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 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 benefit 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: Required (See exceptions in next paragraph)

POLICY: Immune globulin (IVIG) is approved for use in patients under the conditions outlined in CMS LCD document 4I-82AB-R15 (L26774) (1/1/2012 version in Appendix) with the following exceptions:

Prior authorization is NOT required for:
- J1571 Injection, hepatitis B immune globulin (Hepagam B), intramuscular, 0.5 mL (see J1573 for IV use)
- J2788 Injection, RhoD immune globulin, human, minidose, 50 mcg (250 IU)
- J2790 Injection, RhoD immune globulin, human, full dose, 300 mcg (1500 IU)
- J2791 Injection, RhoD immune globulin human, intramuscular or intravenous 100 IU (see also 90384 and 90386 for CPT billing requirements)
- J2792 Injection, RhoD immune globulin, intravenous, human, solvent detergent, 100 IU

These additional codes REQUIRE prior authorization:
- J1459 Injection, immune globulin (Privigen), intravenous, nonlyophilized, 500 mg (added 8/14/13)
- J1559 Injection, immune globulin (Hizentra), 100 mg (For billing prior to 1/1/11 use J3590 or C9399) (see also 90284 for CPT billing requirements)
- J1599 Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), not otherwise specified, 500 mg
- J1460 Injection, gamma globulin, intramuscular, 1 cc
- J1560 Injection, gamma globulin, intramuscular, over 10 cc (always use for any amount injected over 10cc and place number of units) (1cc = 1 unit)

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.
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

POLICY HISTORY:

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<td>11/29/2012</td>
<td>Listed codes excluded from PA requirement, and codes requiring PA in addition to CMS list</td>
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<td>10/3/2013</td>
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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.
7. Lupus Foundation of America, Massachusetts Chapter - Northeast 425 Watertown St., Newton, MA 02158, (617) 332-9014
8. CMS /Medicare website: www.cms.gov
MEDICAL COVERAGE POLICY

SERVICE: Immune Globulin Therapy

<table>
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Appendix

Intravenous Immune Globulin (IVIG)

**LCD ID:** 2965

**Effective Date:** 3/1/2008  
**Status:** Active  
**Revision Date:** 1/1/2012

**LCD Title**

Intravenous Immune Globulin (IVIG) – 4I-82AB-R15

**Contractor’s Determination Number:** 4I-82AB (L26774)

**Contractor Name:** TrailBlazer Health Enterprises

**Contractor Number**

- 04001 (04101, 04201, 04301, 04401, 04901).
- 04002 (04102, 04202, 04302, 04402).

**Contractor Type**

- MAC – Part A.
- MAC – Part B.

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**CMS National Coverage Policy**

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for IVIG services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for IVIG services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies regarding IVIG services are found in the following
MEDICAL COVERAGE POLICY

SERVICE: Immune Globulin Therapy

Policy Number: 045
Effective Date: 10/25/2013
Last Review: 10/3/2013
Next Review Date: 10/3/2014

Internet-Only Manuals (IOMs) published on the CMS Web site:

- Medicare Benefit Policy Manual – Pub. 100-02, Chapters 1 – Inpatient Hospital Services and 15 – Covered Medical and Other Health Services.
- Correct Coding Initiative – Medicare Contractor Beneficiary and Provider Communications Manual – Pub. 100-09, Chapter 5.
- Social Security Act (Title XVIII) Standard References, Sections:
  - 1862(a)(1)(D) Investigational or Experimental.
  - 1833 Incomplete Claim.

Primary Geographic Jurisdiction

- CO
- NM
- OK
- TX:
  - Indian Health Service.
  - End Stage Renal Disease (ESRD) facilities.
  - Skilled Nursing Facilities (SNFs).
  - Rural Health Clinics (RHCs).
- Transitioned WPS legacy providers.

Oversight Region

- Region IV.
- Region VI.

Original Determination Effective Date

03/01/2008
03/21/2008
06/13/2008

Original Determination Ending Date N/A

Revision Effective Date 01/01/2012

Revision Ending Date N/A

Indications and Limitations of Coverage and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier (see "Coding Guidelines" section in the attached article for instructions).
The use of intravenous immune globulin should be reserved for patients with serious defects of antibody function. The goal is to provide immune globulin to those who lack it. Medicare will provide coverage for intravenous immune globulin when it is used in treatment of the following conditions:

- Primary immunodeficiency.
- Immune-mediated Thrombocytopenia (ITP).
- Kawasaki disease.
- Human Immunodeficiency Virus (HIV) (for pediatric use only).
- Bone marrow transplantation.
- Chronic B-cell lymphocytic leukemia.

Intravenous Immune Globulin (IVIG) can replace missing antibodies and decrease infection in primary immune deficiency and chronic lymphocytic leukemia, increase platelets in idiopathic thrombocytopenic purpura, prevent complications in Kawasaki disease and possibly decrease morbidity in some other conditions.

IVIG is the preferred treatment method for patients who require immediate increase in intravascular immunoglobulin antibody levels and are unable to produce sufficient amounts of Immunoglobulin G (IgG) antibodies. The therapeutic effect of IVIG is immediate, well tolerated and less likely to produce side effects if infused at the properly indicated rate(s). Sensitivity to these reactions is usually related to the infusion rate. Caution should be exercised in the administration of intravenous immune globulin; reactions may cause a rapid fall in blood pressure and clinical anaphylaxis.

IVIG is covered for treatment of the following biopsy-proven conditions:

- Pemphigus vulgaris.
- Pemphigus foliaceus.
- Bullous pemphigoid.
- Mucous membrane pemphigoid (aka, cicatricial pemphigoid), benign mucous membrane pemphigoid, with or without mention of ocular movement.
- Epidermolysis bullosa acquisita.

Patients must meet at least one of the following criteria:

- Failed conventional therapy. Contractors have the discretion to define what constitutes failure of conventional therapy.
- Conventional therapy is contraindicated. Contractors have the discretion to define what constitutes contraindications to conventional therapy.
- Have rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, IVIG therapy would be given along with conventional treatment(s) and the IVIG would be used only until conventional therapy could take effect.

**Note:** In addition, IVIG for the treatment of autoimmune mucocutaneous blistering disease must be used only for short-term therapy and not as a maintenance therapy.

Other preparations of IVIG are available:

- RhoD immune globulin for use in preventing postpartum Rhesus isoimmunization.
- Cytomegalovirus immune globulin for use in treating or preventing cytomegaloviral disease in transplant
recipients.

- Hepatitis B immune globulin intravenous for use in treating prevention of hepatitis B recurrence following liver transplantation in hepatitis B surface antigen (HBsAG)-positive liver transplant patients. (FDA approved April 6, 2007.)

Physicians should avoid prescribing IVIG except for patients with severe immune deficiency and who have low antibody levels or for those whom have other well-established indications for therapy with IVIG as described within this LCD.

**Primary Humoral Immunodeficiencies:**

IVIG will be covered for use as replacement therapy in patients with primary immunodeficiencies in whom severe impairment of antibody capacity is present in the following conditions:

- Congenital agammaglobulinemia.
- Common variable immunodeficiency.
- Wiskott-Aldrich syndrome
- X-linked immunodeficiency with hyper-IgM.
- Severe combined immunodeficiencies.
- Deficient qualitative and/or quantitative antibody production.
- Have at least one bacterial infection directly attributable to this deficiency.

**Idiopathic Thrombocytopenic Purpura (ITP):**

IVIG will be covered for both acute and chronic refractory ITP.

Acute ITP, IVIG is covered for:

- Management of acute bleeding due to severe thrombocytopenia (platelet counts usually less than 30,000/ul).
- To increase platelet counts prior to invasive surgical procedures, e.g. splenectomy.
- Severe thrombocytopenia (platelet counts less than 20,000/ul) considered to be at risk for intracerebral hemorrhage.

Chronic refractory ITP is covered for patients meeting all of the following conditions:

- Prior treatment with corticosteroids and splenectomy.
- Duration of illness of greater than six months.
- Age of 10 years or older.
- No concurrent illness/disease explaining thrombocytopenia.
- Platelet counts persistently at or below 20,000/ul.

**Chronic Lymphocytic Leukemia (CLL):**

IVIG will be covered when used to prevent recurrent bacterial infections in patients with B-cell chronic lymphocytic leukemia meeting all of the following conditions:

- Must have unequivocally documented CLL.
- An immunoglobulin G (IgG) level of less than 600 mg/dl.
- Recent history of serious bacterial infection(s) requiring either oral or parenteral antibiotic therapy.

**Human Immunodeficiency Virus (HIV) Infection:**

IVIG will be covered for patients infected with HIV to reduce significant bacterial infection meeting all of the following conditions:

- Age younger than 14 years old.
- Evidence of either qualitative or quantitative humoral immunologic defects.
- Current bacterial infections, despite appropriate antimicrobial prophylaxis.

**Chronic Inflammatory Demyelinating Polyneuritis (CIDP):**

The diagnosis of this condition must be documented in the medical record and must be consistent with published diagnostic criteria for this condition.

- The patient has unequivocal CIDP as defined by the mandatory clinical and physiologic or pathologic criteria of the American Academy of Neurology (*Neurology* 41: pp. 617–618, 1991) or from the Medical Advisory Committee of the Neuropathy Association (J Peripheral Nervous Assn., 2003, 8:282–284).
- The patient has proved refractory to or intolerant of prednisone or azathioprine given in therapeutic doses over at least three months.
- The patient has a neurologic function assessment score of at least three or greater on the Rankin Scale at the time of initial therapy.

IVIG will not be covered as an initial therapy for patients with newly diagnosed CIDP or as maintenance therapy in patients failing to respond to an initial course of IVIG following therapies with other agents. An exception to IVIG as an initial therapy would be in patients with severe CIDP (Rankin scores of 4 or 5) in whom a rapid therapeutic response is deemed medically desirable or in any patient meeting coverage criteria above (bullets one and three) for whom immunosuppressives are contraindicated. Patients responsive to an initial course of IVIG will be eligible for maintenance therapy coverage only if unequivocal neurological deterioration occurs at some future point in time.

**Dermatomyositis, Polymyositis:**

The routine use of IVIG is not usually recommended for polymyositis or dermatomyositis. IVIG may be used in patients with severe active illness for whom other interventions have been unsuccessful, have become intolerable or are contraindicated.

Refractory myopathies are, by definition, diseases that are unresponsive or poorly responsive to high-dose steroids either alone or in combination with other immunosuppressive agents (azathioprine, cyclophosphamide, methotrexate). Also included in this definition are patients responsive to but intolerant of continual high-dose steroids as reflected by severe adverse side effects (e.g., steroids myopathy or severe osteoporosis) in whom trials of other immunosuppressive agents, unless contraindicated, have been unsuccessful in achieving significant long-term steroid dose reductions.

Three other coverage conditions which must all be met, in addition to the above, are:
• Biopsy-proven disease.
• At least a four- to six-month trial of prednisone or prednisone combination therapies.
• Lack of response/poor response to therapies as reflected by persistently elevated serum Creatine Kinase (CK) levels and/or lack of improvement on muscle strength improvement scales.

Inclusion body myositis is generally refractory to all therapies and its rate of progression appears to be unaltered by most therapies. IVIG will not be covered for use in patients with inclusion body myositis.

Immune Modulation prior to Transplantation:

IVIG has not been proven safe and effective when used for immune modulation of highly sensitized patients prior to transplantation and is therefore not covered for this indication.

LCD Individual Consideration

Certain unusual uses of IVIG may be covered on an LCD Individual Consideration basis. Such situations are described in the four conditions below. The LCD Individual Consideration procedure is described in the attached Article.

Autoimmune Hemolytic Anemia:

The routine use of IVIG is not usually recommended. IVIG may have a role in patients with warm-type autoimmune hemolytic anemia that does not respond to corticosteroids or splenectomy or those for whom the latter two treatments are contraindicated. Coverage determination will require LCD Individual Consideration.

Multifocal Motor Neuropathy:

The routine use of IVIG is not usually recommended. IVIG may be considered in patients who have progressive, symptomatic multifocal motor neuropathy that has been diagnosed on the basis of electrophysiologic findings that rule out other possible conditions that may not respond to this treatment. Coverage determination will require LCD Individual Consideration.

Multiple Sclerosis (MS):

The current evidence is inadequate to assess the value of IVIG in the treatment of multiple sclerosis. IVIG may be useful in persons as a second-line therapy in acute relapses of Relapsing Remitting Multiple Sclerosis (MS), but is generally not considered effective for maintenance therapy of MS or in slowing disease progression. LCD Individual Consideration may be given when IVIG is used in the treatment of an acute relapse of Relapsing Remitting MS.

Systemic Lupus Erythematosus:

The routine use of IVIG is not usually recommended. IVIG may be used in patients with severe active systemic lupus erythematosus for whom other interventions have been unsuccessful, have become intolerable or are contraindicated. Coverage determination will require LCD Individual Consideration.

Drug Wastage
MEDICAL COVERAGE POLICY

SERVICE: Immune Globulin Therapy

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Medicare provides payment for the discarded drug/biological remaining in a single-use drug product after administering what is reasonable and necessary for the patient’s condition. If the physician has made good faith efforts to minimize the unused portion of the drug/biological in how patients are scheduled and how he ordered, accepted, stored and used the drug and made good faith efforts to minimize the unused portion of the drug in how it is supplied, then the program will cover the amount of drug discarded along with the amount administered. Documentation requirements are given below. Coding and billing instructions can be referenced in the attached article. Reference to national policy: Medicare Claims Processing Manual – Pub. 100-04, Chapter 17, Section 40.

Notice: This LCD imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member.
  - Furnished in a setting appropriate to the patient’s medical needs and condition.
  - Ordered and furnished by qualified personnel.
  - One that meets, but does not exceed, the patient’s medical needs.
  - At least as beneficial as an existing and available medically appropriate alternative.

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.


**Bill Type Note:** Code 73X end-dated for Medicare use March 31, 2010; code 77X effective for dates of service on or after April 1, 2010.

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Immune Globulin Therapy
Note: TrailBlazer has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual Publication 100-04, Claims Processing Manual, for further guidance.

0250, 0636

CPT/HCPCS Codes

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<th>Description</th>
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<td>J0850</td>
<td>Injection, cytomegalovirus immune globulin intravenous, human, per vial</td>
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<td>J1459</td>
<td>Injection, immune globulin (Privigen™), intravenous, non-lyophilized (e.g. liquid), 500 mg</td>
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<tr>
<td>J1557</td>
<td>Injection, immune globulin (Gammaplex®, intravenous, non-lyophilized (e.g. liquid), 500 mg</td>
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<tr>
<td>J1561</td>
<td>Injection, immune globulin (Gamunex®/Gamunex-C®/Gammaked®), intravenous, non-lyophilized (e.g. liquid), 500 mg</td>
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<tr>
<td>J1566</td>
<td>Injection, immune globulin, intravenous, lyophilized (e.g. powder), not otherwise specified, 500 mg</td>
</tr>
<tr>
<td>J1568</td>
<td>Injection, immune globulin (Octagam), intravenous, non-lyophilized (e.g. liquid), 500 mg</td>
</tr>
<tr>
<td>J1569</td>
<td>Injection, immune globulin (Gammagard Liquid), intravenous, non-lyophilized (e.g. liquid), 500 mg</td>
</tr>
<tr>
<td>J1572</td>
<td>Injection, immune globulin (Flebogamma/Flebogamma dif), intravenous, non-lyophilized (e.g. liquid), 500 mg</td>
</tr>
<tr>
<td>J1573</td>
<td>Injection, hepatitis B immune globulin (Hepagam B), intravenous, 0.5 ml</td>
</tr>
<tr>
<td>J2788</td>
<td>Injection, RhoD immune globulin, human, minidose, 50 mcg (250 IU)</td>
</tr>
<tr>
<td>J2790</td>
<td>Injection, RhoD immune globulin, human, full dose, 300 mcg (1500 IU)</td>
</tr>
<tr>
<td>J2792</td>
<td>Injection, RhoD immune globulin, intravenous, human, solvent detergent, 100 IU</td>
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ICD-9-CM Codes That Support Medical Necessity

The CPT/HCPCS codes included in this LCD will be subjected to “procedure to diagnosis” editing. The following lists include only those diagnoses for which the identified CPT/HCPCS procedures are covered. If a covered diagnosis is not on the claim, the edit will automatically deny the service as not medically necessary.

Medicare is establishing the following limited coverage for CPT/HCPCS code J0850:

Covered for:

- 078.5 Cytomegaloviral disease
- V42.0–V42.7 Organ or tissue replaced by transplant
- V42.81–V42.84 Organ or tissue replaced by transplant, other specified organ or tissue
- V42.89 Organ or tissue replaced by transplant, other specified organ or tissue

Medicare is establishing the following limited coverage for CPT/HCPCS codes J1557 (when used to identify immune globulin (Gammaplex®), J1459, J1561 (when used to identify immune globulin Gamunex®/Gamunex-C®/Gammaked®), J1566, J1568, J1569 and J1572:

Covered for:

Immune Globulin Therapy
042* Human Immunodeficiency Virus (HIV) disease

*Note: Use 042 only for patients younger than 14 years of age.

078.5 Cytomegaloviral disease
204.10–204.11 Lymphoid leukemia, chronic
279.00 Hypogammaglobulinemia, unspecified
279.03–279.06 Deficiency of humoral immunity
279.09 Other deficiency of humoral immunity
279.12 Deficiency of cell mediated immunity, Wiskott Aldrich syndrome
279.2 Combined immunity deficiency
279.50–279.53 Graft-versus-host disease
283.0 Autoimmune hemolytic anemias
283.9 Acq hemolytic anemia nos
284.01 Constitutional (pure) red blood cell aplasia
286.4 Von Willebrand’s disease
286.52–286.53 Hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies or inhibitors
286.59 Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors
287.30–287.33 Primary thrombocytopenic
333.91 Stiff-man syndrome
356.4 Idiopathic progressive polyneuropathy
357.0 Inflammatory and toxic neuropathy, acute infective polyneuritis
357.81–357.82 Inflammatory and toxic neuropathy
358.00–358.01 Myoneural disorders, myasthenia gravis
358.1 Myasthenic syndromes in diseases classified elsewhere
358.30–358.31 Lambert-Eaton syndrome in other classified diseases
358.39 Lambert-Eaton syndrome in other diseases classified elsewhere
446.1 Acute febrile Mucocutaneous Lymph Node Syndrome (MCLS)
656.10–656.11 Rhesus isoimmunization
665.13 Rhesus isoimmunization, antepartum condition or complication
694.4–694.5 Bullous dermatoses
694.60–694.61 Bullous dermatoses
694.8 Bullous dermatoses, other specified
710.3–710.4 Diffuse diseases of connective tissue
765.00–765.05 Premature infant
765.10–765.15 Premature infant
996.85 Complications of transplanted organ, bone marrow
996.88 Complications of transplanted organ, stem cell
V42.0 Kidney replaced by transplant
V42.1 Heart replaced by transplant
V42.6 Lung replaced by transplant
V42.7 Liver replaced by transplant
V42.81 Bone marrow replaced by transplant
V42.82 Trspl sts-perip stm cell

Medicare is establishing the following limited coverage dual diagnosis (two covered diagnoses) requirement for CPT/HCPCS code J1573:

Covered for diagnosis code:

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Additionally required diagnosis codes to be used with V42.7 to meet limited coverage for CPT/HCPCS code J1573:

070.20–070.23 Viral hepatitis B with hepatic coma
070.30–070.31 Viral hepatitis B without mention of hepatic coma.

Medicare is establishing the following limited coverage for CPT/HCPCS codes J2788, J2790 and J2792:

Covered for:

287.31 Immune thrombocytopenic purpura
656.10–656.11 Rhesus isoimmunization
656.13 Rhesus isoimmunization, antepartum condition or complication

Medicare is establishing the following limited coverage for CPT/HCPCS code J1561 (when used to identify immune globulin Gamunex®/Gamunex-C®/Gammaked®):

Covered for:

279.06* Common variable immunodeficiency
*Note: Use 279.06 for primary immunodeficiency
287.31 Immune thrombocytopenic purpura
357.81 Chronic inflammatory demyelinating polyneuritis

Note: Providers should continue to submit ICD-9-CM diagnosis codes without decimals on their claim forms and electronic claims.

Diagnoses That Support Medical Necessity N/A

ICD-9-CM Codes That DO NOT Support Medical Necessity N/A

Diagnoses That DO NOT Support Medical Necessity

All diagnoses not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this LCD.

Documentation Requirements

- Documentation supporting medical necessity should be legible, maintained in the patient’s medical record and made available to Medicare upon request.
- The information contained in the medical record should include all relevant diagnostic laboratory studies, prior history of bleeding, infection, disease progression, prior medical/surgical therapies and any other information essential in establishing that the patient meets the coverage indicators as set forth in this LCD.
- Indications for administration of IVIG therapy must be fully documented in the patient’s medical record.
- Physicians or other providers filing Medicare claims for administration of IVIG therapy at the request of another provider assume full responsibility as to the medical necessity for IVIG under terms and conditions of this LCD. These providers must also be able to meet documentation requirements given above, either directly
through their own medical records or indirectly through records obtained from the referring physician.

**Drug Wastage Documentation Requirements**

Any amount wasted must be clearly documented in the medical record, regardless of whether the JW modifier will be used in billing for the drug/biological, with:

- Date and time.
- Amount of medication wasted.
- Reason for the wastage.

**Appendices** N/A

**Utilization Guidelines**

Medicare would expect to see IVIG used only for the indications listed within this LCD.

**Notice:** This LCD imposes utilization guideline limitations. Despite Medicare's allowing up to these maximums, each patient's condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient's medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.

**Sources of Information and Basis for Decision**

**J4 (CO, NM, OK, TX) MAC Consolidation**

TrailBlazer adopted the TrailBlazer LCD, "Intravenous Immune Globulin (IVIG)," for the Jurisdiction 4 (J4) MAC transition, incorporating additional diagnoses into J1561, J1566, J1568, J1569 and J1572 limited coverage indications.

Full disclosure of the sources of information is found with original contractor LCD.

**Other Contractor Local Coverage Determinations**

"Intravenous Immune Globulin (IVIG)," TrailBlazer LCD, (00400) L17363, (00900) L22969.


"Immune Globulin, Intravenous," Arkansas BlueCross BlueShield (Pinnacle) LCD, (NM, OK) L13458.

**Start Date of Notice Period**

12/20/2007

**Revision History**

<table>
<thead>
<tr>
<th>Number</th>
<th>Date</th>
<th>Explanation</th>
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<tr>
<td>R15</td>
<td>01/01/2012</td>
<td>Corrected description for ICD-9-CM diagnosis code 356.4 from &quot;Idiopathic peripheral neuropathy&quot; to &quot;Idiopathic progressive polyneuropathy&quot; in the &quot;ICD-9-CM Codes That Support Immune Globulin Therapy&quot;</td>
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Medical Necessity section of the LCD. Updated the AMA CPT/ADA CDT copyright statement. Effective date: 01/01/2012.

R14 01/01/2012
Per CR 7540, 2012 Annual CPT/HCPCS Updates, replaced CPT/HCPCS codes C9270 and J3590, used to represent GAMMAPLEX®, with J1557, and updated the description for CPT/HCPCS code J1561 (GAMUNEX®/GAMUNEX-C®/GAMMAKED®) in the LCD and related article. Effective date: 01/01/2012.

R13 10/01/2011
For newly approved immune globulin Gammaked®, added ICD-9-CM diagnosis codes 279.06, 287.31 and 357.81 for CPT/HCPCS code (OPPS and ASC)/J3590 in the “ICD-9-CM Codes that Support Medical Necessity” section of the LCD. Removed language that is no longer applicable (NCD reference to use of IVIG with BMT; CAP drug program; HCPCS code G0332) in LCD and article. Effective date: 10/01/2011.

R12 10/01/2011
Per CR 7454 (annual ICD-9-CM diagnosis code update) added diagnosis code 358.30, 358.31, 358.39 and 996.88 and replaced diagnosis code 286.5 with diagnosis codes 286.52-286.53 and 286.59 for CPT/HCPCS codes C9270 (OPPS and ASC)/J3590 (when used to identify immune globulin (Gammaplex®), J1459, J1561, J1566, J1568, J1569 and J1572 in the “ICD-9-CM Codes that Support Medical Necessity” section of the LCD. Effective date: 10/01/2011.

Per business decision, dual diagnosis language was updated for CPT/HCPCS code J1573 to reflect current processes. Effective date: 10/01/2011.

R11 07/01/2011
Per CR 7228, notice of automatic denial for claim line items with a GZ modifier added to definition of GZ modifier in “Coding Guidelines” section of related article. Effective date: 07/01/2011.

R10 01/01/2011
Per CR 7121 (annual HCPCS update), description changed for the GA modifier. Effective date: 01/01/2011.

R9 10/01/2010
Added HCPCS code C9270 (injection, immune globulin (Gammaplex®), intravenous, non-lyophilized (e.g. liquid), 500 mg) to the CPT/HCPCS codes list and limited coverage statement for CPT/HCPCS codes J1459, J1561, J1566, J1568, J1569 and J1572. Effective date: 10/01/2010.

R8 10/18/2010
Use of LCD and related article made applicable to providers transitioning from WPS to TrailBlazer with addition of contractor number 04901. Effective date: dates of service on or after 10/18/2010.

R7 07/12/2010
Per provider request, added ICD-9-CM code V42.82 (trsp lst-perip stem cell) to the limited coverage list for CPT/HCPCS codes J1459, J1561, J1566, J1568, J1569 and J1572. Effective date: 06/15/2010.

R6 06/11/2010
Per CR 6711, updated language within the sections titled “Drug Wastage,” “Coding Drug Wastage JW Modifier” and “Documentation Requirements” of the LCD and article. Effective date: 07/30/2010.

R5 04/12/2010
Per provider request, added ICD-9-CM diagnoses codes 283.0 (autoimmune hemolytic anemias) and 283.9 (acq hemolytic anemia nos) to the limited coverage list for CPT/HCPCS codes J1459, J1561, J1566, J1568, J1569 and J1572 in the LCD section titled “ICD-9-CM Codes That Support Medical Necessity.” Effective date: 04/01/2010.

R4 12/11/2009
Per CR 6338, added end date of 03/31/2010 for TOB code 73X (no longer to be used for Medicare billing) and added TOB code 77X for use with dates of service on or after 04/01/2010 when billing for services rendered in a freestanding FQHC or a provider-based FQHC in the “Type of Bill Codes” section of the LCD and related article. Effective date: 01/04/2010.

R3 10/30/2009
Per provider request, added ICD-9-CM diagnosis code 333.91 (stiff-man syndrome) to the limited coverage for HCPCS codes J1459, J1561, J1566, J1568, J1569 and J1572 in the LCD section titled “ICD-9-CM Codes That Support Medical Necessity.” Effective date: 10/19/2009.
MEDICAL COVERAGE POLICY

SERVICE: Immune Globulin Therapy

Policy Number: 045
Effective Date: 10/25/2013
Last Review: 10/3/2013
Next Review Date: 10/3/2014

R2 12/15/2008 Per 6236, removed HCPCS code Q4097 and replaced with new HCPCS code J1459. No change in coverage. Added the following statement to the Article “Abstract” section: "NOTE: Effective January 1, 2009, HCPCS code G0332 will be deleted. Separate payment for preadministration-related services associated with administration of IVIG will no longer be made." Removed all other text regarding G0332 from the LCD and Article. Revised description of J1572, J2788 and J2790. Effective date: 01/01/2009.

R1 10/01/2008 Per CR 6107 (Annual ICD-9-CM Diagnosis Coding Update), diagnosis codes 279.50, 279.51, 279.52 and 279.53 added and description of diagnosis code 204.10 updated in limited coverage for CPT/HCPCS codes G0332, J1561, J1566, J1568, J1569, J1572 and Q4097. Effective date: 10/01/2008.

N/A 06/13/2008 LCD effective in TX Part A and Part B and Part A CO and NM 06/13/2008

04/22/2008 Per CR 5981: April 2008 HCPCS update, HCPCS code Q4097 (injection, immune globulin (Privigen™), intravenous, non-lyophilized (e.g. liquid), 500 mg) added to CPT/HCPCS Code list in LCD and Article and to limited coverage statement for IVIG ("Medicare is establishing the following limited coverage for CPT/HCPCS codes G0332, J1561, J1566, J1568, J1569, J1572 and Q4097" in the LCD. Reference to IVIG as self-administered corrected to read "HCPCS codes J1562 and 90284 immune globulins are non-covered as this formulation is usually self-administered." Effective date for OK (Part A & Part B), for CO (Part B) and NM (Part B): 04/01/2008. Effective date for CO (Part A), NM (Part A) and TX (Part A & Part B): 06/13/2008 (cutover date).

N/A 03/21/2008 LCD effective in CO Part B 03/21/2008

N/A 03/01/2008 LCD effective in NM Part B and OK Part A and Part B 03/01/2008

12/20/2007 Consolidated LCD posted for notice effective: 12/20/2007

Article Title
Intravenous Immune Globulin (IVIG) – 4I-82AB-R15

Contractor’s Determination Number 4I-82AB

Contractor Name TrailBlazer Health Enterprises

Contractor Number
• 04001 (04101, 04201, 04301, 04401, 04901).
• 04002 (04102, 04202, 04302, 04402).

Contractor Type
• MAC – Part A.
• MAC – Part B.

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Primary Geographic Jurisdiction
• CO
• NM
• OK
• TX:
  o Indian Health Service.
  o End Stage Renal Disease (ESRD) facilities.
  o Skilled Nursing Facilities (SNFs).
  o Rural Health Clinics (RHCs).
• Transitioned WPS legacy providers.
Oversight Region
• Region IV.
• Region VI.

Original Article Effective Date
03/01/2008
03/21/2008
06/13/2008

Article Revision Effective Date 01/01/2012
Article Ending Effective Date N/A

Abstract
Intravenous Immune Globulin (IVIG) is a solution of human immunoglobulins specifically prepared for intravenous infusion. Immunoglobulins contain a broad range of antibodies that act specifically against bacterial and viral antigens.

Part A Program Instructions:

Reasons for Denial
• HCPCS codes J1562 and 90284 immune globulins are non-covered as this formulation is usually self-administered. The process for determining self-administration of a drug is detailed on the TrailBlazer Web site.
• All other indications not listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of the related LCD.
• Service(s) rendered is (are) not consistent with accepted standards of medical practice.
• The medical record does not verify that the service described by the CPT/HCPCS code was provided.
• The medical record does not verify that the route of administration was medically necessary.
• The medical record does not verify that the service described by the HCPCS code was provided.
• The amount of drug wasted is not reasonable or not documented.
• The service does not follow the guidelines of the related LCD.
• The service is considered:
  o Investigational.
  o A program exclusion.
  o Otherwise not covered.

LCD Individual Consideration Instructions
LCD Individual Consideration for coverage of denied IVIG (and related services) may be given for the four indications listed in the LCD section titled “Indications and Limitations of Coverage and/or Medical Necessity.” Medical records must be submitted when requesting a redetermination that documents the patient’s condition meets individual consideration requirements. The redetermination submission must have “LCD INDIVIDUAL CONSIDERATION REQUEST” indicated on the request form to receive LCD Individual Consideration.

Coding Guidelines
• Refer to the Correct Coding Initiative (CCI) for correct coding guidelines and specific applicable code combinations prior to billing Medicare. Provisions of this LCD do not take precedence over CCI edits.
• Diagnosis(es) must be present on any claim submitted and coded to the highest level of specificity for that date of service.
• To report these services, use the appropriate HCPCS or CPT code(s).
• All coverage criteria must be met before Medicare can reimburse this service.
• Providers should reference SNF consolidated billing guidelines for patients in a SNF setting.
• When billing for this service in a non-covered situation (e.g., does not meet indications of the related LCD), use the appropriate modifier (see below). To bill the patient for services that are not covered (investigational/experimental or not reasonable and necessary) will generally require an Advance Beneficiary Notice (ABN) be obtained before the service is rendered.
**MEDICAL COVERAGE POLICY**

**SERVICE:** Immune Globulin Therapy

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<th>Policy Number:</th>
<th>045</th>
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<td>Effective Date:</td>
<td>10/25/2013</td>
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<tr>
<td>Last Review:</td>
<td>10/3/2013</td>
</tr>
<tr>
<td>Next Review Date:</td>
<td>10/3/2014</td>
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</tbody>
</table>

**Modifiers:**
- GA: Waiver of liability statement issued as required by payer policy, individual case. (Use for patients who do not meet the covered indications and limitations of this policy and for whom an ABN is on file.) (ABN does not have to be submitted, but must be made available upon request.)
- GZ: Item or service expected to be denied as not reasonable and necessary. (Use for patients who do not meet the covered indications and limitations of this LCD and who did not sign an ABN and the provider expects the item/service to be denied. All claim line items submitted with the GZ modifier will be denied automatically and will not be subject to complex medical review.)
- GY: Item or service is statutorily excluded or does not meet the definition of any Medicare benefit.

**Part B Program Instructions:**

**Reasons for Denial**
- HCPCS codes J1562 and 90284 immune globulins are non-covered as this formulation is usually self-administered. The process for determining self-administration of a drug is detailed on the TrailBlazer Web site.
- All other indications not listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of the related LCD.
- Service(s) rendered is (are) not consistent with accepted standards of medical practice.
- The medical record does not verify that the service described by the CPT/HCPCS code was provided.
- The medical record does not verify that the route of administration was medically necessary.
- The medical record does not verify that the service described by the HCPCS code was provided.
- The amount of drug wasted is not reasonable or not documented.
- The service does not follow the guidelines of the related LCD.
- The service is considered:
  - Investigational.
  - A program exclusion.
  - Otherwise not covered.

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**Coding Guidelines**
- Refer to the Correct Coding Initiative (CCI) for correct coding guidelines and specific applicable code combinations prior to billing Medicare. Provisions of this LCD do not take precedence over CCI edits.
- Diagnosis(es) must be present on any claim submitted and coded to the highest level of specificity for that date of service.
- To report these services, use the appropriate HCPCS or CPT code(s).
- All coverage criteria must be met before Medicare can reimburse this service.
- When billing for this service in a non-covered situation (e.g., does not meet indications of the related LCD), use the appropriate modifier (see below). To bill the patient for services that are not covered (investigational/experimental or not reasonable and necessary) will generally require an Advance Beneficiary Notice (ABN) be obtained before the service is rendered.
  - Modifiers:
    - GA: Waiver of liability statement issued as required by payer policy, individual case. (Use for patients who do not meet the covered indications and limitations of this policy and for whom an ABN is on file.) (ABN does not have to be submitted, but must be made available upon request.)
GZ: Item or service expected to be denied as not reasonable and necessary. (Use for patients who do not meet the covered indications and limitations of this LCD and who did not sign an ABN and the provider expects the item/service to be denied. All claim line items submitted with the GZ modifier will be denied automatically and will not be subject to complex medical review.)

GY: Item or service is statutorily excluded or does not meet the definition of any Medicare benefit.

• Bill Type and Revenue Codes below DO NOT apply to Part B.

**Coding Drug Wastage (JW Modifier)**

Medicare provides payment for the discarded drug/biological remaining in a single-use drug product after administering what is reasonable and necessary for the patient’s condition. If the physician has made good faith efforts to minimize the unused portion of the drug/biological in how patients are scheduled and how he ordered, accepted, stored and used the drug and made good faith efforts to minimize the unused portion of the drug in how it is supplied, then the program will cover the amount of drug discarded along with the amount administered. If after taking the above measures a portion of the single-use vial must be discarded, HCPCS modifier JW may be used to indicate the drug amount discarded/not administered to any patient. The amount administered and the amount wasted must be billed on the same claim. The amount administered must be on a separate detail line from the amount wasted, indicated with the modifier JW (when applicable). The modifier JW would not be used for claim billings when the actual dose of the drug/biological administered is less than the billing unit established by HCPCS description (e.g., the description of the HCPCS code already includes the amount administered along with the amount wasted. Example: 75 mg of meperidine HCI (J2175, meperidine hydrochloride, per 100 mg) is administered. Bill HCPCS code J2175 quantity “1.” Payment will be provided for J2175, 100 mg, which includes the amount administered (75 mg) and the amount discarded (25 mg)). Please reference “Drug Wastage” at [http://www.trailblazerhealth.com/Publications/Job%20Aid/Drug%20Wastage.pdf](http://www.trailblazerhealth.com/Publications/Job%20Aid/Drug%20Wastage.pdf) for examples of determining the correct way of billing drug wastage to Medicare.

**Bill Type Codes**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.


**Bill Type Note:** Code 73X end-dated for Medicare use March 31, 2010; code 77X effective for dates of service on or after April 1, 2010.

**Revenue Codes**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

**Note:** TrailBlazer has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual Publication 100-04, *Claims Processing Manual*, for further guidance.

0250, 0636

**CPT/HCPCS Codes**

**Note:** Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. The American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS) require the use of short
CPT descriptors in policies published on the Web.

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®), intravenous, 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
J1573  Injection, hepatitis B immune globulin (Hepagam B), intravenous, 0.5 ml
J2788  Injection, RhoD immune globulin, human, minidose, 50 mcg (250 IU)
J2790  Injection, RhoD immune globulin, human, full dose, 300 mcg (1500 IU)
J2792  Injection, RhoD immune globulin, intravenous, human, solvent detergent, 100 IU

Other Comments
Physicians should avoid prescribing IVIG except for patients with severe immune deficiency and who have low antibody levels or for those whom have other well-established indications for therapy with IVIG as described within the related LCD.

[N/A]
[No additional information has been specified for this record]
Comments are closed.

This content pertains to...

Programs:  Part A, Part B
Topics:  Facility Types, LCDs, Policies, Specialty Services
Subtopics:  CAH, Drugs and Biologicals, Indian Health, Inpatient Acute, IRF, Local Coverage Determinations, LTCH, OPPS, ORF/CORF, RHC, SNF