Drug Policy:

Intravenous Immune Globulin (IG)

POLICY NUMBER UM ONC_1180	SUBJECT Intravenous Immune Globulin (IG)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
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	**APPROVAL DATE** August 12, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 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	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**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 available, generic alternatives are preferred over brand-name drugs.

B. Non- Familial/Acquired/Secondary Hyogammaglobulinemia (e.g. that is associated with Chronic Lymphocytic Leukemia (CLL), Multiple Myeloma, and other hematologic malignancies)

1. The member has B-cell CLL/SLL, multiple myeloma or another hematologic malignancy with a documented history of recurrent bacterial infections or a low IVIg level (< 600) and Intravenous Immune Globulin (IG) will be used for acquired hypogammaglobulinemia or reducing the frequency of documented recurrent infections with any of the following criteria:
   a. For initial requests: The member has a documented IgG level < 600 mg/dL within the last 4 weeks OR a documented history of frequent sino-bronchial, skin, or other site bacterial infections.
   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 OR
      iii. The IgG level ≤ 1,000 mg/dL within the last 4 weeks.

C. Idiopathic Thrombocytopenic Purpura (ITP)

1. Intravenous Immune Globulin (IG) may be used for 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. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

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 2019.

B. Gammagard prescribing information. Baxalta US Inc. Lexington, MA 2018.

C. Gammaplex prescribing information. BPL, Inc. Raleigh, NC 2018.

D. Carimune NF prescribing information. CSL Behring LLC. Kankakee, IL 2018.

E. Privigen prescribing information. CSL Behring LLC. Kankakee, IL 2018.

F. Flebogamma DIF prescribing information. Grifols Therapeutics Inc. Research Triangle Park, NC. 2018.

G. Octagam prescribing information. Octapharma USA Inc.Hoboken, NJ 2019.

H. Gamunex – C prescribing information. Grifols Therapeutics Inc. Research Triangle Park, NC 2018.

I. GamaSTAN SD prescribing information. Grifols Therapeutics Inc. Research Triangle Park, NC 2018.

J. Bivigam prescribing information. Biotest Pharmaceuticals Corporation Boca Raton, Fl. 2018.

K. Gammaked prescribing information. Grifols Therapeutics Inc. Research Triangle Park, NC. 2019.

L. Clinical Pharmacology Elsevier Gold Standard. 2020.

M. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

N. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.