OncoHealth

Intravenous Immune Globulin:

Alyglo, Asceniv, Bivigam, Flebogamma, Gamunex-C, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Octagam, Privigen, Panzyga, Yimmugo

Original Effective Date: 3/1/2021
Revision Date(s): 3/1/2021**,** 9/30/2021, 8/24/2022, 2/19/2024, 3/27/2024, 7/30/2024; 11/4/2024, 12/3/2024
Review Date: 12/3/2024
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are reviewed for efficacy, safety and tolerability.

Indication Specific Criteria:

Hypogammaglobulinemia in Multiple Myeloma

- Member has a documented secondary diagnosis of hypogammaglobulinemia defined as IgG <400mg/dL; **OR**
- Member has a history of serious or recurrent bacterial infections

Hypogammaglobulinemia in Chronic Lymphocytic Leukemia

- Member has a documented secondary diagnosis of hypogammaglobulinemia defined as IgG <500mg/dL; **AND**
- Member has a history of recurrent bacterial infections

Management of Checkpoint Inhibitor Related Toxicities

- Member has been receiving therapy with a checkpoint inhibitor; **AND**
- IVIG is being used for management of the following immunotherapy-related toxicities:
    - Member is experiencing myocarditis that is not improved within 24-48 hours of starting pulse-dose methylprednisolone; **OR**
    - May be considered as an adjunctive therapy to rituximab for severe or life-threatening bullous dermatitis; **OR**
    - May be considered for Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis; **OR**
    - May be considered for moderate or severe steroid-refractory myalgias or myositis; **OR**
    - Member is experiencing severe myasthenia gravis; **OR**

- Being used as an adjunctive therapy to methylprednisolone for moderate or severe Guillain-Barré Syndrome or severe peripheral neuropathy; **OR**
- Being used in combination with methylprednisolone for severe encephalitis; **OR**
- Member is experiencing transverse myelitis; **OR**
- May be considered for moderate or severe pneumonitis if no improvement after 48-72 hours of corticosteroids

Management of CAR-T Cell Related Toxicities

- Member has received treatment with CAR-T cell therapy; **AND**
- Member has a documented secondary diagnosis of hypogammaglobulinemia defined as IgG <600mg/dL; **AND**
  - Member has a history of serious or recurrent bacterial infections associated with CAR-T cell therapy; **OR**
- Member is experiencing cytokine release syndrome (CRS); **AND**
  - CRS is refractory to high-dose corticosteroids; **AND**
  - CRS is refractory to anti-IL-6 therapy

Universal Approval Criteria:

Unless otherwise noted, the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- National Comprehensive Cancer Network® (NCCN) - use consistent with NCCN recommendations carrying a Category 1 or 2A level of evidence; **OR**
- United States Food and Drug Administration (FDA) labeling - new drugs or regimens (combinations of drugs) consistent with all components of the product labeling; **OR**
- Indications not included in the official FDA labeling or recommended by NCCN (Category 1 or 2A level of evidence) may be considered if determined to be medically necessary per one or more of the following compendia:
  - Clinical Pharmacology (Strong For); **OR**
  - Wolters Kluwer Lexi-Drugs® (Level A); **OR**
- Other uses of drugs and biologics may be considered medically necessary if supported as safe and effective according to peer-reviewed articles from one of the following journals:
  - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology;
  - **Meeting abstracts and case reports are excluded from consideration;**
- Non-standard protocols may be approved based on unique clinical circumstances;

- Dose and frequency should be consistent with United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature;
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Billing

Subcutaneous (SC) and intramuscular (IM) do not have oncologic indications and therefore are out of scope (OOS) for OncoHealth.

Drug Name	HCPCS Code	Description
Alyglo	J1552	Injection, immune globulin (alyglo), 500 mg
Asceniv	J1554	Injection, immune globulin (asceniv), 500 mg
Bivigam	J1556	Injection, immune globulin (bivigam), 500 mg
Flebogamma DIF	J1572	Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
Gamunex-C	J1561	Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg
Gammagard Liquid	J1569	Injection, immune globulin, (Gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
Gammagard S/D	J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
Gammaked	J1561	Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg
Gammaplex	J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
Octagam	J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
Privigen	J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
Panzyga	J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
Yimmugo	J1599	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg

References

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6. Flebogamma 5% DIF [package insert]. Instituto Grifols, S.A. Barcelona, Spain. Available at: https://www.fda.gov/media/76962/download.
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18. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed November 21, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

Disclaimer

Drug Coverage Policies are developed as needed, reviewed and updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed

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Date	Updates
9/30/21	Policy creation
3/8/23	Updated Indication Specific Criteria; Updated references
2/19/24	Annual Review; Updated Universal Criteria; Updated/condensed Billing; Updated references
3/27/24	Addition of Alyglo under HCPCS J1599
7/30/2024	Addition of Yimmugo; Update Universal Criteria and disclaimer
11/4/2024	For 1/1/2025 – update to permanent HCPCS Code for Alyglo
12/3/2024	For 1/1/2025 – update to code description for J1552 (Alyglo)