVIg)			
L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses	A52446 Billing and Coding: Intravenous Immune Globulin (IVIG) **Retired 10/31/2022**	NGS	CT, IL, MA, ME, MN, NH, NY (Entire State), RI, VT, WI	CT, IL, MA, ME, MN, NH, NY (Upstate, Downstate, Queens), RI, VT, WI

LCD	Article	Contractor	DME MAC
L33610 Intravenous Immune Globulin	A52509 Intravenous Immune Globulin – Policy Article	CGS	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY (Entire State), OR, PA, RI, SD, UT, VT, WA, WY, MP
L33794 External Infusion Pumps	A52507 External Infusion Pumps - Policy Article	CGS	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY (Entire State), OR, PA, RI, SD, UT, VT, WA, WY, MP

CMS Benefit Policy Manual

Chapter 15 § 50 Drugs and Biologicals
Chapter 15 § 50.6 Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home

CMS Claims Processing Manual

Chapter 17; § 80.6 Intravenous Immune Globulin

CMS Transmittal(s)

Transmittal 259, Change Request 11295, Dated 07/12/2019 (Update to Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home)

MLN Matters

Intravenous Immune Globulin Demonstration
Article MM11295, Update to Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home

Other(s)

Intravenous Immune Globulin Demonstration (PDF)
CMS Medicare Part B ASP Drug Pricing Files
Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
02/23/2024	**Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version MPG176.17

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section above to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.
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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.