



## MVP Health Care Medical Policy

### Medicare Part B: Immunoglobulin Therapy

**Type of Policy:** Medical Therapy

**Prior Approval Date:** 04/01/2024

**Approval Date:** 08/01/2025

**Effective Date:** 10/01/2025

**Related Policies:** Experimental or Investigational Procedures, Behavioral Health Services, Drugs & Treatments, Off-Label use of FDA Approved Drugs, Clinical Trials

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

**Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available**

#### Drugs Requiring Prior Authorization under the medical benefit

| Billing Code(s) | Medication                                                                                           |
|-----------------|------------------------------------------------------------------------------------------------------|
| J1459           | Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg            |
| J1552           | Injection, immune globulin (Alyglo), 500 mg                                                          |
| J1554           | Injection, immune globulin (Asceniv), 500 mg                                                         |
| J1556           | Injection, immune globulin (Bivigam), 500mg                                                          |
| J1555           | Injection, immune globulin (Cuvitru)                                                                 |
| J1557           | Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500mg           |
| J1561           | Injection, immune globulin (Gamunex-C, Gammaked), intravenous, non-lyophilized (e.g. liquid), 500 mg |

|       |                                                                                                                                                                           |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| J1566 | Injection, immune globulin, intravenous, lyophilized (e.g. powder), not otherwise specified, 500 mg (Only Carimune NF and Gammagard S/D should be billed using this code) |
| J1568 | Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g. liquid), 500 mg                                                                                 |
| J1569 | Injection, immune globulin, (Gammagard), intravenous, non-lyophilized, (e.g. liquid), 500 mg                                                                              |
| J1572 | Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g. liquid), 500 mg                                                               |
| J1559 | Injection, immune globulin, (Hizentra), subcutaneous, 100 mg                                                                                                              |
| J1575 | Injection, immune globulin, (HyQvia), subcutaneous 100 mg                                                                                                                 |
| J1576 | Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), not otherwise specified, 500mg (Panzyga)                                                          |
| J1551 | Immune globulin (SCIg) (Cutaquig), subcutaneous, 100mg                                                                                                                    |
| J1558 | immune globulin (Xembify), subcutaneous, 100mg                                                                                                                            |

### (Common Procedure Codes)

CPT Codes: 96365, 96366, 96367, 96368, 96374, 96375, 90284

### Overview/Summary of Evidence

#### Intravenous Immunoglobulin Therapy (IVIG)

The administration of Intravenous Immunoglobulin Therapy (IVIG) is used to provide antibodies in people who are susceptible to diseases for which there are no immunizations or who are immune deficient.

#### Immune Globulin Subcutaneous (Human)

The administration of Immune Globulin Subcutaneous (Human) is for the treatment of primary immune deficiency. Immune Globulin Subcutaneous (Human) supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial agents.

This policy does not address other immunoglobulin preparations that are used for pre or post exposure prophylaxis for specific infectious diseases, such as tetanus, rabies, hepatitis B, or cytomegalovirus.

## Indications/Criteria

### Intravenous Immunoglobulin

- **This policy is a supplement to Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). Refer to the applicable NCD or LCD at [www.cms.gov](http://www.cms.gov) for the most up to date coverage guidance.**
- IVIG and SCIG must be obtained from a preferred contracted IVIG vendor.

### **Medicare Coverage:**

- Please refer to the current coverage guidelines at [www.cms.gov](http://www.cms.gov).
- IVIG is covered under the Part B benefit in all treatment settings for Primary Immunodeficiency. Refer to LCD L33610 for Intravenous Immune Globulin and the accompanying Policy Article A52509 for coverage guidance.
  - Conditions not addressed in this policy will be reviewed on a case-by-case basis and must meet criteria for Experimental & Investigational therapies for coverage under Part B.
- Part B coverage of subcutaneous immune globulin administered in the home setting follows Medicare guidance under LCD L33794 for External Infusion Pumps. Please refer to LCD L33794 and the accompanying Policy Article A52507 for coverage guidance.
- Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.
- Medicare members are not required to receive IVIG in the home setting.

### **Initial Coverage**

Initial coverage period will be for up to 3 months

### **Extension of Therapy**

Continuation of therapy requests must be submitted along with documentation of all pertinent laboratory reports and objective evidence of improvement. Extensions of therapies will be for up to 6 months.

## Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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## References

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4. Centers for Medicare & Medicaid Services. LCD for external infusion pumps (L5044). Original Determination Effective Date 10/1/1993. Revision Effective Date 1/1/2014. Available: [www.cms.hhs.gov/](http://www.cms.hhs.gov/)
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6. Hizentra™, Immune Globulin Subcutaneous (Human), 20% Liquid. Prescribing information. Kankakee, IL: CSL Behring LLC; January 2015.
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8. Centers for Medicare & Medicaid Services. Article for Self-Administered Drug Exclusion List – Medical Policy Article (A47846). Original Article Effective Date 7/18/2008. Article Revision Effective Date 8/1/2014.
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11. Gamunex-C [immune globulin injection (Human), 10% caprylate/chromatography purified]. Prescribing Information. Grifols Therapeutics, Inc.; July 2014.
12. IVIG Toolkit. Eight guiding principles for effective use of IVIG for patients with primary immunodeficiency [Internet]. Milwaukee (WI): American Academy of Allergy, Asthma, and Immunology; 2011 Dec [cited 2016 Sep 19]. Available from <http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20Resources/IVIG-guiding-principles.pdf>
13. Panzyga [immune globulin intravenous, human-ifas 10% liquid preparation]. Prescribing Information. Octapharma USA, Inc. August 2018.
14. Xembify (immune globulin subcutaneous, human- klhw) 20% solution. Prescribing Information. Grifols Therapeutics LLC. Research Triangle Park, NC. July 2019. <https://www.xembify.com/documents/90180901/0/Xembify+Prescribing+Information+-+2019+-++3054808/9ff0e9a4-1249-4cd7-8b10-3ce50a8fad5d>
15. Cutaquig (immune globulin subcutaneous (human)- hipp\_ 16.5% solution. Prescribing Information. Octapharma. Hoboken, NJ. May 2020. <https://www.fda.gov/media/119234/download>
16. Cutaquig (Immune Globulin Subcutaneous (Human) – hipp) 16.5% solution. Prescribing Information. Octapharma USA Inc. Hoboken, NJ. November 2021.
17. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for Intravenous Immune Globulin (L33610) Original Effective Date 10/01/2015. Revision Effective Date 01/01/2025.
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