

# Intravenous Immune Globulin (IVIg)

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[↪ Terms and Conditions](#)

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| Related Medicare Advantage Coverage Summary |   |
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| •   | <a href="#">Medications/Drugs (Outpatient/Part B)</a> |

## Policy Summary

[↪ See Purpose](#)

### Overview

Intravenous Immune Globulin (IVIg) is a solution of human immunoglobulin specifically prepared for intravenous infusion. Immunoglobulin contains a broad range of antibodies that specifically act against bacterial and viral antigens.

The use of intravenous immune globulin should be reserved for patients with serious defects of antibody function. The goal is to provide immunoglobulin antibodies to those who lack them.

IVIg is the preferred treatment method for patients who require immediate increase in intravascular immunoglobulin antibody levels and are unable to produce sufficient amounts of Immunoglobulin G (IgG) antibodies. The therapeutic effect of IVIG is immediate, well tolerated and less likely to produce side effects if infused at the properly indicated rate(s).

### Guidelines

The following are examples of indications for which intravenous immune globulin may be necessary:

- Primary humoral immunodeficiency
- Immune-mediated Thrombocytopenia (ITP); acute and chronic
- Kawasaki disease
- Human Immunodeficiency Virus (HIV)
- Bone marrow transplantation
- Chronic B-cell lymphocytic leukemia
- Neurological disorders such as Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and Multifocal Motor Neuropathy

The following are examples of indications for which intravenous immune globulin may be necessary for treatment of the following biopsy-proven conditions:

- Pemphigus vulgaris
- Pemphigus foliaceus
- Bullous pemphigoid
- Mucous membrane pemphigoid (aka, cicatricial pemphigoid), benign mucous membrane pemphigoid, with or without mention of ocular movement

- Epidermolysis bullosa acquisita

Patients with biopsy-proven conditions must meet at least one of the following criteria:

- Failed conventional therapy. UnitedHealthcare have the discretion to define what constitutes failure of conventional therapy.
- Conventional therapy is contraindicated. UnitedHealthcare have the discretion to define what constitutes contraindications to conventional therapy.
- Have rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, IVIG therapy would be given along with conventional treatment(s) and the IVIG would be used only until conventional therapy could take effect.

## 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.

| 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), intravenous, 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                               |
| Q2052      | Services, supplies and accessories used in the home under the Medicare intravenous immune globulin (IVIG) demonstration (Not covered) |

Coding Clarifications: For diagnosis codes, see related Local Coverage Determinations (LCD's and Local Coverage Articles).

## 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. |

## References

### CMS National Coverage Determinations (NCDs)

[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                               |
|---|--|-------------|--|---|
| <a href="#">L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses</a> | <a href="#">A52446 Billing and Coding: Intravenous Immune Globulin IVIG</a>  | NGS         | CT, IL, MA, ME, MN, NH, NY, RI, VT, WI   | CT, IL, MA, ME, MN, NH, NY, RI, VT, WI        |
| <a href="#">L34007 Intravenous Immune Globulin</a>                                      | <a href="#">A57778 Billing and Coding: Intravenous Immune Globulin</a>   | First Coast | FL, PR, VI   | FL, PR, VI                                    |
| <a href="#">L34580 Immune Globulin Intravenous IVIg</a>                                 | <a href="#">A56718 Billing and Coding: Intravenous Immunoglobulin IVIG</a>   | Palmetto    | AL, GA, NC, SC, TN, VA, WV   | AL, GA, NC, SC, TN, VA, WV                    |
| <a href="#">L34771 Immune Globulins</a>   | <a href="#">A57554 Billing and Coding: Immune Globulins</a>  | 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                        |
| <a href="#">L35093 Intravenous Immune Globulin IVIG</a>                                 | <a href="#">A56786 Billing and Coding: Intravenous Immune Globulin IVIG</a>  | 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 |
| <a href="#">L35891 Intravenous Immune Globulin</a>                                      | <a href="#">A56779 Billing and Coding: Intravenous Immune Globulin</a>   | CGS         | KY, OH   | KY, OH  |
| <a href="#">L34314 Immune Globulin Intravenous IVIg</a>                                 | <a href="#">A54641 Intravenous Immune Globulin IVIg-NCD 250.3</a><br><a href="#">A54660 (Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home – Medicare Benefit Policy Manual, Chapter 15, 50.6</a><br><a href="#">A57187 Billing and Coding: Immune Globulin Intravenous IVIg</a> | Noridian    | AS, CA (Entire State), GU, HI, MP, NV  | AS, CA (Entire State), GU, HI, MP, NV         |
| <a href="#">L34074 Immune Globulin Intravenous IVIg</a>                                 | <a href="#">A54643 Intravenous Immune Globulin IVIg-NCD 250.3</a><br><a href="#">A54662 Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home – Medicare Benefit Policy Manual, Chapter 15, 50.6</a><br><a href="#">A57194 Billing and Coding: Immune Globulin Intravenous IVIg</a>  | Noridian    | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY   | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY        |

| LCD  | Article  | Contractor | Medicare Part A | Medicare Part B |
|--|--|------------|-----------------|-----------------|
| <a href="#">L38268 (Immune Thrombocytopenia ITP Therapy)</a> | <a href="#">A57160 Billing and Coding: Immune Thrombocytopenia ITP Therapy</a> | CGS        | KY, OH          | KY, OH          |

## CMS Local Coverage Determinations (LCDs) and Articles

| LCD  | Article   | Contractor | DME MAC   |
|--|---|------------|---|
| <a href="#">L33610 Intravenous Immune Globulin</a> | <a href="#">A52509 Intravenous Immune Globulin – Policy Article</a> | 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](#)

## MLN Matters

[Article MM10343, IVIG Demonstration: Payment Update for 2018](#)

[Article SE17008, Scheduled End of the Intravenous Immune Globulin \(IVIG\) Demonstration](#)

## UnitedHealthcare Commercial Policies

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

[Immune Globulin – Site of Care](#)

## Other(s)

[CMS Medicare Part B ASP Drug Pricing Files](#)

[Medicare Intravenous Immune Globulin \(IVIG\) Demonstration, dated June 2016, Noridian website](#)

[Medicare Innovation Models: Intravenous Immune Globulin \(IVIG\) Demonstration, CMS website](#)

[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   |
|------------|--|
| 04/01/2021 | <b>Template Update</b> <ul style="list-style-type: none"> <li>Reformatted policy; transferred content to new template</li> </ul>   |
| 10/14/2020 | <b>Coding Clarification</b> <ul style="list-style-type: none"> <li>Added instruction to refer to the related Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) for ICD-10 diagnosis codes</li> </ul> <b>Supporting Information</b> |

| Date | Summary of Changes   |
|------|--|
|      | <ul style="list-style-type: none"><li>Archived previous policy version MPG176.10</li></ul> |

## 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.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

\*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](#).