Immune Globulins Intravenous (IVIg) **Policy Number:** M-0029

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

J1459, J1557, J1561, J1566, J1568, J1569, J1572 and J1599
FDA:

- Primary Immunodeficiency
- Idiopathic Thrombocytopenic Purpura (ITP)
- Kawasaki Disease
- Chronic Lymphocytic Leukemia (CLL)
- Bone Marrow Transplantation
- Pediatric Human Immunodeficiency Virus (HIV)

Off-Label:

- Autoimmune Mucocutaneous Blistering Diseases
- Dermatomyositis
- Pemphigus and Pemphigoid
- Other Specified Bullous Dermatoses
- Erythema Multiforme
- Polymyositis
- Guillain-Barre' Syndrome (GBS)
- Hyperimmunoglobulinemia E. Syndrome
- Lambert-Eaton Myasthenic Syndrome
- Myasthenia Gravis
- Multifocal Motor Neuropathy
- Relapsing-Remitting Multiple Sclerosis

- High-Risk, Preterm, Low Birth Weight Neonatal Infections
- Chronic Parvovirus B19 Infection with Severe Anemia secondary to bone marrow suppression
- Chronic Inflammatory Demyelinating Polyneuropathies
- Renal Transplant
    - prophylaxis - reduction of renal transplant rejection (pre and post) by reducing HLA/ABO antibodies in highly sensitized patients
    - acute rejection - reducing HLA/ABO antibodies

J0850

- Cytomegalovirus Immune Globulin Intravenous (Human) is indicated for the prophylaxis of cytomegalovirus disease associated with Medicare approved transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir.

Limitations:

J1459, J1557, J1561, J1566, J1568, J1569, J1572 and J1599

IVIg for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short-term therapy and not as a maintenance therapy.

Coding Information:

CPT/HCPCS Code(s)

J0850	INJECTION, CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN), PER VIAL
J1459	INJECTION, IMMUNE GLOBULIN (PRIVIGEN), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG
J1557	INJECTION, IMMUNE GLOBULIN, (GAMMAPLEX), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG
J1561	INJECTION, IMMUNE GLOBULIN, (GAMUNEX/GAMUNEX-C/GAMMAKED), NON-LYOPHILIZED (E.G. LIQUID), 500 MG

J1566	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, LYOPHILIZED (E.G. POWDER), NOT OTHERWISE SPECIFIED, 500 MG
J1568	INJECTION, IMMUNE GLOBULIN, (OCTAGAM), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG
J1569	INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), INTRAVENOUS, NON-LYOPHILIZED, (E.G. LIQUID), 500 MG
J1572	INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA/FLEBOGAMMA DIF), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG
J1599	INJECTION, IMMUNE GLOBULIN, INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), NOT OTHERWISE SPECIFIED, 500 MG

ICD-9 Code(s):

For J1459, J1557, J1561, J1566, J1568, J1569, J1572, and J1599

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
204.10-204.12	CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC LYMPHOID LEUKEMIA, IN RELAPSE
273.1	MONOCLONAL PARAPROTEINEMIA
279.00	HYPOGAMMAGLOBULINEMIA UNSPECIFIED
279.03-279.06	OTHER SELECTIVE IMMUNOGLOBULIN DEFICIENCIES - COMMON VARIABLE IMMUNODEFICIENCY
279.09	OTHER DEFICIENCY OF HUMORAL IMMUNITY
279.12	WISKOTT-ALDRICH SYNDROME
279.2	COMBINED IMMUNITY DEFICIENCY
279.3*	UNSPECIFIED IMMUNITY DEFICIENCY
279.41	AUTOIMMUNE LYMPHOPROLIFERATIVE SYNDROME
279.49	AUTOIMMUNE DISEASE, NOT ELSEWHERE CLASSIFIED
282.0-282.9	HEREDITARY SPHEROCYTOSIS - HEREDITARY HEMOLYTIC ANEMIA UNSPECIFIED
283.0-283.9	AUTOIMMUNE HEMOLYTIC ANEMIAS - ACQUIRED HEMOLYTIC ANEMIA UNSPECIFIED

284.11	ANTINEOPLASTIC CHEMOTHERAPY INDUCED PANCYTOPENIA
284.12	OTHER DRUG INDUCED PANCYTOPENIA
284.19	OTHER PANCYTOPENIA
284.81-284.89	RED CELL APLASIA (ACQUIRED) (ADULT) (WITH THYMOMA) - OTHER SPECIFIED APLASTIC ANEMIAS
284.9	APLASTIC ANEMIA UNSPECIFIED
287.30	PRIMARY THROMBOCYTOPENIA,UNSPECIFIED
287.31	IMMUNE THROMBOCYTOPENIC PURPURA
287.32	EVANS' SYNDROME
287.33	CONGENITAL AND HEREDITARY THROMBOCYTOPENIC PURPURA
287.41	POSTTRANSFUSION PURPURA
287.49	OTHER SECONDARY THROMBOCYTOPENIA
288.1	FUNCTIONAL DISORDERS OF POLYMORPHONUCLEAR NEUTROPHILS
333.91	STIFF-MAN SYNDROME
340	MULTIPLE SCLEROSIS
356.0	HEREDITARY PERIPHERAL NEUROPATHY
356.2-356.4	HEREDITARY SENSORY NEUROPATHY - IDIOPATHIC PROGRESSIVE POLYNEUROPATHY
356.9	UNSPECIFIED IDIOPATHIC PERIPHERAL NEUROPATHY
357.0-357.9	ACUTE INFECTIVE POLYNEURITIS - UNSPECIFIED INFLAMMATORY AND TOXIC NEUROPATHIES
358.00	MYASTHENIA GRAVIS WITHOUT (ACUTE) EXACERBATION
358.01	MYASTHENIA GRAVIS WITH (ACUTE) EXACERBATION
358.1	MYASTHENIC SYNDROMES IN DISEASES CLASSIFIED ELSEWHERE
358.30	LAMBERT-EATON SYNDROME, UNSPECIFIED
358.31	LAMBERT-EATON SYNDROME IN NEOPLASTIC DISEASE
358.39	LAMBERT-EATON SYNDROME IN OTHER DISEASES CLASSIFIED ELSEWHERE
446.1	ACUTE FEBRILE MUCOCUTANEOUS LYMPH NODE SYNDROME (MCLS)
446.6	THROMBOTIC MICROANGIOPATHY
694.4	PEMPHIGUS
694.5	PEMPHIGOID

694.60	BENIGN MUCOUS MEMBRANE PEMPHIGOID WITHOUT OCULAR INVOLVEMENT
694.61	BENIGN MUCOUS MEMBRANE PEMPHIGOID WITH OCULAR INVOLVEMENT
694.8	OTHER SPECIFIED BULLOUS DERMATOSES
695.10-695.19	ERYTHEMA MULTIFORME, UNSPECIFIED - OTHER ERYTHEMA MULTIFORME
710.3	DERMATOMYOSITIS
710.4	POLYMYOSITIS
795.79	OTHER AND UNSPECIFIED NONSPECIFIC IMMUNOLOGICAL FINDINGS
996.81	COMPLICATIONS OF TRANSPLANTED KIDNEY
996.85	COMPLICATIONS OF TRANSPLANTED BONE MARROW
996.88	COMPLICATIONS OF TRANSPLANTED ORGAN, STEM CELL
V42.81	BONE MARROW REPLACED BY TRANSPLANT
V42.82	PERIPHERAL STEM CELLS REPLACED BY TRANSPLANT

279.3 (unspecified immunity deficiency) is to be used for normal total IgG levels with polysaccharide non-responsiveness.

For J0850

V07.2	NEED FOR PROPHYLACTIC IMMUNOTHERAPY

AND one of the following ICD-9 Codes

V42.0	KIDNEY REPLACED BY TRANSPLANT
V42.1	HEART REPLACED BY TRANSPLANT
V42.6	LUNG REPLACED BY TRANSPLANT
V42.7	LIVER REPLACED BY TRANSPLANT
V42.83	PANCREAS REPLACED BY TRANSPLANT

Background:

This medication is used to strengthen the body's natural defense system (immune system) to lower the risk of infection in persons with a weakened immune system. This medication is made from healthy human blood that has a high level of certain defensive substances (antibodies),

which help fight infections. It is also used to increase the blood count (platelets) in persons with a certain blood disorder (idiopathic thrombocytopenia purpura-ITP).

Black Box Warning

Injection (Solution)

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Gammagard Liquid(R) and Gamunex(R)-C, do not contain sucrose. For patients at risk of renal dysfunction or failure, administer at the minimum rate of infusion practicable.

Intravenous (powder for Solution; Solution)

Immune globulin intravenous (IGIV) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Use caution in patients predisposed to acute renal failure and administer at the minimum concentration available and the minimum rate of infusion practicable in such patients. Higher rates of renal failure were associated with IGIV products containing sucrose. Flebogamma(R) 5%, Flebogamma(R) 5% DIF, Flebogamma(R) 10% DIF, and Privigen(R) do not contain sucrose.

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

1. Local Coverage Article for Gammagard Liquid® (J1569) Added as Covered Subcutaneous Immune Globulin (A51354). Available at: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=51354&ver=2&ContrId=140&ContrVer=2&CntrctrSelected=140*2&Cntrctr=140&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&LCntrctr=140*2&bc=AgABAAEAAAAA&#0. Accessed May 28, 2012.
2. Local Coverage Determination (LCD) for Drugs and Biologicals: Immune Globulin Intravenous (IVIg) (L30029). Revision 8. Available at: http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=30029&ContrId=213&ver=38&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Alabama&CptHcpcsCode=J1459&clickon=search&bc=gAAAABAAAAAA&. Accessed August 31, 2012.
3. Immune Globulin. Available at: http://www.thomsonhc.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/E70303/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/9E8232/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=298670&contentSetId=100&title=Immune+Globulin&servicesTitle=Immune+Globulin. Accessed August 31, 2012.

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