

Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (NCD 250.3)

Guideline Number: MPG177.06

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<p>Related Medicare Advantage Reimbursement Policy</p> <ul style="list-style-type: none"> Medically Unlikely Edits Policy
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Policy Summary

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Overview

Intravenous immune globulin (IVIg) is a blood product prepared from the pooled plasma of donors. It has been used to treat a variety of autoimmune diseases, including mucocutaneous blistering diseases. It has fewer side effects than steroids or immunosuppressive agents.

Indications and Limitations of Coverage

Effective October 1, 2002, IVIg is covered for the treatment of biopsy-proven (1) Pemphigus Vulgaris, (2) Pemphigus Foliaceus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid), and (5) Epidermolysis Bullosa Acquisita for the following patient subpopulations:

- Patients who have failed conventional therapy. UnitedHealthcare has the discretion to define what constitutes failure of conventional therapy;
- Patients in whom conventional therapy is otherwise contraindicated. UnitedHealthcare has the discretion to define what constitutes contraindications to conventional therapy; or
- Patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations IVIg therapy would be given along with conventional treatment(s) and the IVIg would be used only until the conventional therapy could take effect.

In addition, IVIg for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short-term therapy and not as a maintenance therapy. UnitedHealthcare has the discretion to decide what constitutes short-term therapy.

Applicable Codes

The following list(s) of 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.

HCPCS Code	Description
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1556	Injection, immune globulin (bivigam), 500 mg
J1557	Injection, immune globulin, (Gammalex), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1561	Injection, immune globulin, (Gamunex/Gamunex-C/Gammaked), nonlyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg

Coding Clarification: Refer to the Medicare Advantage Policy Guideline titled [Intravenous Immune Globulin \(IVIG\)](#) for a list of other covered diagnoses not related to this NCD.

Diagnosis Code	Description
L10.0	Pemphigus vulgaris
L10.1	Pemphigus vegetans
L10.2	Pemphigus foliaceus
L10.3	Brazilian pemphigus [fogo selvagem]
L10.4	Pemphigus erythematosus
L10.5	Drug-induced pemphigus
L10.81	Paraneoplastic pemphigus
L10.89	Other pemphigus
L10.9	Pemphigus, unspecified
L12.0	Bullous pemphigoid
L12.1	Cicatricial pemphigoid
L12.8	Other pemphigoid
L12.9	Pemphigoid, unspecified
L13.8	Other specified bullous disorders

References

CMS National Coverage Determination (NCD)

[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
L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses	A52446 Billing and Coding: Intravenous Immune Globulin (IVIG)	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L34007 Intravenous Immune Globulin	A57778 Billing and Coding: Intravenous Immune Globulin	First Coast	FL, PR, VI	FL, PR, VI
L34074 Immune Globulin Intravenous (IVIg)	N/A	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L34580 Immune Globulin Intravenous (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	AK, AL, AR, AZ, CA (Entire State), CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO (Entire State), MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, KS, MO, NE, IN, MI
L35093 Intravenous Immune Globulin (IVIG)	A56786 Billing and Coding: Intravenous Immune Globulin (IVIG)	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
L34314 Immune Globulin Intravenous (IVIg)	A54641 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 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)			

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L34074 Immune Globulin Intravenous (IVIg)	A54643 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 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)			
L38268 Immune Thrombocytopenia (ITP) Therapy	A57160 Billing and Coding: Immune Thrombocytopenia (ITP) Therapy	CGS	KY, OH	KY, OH

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

CMS Benefit Policy Manual

[Chapter 15: § 50 Drugs and Biologicals](#)

CMS Claims Processing Manual

[Chapter 17: § 80.6 Intravenous Immune Globulin](#)

UnitedHealthcare Commercial Policies

[Immune Globulin \(IVIg and SCIG\)](#)

[Immune Globulin Site of Care](#)

Other(s)

[FDA Clinical Pharmacology Review; Trade Name Bivigam, FDA Website](#)

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
04/01/2021	Template Update <ul style="list-style-type: none"> Reformatted policy; transferred content to new template
05/13/2020	Policy Summary <i>Indications and Limitations of Coverage</i> <ul style="list-style-type: none"> Replaced reference to “contractors” with “UnitedHealthcare”

Date	Summary of Changes
	<p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information Archived previous policy version MPG177.05

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 below 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](#).