Drug Policy:

Intravenous Immune Globulin (IG)

POLICY NUMBER UM ONC_1180	**SUBJECT** Intravenous Immune Globulin (IG)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 4**
DATES COMMITTEE REVIEWED 09/20/11, 10/02/13, 11/13/13, 03/06/15, 03/27/15, 08/19/15, 08/22/16, 06/12/17, 06/13/18, 05/08/19, 07/10/19, 10/09/19, 12/11/19, 02/12/20, 05/13/20, 08/12/20, 08/11/21, 11/15/21, 01/12/22	**APPROVAL DATE** January 12, 2022	**EFFECTIVE DATE** January 28, 2022	**COMMITTEE APPROVAL DATES** 09/20/11, 10/02/13, 11/13/13, 03/06/15, 03/27/15, 08/19/15, 08/22/16, 06/12/17, 06/13/18, 05/08/19, 07/10/19, 10/09/19, 12/11/19, 02/12/20, 05/13/20, 08/12/20, 08/11/21, 11/15/21, 01/12/22	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Intravenous Immune Globulin (IG) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Non- Familial/Acquired/Secondary Hypogammaglobulinemia (e.g., that is associated with Chronic Lymphocytic Leukemia, Multiple Myeloma, or post hematopoietic stem cell transplant

1. Intravenous Immune Globulin (IG) may be used in adult or pediatric members with Non-Familial/Acquired/Secondary Hypogammaglobulinemia (e.g., B-cell CLL/SLL, multiple myeloma, or is post Hematopoietic Stem Cell Transplant) with a documented history of recurrent bacterial infections AND a low IgG level (< 600 mg/dL) prior to intravenous immune globulin (IG) replacement.
    a. For initial requests: The member has a documented IgG level < 600 mg/dL within the last 4 weeks AND a documented history of frequent sino-bronchial, skin, other site bacterial infections, or is clinically felt to be immunocompromised.
    b. For continuation requests:
        i. The member has had a documented clinical benefit from IVIG therapy, e.g., reduced incidence of infections OR
        ii. The member has a history of an increase in recurrent infections within the last 6 months.

C. Idiopathic Thrombocytopenic Purpura (ITP)

1. Intravenous Immune Globulin (IG) may be used in adult and pediatric members with a suspected/confirmed diagnosis of ITP and the platelet count is less than ≤ 30,000 cell/mL.

III. EXCLUSION CRITERIA

A. For CLL/Multiple Myeloma/Acquired Hypogammaglobulinemia the dosing exceeds 400 mg/kg for each dose and the frequency of administration is more frequent than once every 28 days.

B. For ITP, the dosing exceeds 400 mg/kg daily x 5 days or 1 gm/kg x 1-2 days.

C. Investigational use of Intravenous Immune Globulin (IG) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

2. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
3. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
4. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those

recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

5. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
6. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
7. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
8. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Asceniv prescribing information. ADMA Biologics, Inc. Boca Raton, FL 2021.

B. Gammagard prescribing information. Baxalta US Inc. Lexington, MA 2021.

C. Gammaplex prescribing information. BPL, Inc. Durham, NC 2020.

D. Privigen prescribing information. CSL Behring LLC. Kankakee, IL 2020.

E. Flebogamma DIF prescribing information. Grifols Therapeutics Inc. Research Triangle Park, NC 2019.

F. Octagam prescribing information. Octapharma USA Inc.Hoboken, NJ 2020.

G. Gamunex – C prescribing information. Grifols Therapeutics Inc. Research Triangle Park, NC 2020.

H. GamaSTAN SD prescribing information. Grifols Therapeutics Inc. Research Triangle Park, NC 2020.

I. Bivigam prescribing information. ADMA Biologics Boca Raton, FL 2021.

J. Gammaked prescribing information. Grifols Therapeutics Inc. Research Triangle Park, NC 2020.

K. Clinical Pharmacology Elsevier Gold Standard 2022.

L. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.

M. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2022.

N. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

O. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.