Intravenous Immune Globulin (Asceniv, Bivigam, Flebogamma, Gamunex-C, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Octagam, Privigen, Panzyga)

Effective Date: 7/1/23
Revision Date(s): 9/30/2021, 8/24/2022
Review Date: 03/08/2023
Policy type: Medical Necessity

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.

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

Approval Criteria:

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

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
  - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
  - Clinical Pharmacology (Strong For)
  - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
  - Thompson Micromedex DrugDex® (Class I and IIa)
  - Wolters Kluwer Lexi-Drugs® (Level A)
- Other use of drugs and biologics may be considered medically accepted 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.

OncoHealth

Billing

Drug Name	HCPCS Code	Description
Asceniv	J1554	Injection, immune globulin (asceniv), 500 mg
Bivigam	J1556	Injection, immune globulin (bivigam), 500 mg
Flebogamma 10% DIF	J1572	Injection, immune globulin, (Flebogamma/Flebogamma Dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
Flebogamma 5% 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 5%	J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
Gammaplex 10%	J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
Octagam 10%	J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
Octagam 5%	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

References

1. Immune Globulin. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 3/8/2023
2. Asceniv [package insert]. ADMA Biologics. Boca Raton, FL. Available at: https://www.asceniv.com/ASCENIV%2BPI.pdf. Accessed 3/8/2023
3. Bivigam [package insert]. ADMA Biologics, Inc. Boca Raton, FL. Available at: https://d1io3yog0oux5.cloudfront.net/_9974e5abfcbdc473c844c39763160f16/bivigam/files/documents/20211224_a2244aa0-a6d0-11df-b385-0002a5d5c51b.pdf. Accessed 3/8/2023
4. Flebogamma 10% DIF [package insert]. Instituto Grifols, S.A. Barcelona, Spain. Available at: https://www.fda.gov/media/83042/download. Accessed 3/8/2023
5. Flebogamma 5% DIF [package insert]. Instituto Grifols, S.A. Barcelona, Spain. Available at: https://www.fda.gov/media/76962/download. Accessed 3/8/2023
6. Gammagard Liquid [package insert]. Baxalta US Inc. Westlake Village, CA. Available at: https://www.fda.gov/media/70812/download. Accessed 3/8/2023

7. Gammagard S/D Less IgA [package insert]. Baxalta US Inc. Westlake Village, CA. Available at: https://www.fda.gov/media/70812/download. Accessed 3/8/2023
8. Gamunex-C [package insert]. Grifols Therapeutics, Inc. Research Triangle, NC. Available at: https://www.gamunex-c.com/documents/27482625/27482925/Gamunex-C+Prescribing+Information.pdf/9258bd0f-4205-47e1-ab80-540304c1ff8e, Accessed 3/8/2023
9. Gammaked [package insert]. Grifols Therapeutics, Inc. Research Triangle, NC. Available at: https://www.gammaked.com/clientuploads/GAMMAKED_Web-Fax_3052575-3052576_21686.pdf?_t=1562867757. Accessed 3/8/2023
10. Gammaplex 5% [package insert]. Bio Products Laboratory Ltd. Durham, NC. Available at: https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Package-Insert---Gammaplex-5-.pdf. Accessed 3/8/2023
11. Gammaplex 10% [package insert]. Bio Products Laboratory Ltd. Durham, NC. Available at: https://www.fda.gov/media/102800/download. Accessed 3/8/2023
12. Octagam 5% [package insert]. Octapharma USA Inc. Hoboken, NJ. Available at: https://www.fda.gov/media/157417/download. Accessed 3/8/2023
13. Octagam 10% [package insert]. Octapharma USA Inc. Hoboken, NJ. Available at: https://www.fda.gov/media/70911/download. Accessed 3/8/2023
14. Privigen [package insert]. CSL Behring LLC. Berne, Switzerland. Available at: http://cslbehring.vo.llnwd.net/o33/u/central/PI/US/Privigen/EN/Privigen-Prescribing-Information.pdf. Accessed 3/8/2023
15. Panzyga [package insert]. Octapharma USA Inc. Hoboken, NJ. Available at: https://labeling.pfizer.com/ShowLabeling.aspx?id=12355. Accessed 3/8/2023

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, 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 prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.