MVP Health Care Medical Policy

Medicare Part B: Immunoglobulin Therapy

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**1/01/2024**
Effective Date:	**01/01/2024**

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

Codes Requiring Prior Authorization

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

- J1459 Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 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,intravenuous, 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
Intravenous Immunoglobin 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 at are used for pre or post exposure prophylaxis for specific infectious diseases, such as tetanus, rabies, hepatitis B, or cytomegalovirus.

Indications/Criteria

Intravenous Immunoglobulin

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- 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 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.
- 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 33794 for External Infusion Pumps. Please refer to LCD 33794 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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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 01/01/2023.
18. Centers for Medicare & Medicaid Services. Intravenous Immune Globulin – Policy Article (A52509) Original Effective Date 10/01/2015. Revision Effective Date: 01/01/2023.
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