MEDICAL COVERAGE POLICY
SERVICE: Immune Globulin Therapy

Policy Number:	**045**
Effective Date:	**11/01/2024**
Last Review:	**08/12/2024**
Next Review:	**08/12/2025**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Immune Globulin Therapy

PRIOR AUTHORIZATION: Varies

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to Medicare NCD (National Coverage Determination) 250.3 Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases, LCD (Local Coverage Determination) L35093 Immune Globulin, and LCA (Local Coverage Article) A56786 Billing and Coding: Immune Globulin.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

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 J1551 (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

BACKGROUND:

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.

CODES:

Important note: *Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes:	90281 Immune Globulin (Ig), human, for intramuscular use 90283 Immune globulin (IgIV), human, for intravenous use 90284 Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each
HCPCS Codes:	J0850 CMV immune globulin intravenous (human), per vial J1459 Immune globulin (Privigen), intravenous, nonlyophilized, 500 mg J1551 Injection, immune globulin (Cutaquig) J1554 Immune globulin (Asceniv), 500 mg J1555 Injection, immune globulin (Cuvitru), 100 mg J1556 Immune globulin (Bivigam), 500 mg J1557 Immune globulin (Gammaplex) J1558 Injection, immune globulin (Xembify), 100 mg J1559 Injection, immune globulin (Hizentra), 100 mg 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 J1571 Hepatitis B immune globulin (Hepagam B) J1572 Immune globulin, (Flebogamma/Flebogamma Dif), intravenous, nonlyophilized, 500 mg J1573 Hepatitis B immune globulin (Hepagam B) J1575 Injection, immune globulin/hyaluronidase, 100 mg immunoglobulin: HyQvia J1576 Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg J1599 Immune globulin, intravenous, nonlyophilized, not otherwise specified, 500 mg 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.) J2791 Injection, rho(d) immune globulin (human), (rhophylac), intramuscular or intravenous, 100 iu

	J2792 Injection, Rho D immune globulin, intravenous, human, solvent detergent, 100 IU
ICD10 codes:	
ICD10 Not covered:	

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
Reviewed	02/24/2022	No changes
Reviewed	02/23/2023	No changes
Revised	09/28/2023	Clarified NCD and LCD apply for Medicare. Added HB1584 applicability for Medicaid. Updated Codes.
Revised	08/12/2024	Applied new format and layout, updated codes, added CMS hyperlinks.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and make modifications 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 BSWHP 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. https://www.arthritis.org/
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

***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.