MEDICAL COVERAGE POLICY	
SERVICE: Immune Globulin Therapy	
Policy Number:	**045**
Effective Date:	**05/01/2021**
Last Review:	**03/25/2021**
Next Review Date:	**03/25/2022**

Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Immune Globulin Therapy

PRIOR AUTHORIZATION: Varies

POLICY:

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination). If there is no applicable LCD, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

All claims for immune globulin products are subject to review for a qualifying condition, quantity of medication used and frequency of administration. Qualifying conditions are generally limited to FDA label indications and recognized off-label indications as defined by Interqual® and the Medications Covered Under Medical Insurance Policy.

In order for subcutaneous immune globulin products J1555 (Cuvitru®), J1558 (Xembify®), J1559 (Hizentra®), J1575 (HyQvia®), or J3590 (Cutaquig®) to be authorized, the member must have a qualifying condition as defined above AND must have failed or not tolerated:

- one of the following immune globulin products administered intravenously: Gamunex-C, Gammagard, Octagam, Privigen, Carimune, Flebogamma Dif, Gammaplex, Gammaked, Panzyga, Bivigam

  AND
- one of the following immune globulin products administered subcutaneously: Gamunex-C, Gammagard, Gammaked

ADDITIONAL INFORMATION:

Immune Globulin Products:

HCPCS	Description
J0850	CMV immune globulin intravenous (human), per vial
J1571	Hepatitis B immune globulin (Hepagam B)
J1573	Hepatitis B immune globulin (Hepagam B)

J1459	Immune globulin (Privigen), intravenous, nonlyophilized, 500 mg
J1554	Immune globulin (Asceniv), 500 mg
J1556	Immune globulin (Bivigam), 500 mg
J1557	Immune globulin (Gammaplex)
J1560	Immune globulin, (Gamastan S/D), intramuscular, over 10 cc
J1561	Immune globulin, (Gamunex/Gamunex-C/Gammaked), nonlyophilized, 500 mg
J1562	Immune globulin (Vivaglobin), 100 mg
J1566	Immune globulin, intravenous, lyophilized, not otherwise specified, 500 mg
J1568	Immune globulin, (Octagam), intravenous, nonlyophilized, 500 mg
J1569	Immune globulin, (Gammagard liquid), nonlyophilized, 500 mg
J1572	Immune globulin, (Flebogamma/Flebogamma Dif), intravenous, nonlyophilized, 500 mg
J1599	Immune globulin, intravenous, nonlyophilized, not otherwise specified, 500 mg

J1555	Injection, immune globulin (Cuvitru), 100 mg
J1558	Injection, immune globulin (Xembify), 100 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1575	Injection, immune globulin/hyaluronidase, 100 mg immunoglobulin: HyQvia
J3590	Injection, immune globulin (Cutaquig)

J2788	Injection, Rho D immune globulin, human, minidose, 50 mcg (250 i.u.)
J2790	Injection, Rho D immune globulin, human, full dose, 300 mcg (1500 i.u.)
J2792	Injection, Rho D immune globulin, intravenous, human, solvent detergent, 100 IU

90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each

OVERVIEW:

Immune globulin (IVIG) derived from human plasma, is a collection of antibodies pooled together from multiple human donors. It is a mixture of various normal human antibodies, and, when administered by intravenous infusion, provides immediate antibody levels.

High dose immune globulin therapy can provide lifesaving treatment for patients with primary immunodeficiencies, and has become an important therapy for various neurologic diseases and immune system abnormalities.

CMS:

NCD: Medicare covers intravenous immune globulin (IVIG) when criteria are met. See the Medicare Benefit Policy Manual (Pub. 100-2) Chapter 15 - Covered Medical and Other Health Services, Section 50.6 Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf

LCD: L35093 effective 4/13/2018 Novitas Solutions

POLICY HISTORY:

Status	Date	Action
New	12/06/2010	New policy
Reviewed	12/06/2011	Reviewed.

Reviewed	10/25/2012	Major revision.
Revised	11/29/2012	Listed codes excluded from PA requirement, and codes requiring PA in addition to CMS list
Reviewed	10/03/2013	No changes
Reviewed	07/24/2014	LCD information updated. Revised criteria section
Reviewed	08/21/2014	Again revised to clarify policy criteria.
Reviewed	08/11/2015	No changes
Reviewed	09/08/2016	Added new CMS indications
Revised	10/24/2017	Redesigned. Removed PA requirement
Revised	01/23/2018	Codes added.
Revised	09/11/2018	Code list revised
Revised	05/22/2019	Code list removed and claim editing explained
Reviewed	06/29/2020	Logo and language changed to include FC
Revised	03/25/2021	Updated PA and subcutaneous requirements, code list revised

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Arthritis Foundation
2. National Office, 1330 West Peachtree Street, Atlanta, Georgia 30309 Toll-free Information Line: 1-800-283-7800
3. Myasthenia Gravis Foundation of America 222 S. Riverside Plaza, Suite 1540, Chicago, IL 60606 Telephone - (312) 258-0522 or (800) 541-5454, Fax - (312) 258-0461 Email Address - MGFA@AOL.COM Web: http://www.med.unc.edu/mgfa/mgf-home.htm
4. Neurological Institute, P.O. Box 5801, Bethesda, MD 20824 (301)496-5751, (800)352- 9424. The NINDS conducts and supports a wide range of research on neurological disorders, including Guillain-Barre syndrome.
5. Guillain-Barre Syndrome Foundation International P.O. Box 262, Wynnewood, PA 19096, (215) 667-0131 Printed information and assistance to Guillain-Barre patients.
6. Lupus Foundation of America., Inc. – National 1300 Piccard Drive, Suite 200, Rockville, MD 20850-4303 301-670-9292, 800-558-0121, Web: http://internet-plaza . net/lupus/
7. Lupus Foundation of America, Massachusetts Chapter - Northeast 425 Watertown St., Newton, MA 02158, (617) 332-9014
8. CMS /Medicare website: www.cms.gov