

TO: EXECUTIVE OFFICERS OF FACILITIES SERVICED BY CAREFIRST INC.,  
MEDICARE PART A

FROM: CAREFIRST INC., MARYLAND MEDICARE PART A MEDICAL  
REVIEW

DATE: AUGUST 10, 2001.

SUBJECT: Local Medical Policy Updates

The following Local Medical Policy updates will become **effective September 10, 2001.**

The following general Medicare guidelines apply to all Local Medical Review Policies (LMRPs) addressed in this bulletin:

- **Medically Necessary and Reasonable**

Title XVIII of the Social Security Act, Section 1862 (a)(1)(A) states "...no payment may be made under Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Medicare limits coverage of many procedures to certain ICD-9-CM diagnosis codes. Please be aware that it is not enough to link the procedure code to a payable ICD-9-CM diagnosis code.

The diagnosis must be present for the procedure to be paid, but in addition, the procedure must be medically reasonable and necessary and representative of the patient's condition. Medicare may require documentation of medical necessity on a pre-payment and /or post-payment basis or comprehensive medical review basis.

Please note that the ICD-9-CM codes must be coded to the highest level of specificity, coding to the fourth or fifth digit. This is a requirement for all claims.

- **Documentation**

At the present time, the Health Care Financing Administration requires the use of HCPCS codes only for outpatient services. Documentation supporting the medical necessity of the service(s) should be legible, maintained in the patient's medical record, and available to Medicare upon request.

- **Reimbursement**

All of the coverage criteria listed for an individual Local Medical Review Policy must be met.

- **National Policy**

In the event that a national policy is established for any of these local medical policies, the national policy will take precedence over the local policy.

- **Focused Medical Review**

Medicare will continue to monitor the utilization of services through the Focused Medical Review (FMR) process.

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Questions related to Claims should be directed to Donald Doyle, (410) 561-4036; Audit and Reimbursement to Adam Weber, (410) 561-7948; and Medical Review to Trish Neal, (410) 561-4041.

**Contractor's Policy Number**

96-05-R1

**Contractor Name**

CareFirst of Maryland Inc., Medicare Part A

**Contractor Number**

00190

**Contractor Type**

Fiscal Intermediary

**LMRP Title**

Intravenous Immune Globulin

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**HCFA National Coverage Policy**

- Establishment of national policy supercedes all previous contractor policy statements, including Local Medical Policy coverage guidelines.
- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

**Primary Geographic Jurisdiction**

Maryland

Washington, DC

**Secondary Geographic Jurisdiction**

Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

**HCFA Region**

Region III

**HCFA Consortium**

Northeast

**Original Policy Effective Date**

October 12, 1996

**Original Policy Ending Date**

08/30/2001

**Revision Effective Date**

08/31/2001

**Revision Ending Date**

Not applicable at this time.

**LMRP Description**

Intravenous immune globulin (IVIG) is a sterile solution of plasma proteins containing IgG antibodies from pooled human plasma. The preparation contains no less than 90% immunoglobulin consisting of all the IgG substances and trace amounts of IgA and IgM.

**Indications and Limitations of Coverage and/or Medical Necessity**

- Immune globulin provided to those who lack it.
- Intravenous immune globulin should be used for those who demonstrate serious defects of antibody function.
- Intravenous immune globulin is used in the treatment of the following conditions:
- Immune-mediated or Idiopathic Thrombocytopenia Purpura (ITP)
- Kawasaki syndrome
- Primary immuno-deficiencies
- Chronic lymphocytic leukemia (CLL)
- Bone marrow transplantation, and;
- Human Immunodeficiency Virus (HIV)-pediatric use only
- Intravenous immune globulin (IVIG) can replace missing antibodies and decrease infection(s) in primary immune deficiency and chronic lymphocytic leukemia, increase platelets in idiopathic thrombocytopenic purpura, prevent complications of Kawasaki syndrome, and possibly decrease morbidity in some other conditions.
- Intravenous immune globulin is the preferred treatment method for those who require an immediate increase in intravascular immunoglobulin antibody levels and are unable to produce sufficient amounts of IgG antibodies.

**CPT/HCPCS Section(s) & Benefit Category**

HCPCS Level II Code

**Type of Bill Code(s)**

13X

**Revenue Code**

636

**CPT/HCPCS Codes(s)**

J1561	Injection; Immune Globulin, intravenous, 500mg
J1563	Injection, immune globulin, intravenous, 1 Gm
J2792	Injection, Rho D Immune Globulin, intravenous, human, solvent detergent, 100 I.U.

## **ICD-9-CM Codes that Support Medical Necessity**

### **Covered for:**

042	Human Immunodeficiency Virus (HIV) disease Note: Use this code only for patients younger than 14 years of age.
204.10	Lymphoid leukemia, chronic, without mention of remission
204.11	Lymphoid leukemia, chronic, in remission
279.00	Hypogammaglobulinemia, unspecified
279.04	Congenital hypogammaglobulinemia
279.05	Immunodeficiency with increased IgM
279.09	Other deficiency of humoral immunity
279.12	Deficiency of cell-mediated immunity, Wiskott-Aldrich syndrome
279.2	Combined immunity deficiency
287.3	Primary thrombocytopenia
357.0	Inflammatory and toxic neuropathy, acute
357.8	Inflammatory and toxic neuropathy, other Note: Use only when reporting chronic inflammatory demyelinating polyneuritis.
358.0	Myoneural disorders, myasthenia gravis
446.1	Acute febrile Mucocutaneous Lymph Node Syndrome (MCLS) (Kawasaki's disease)
656.10	Rhesus isoimmunization, unspecified as to episode of care or not applicable
656.11	Rhesus isoimmunization, delivered with or without mention of antepartum condition
656.12	Rhesus isoimmunization, antepartum condition or complication
996.85	Complications of transplanted organ, bone marrow

### **Reasons for Denial**

- The service does not follow the guidelines of this policy.
- The medical record does not verify that the service described by the HCPCS code was provided.
- The supporting documentation in the medical record does not reflect the medical necessity for the performance of this procedure.
- All other indications not listed in the "Indications and Limitations of Coverage" section of this policy.
- The service is considered
  - investigational,
  - a program exclusion, or;
  - otherwise not covered.

### **Non-covered ICD-9-CM Code(s)**

Any diagnosis code not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

### **Coding Guidelines**

- Coverage can be provided if medical necessity exists for administration of the intravenous form of the drug only.
- Treatment for any of the approved disorders must be supervised by a physician, experienced with the use of IVIG.
- Reimbursement can be allowed for chronic use as long as the drug is effective in the immuno-deficiency states.
- Dosage should range between 100 to 500 mg/kg., IV, every month. Trade names for intravenous immune globulin include Gamimune-N, Gammagard, Gammar-IV, Iveegam, Sandoglobulin, and Venoglobulin-1. Documentation must be submitted for primary or acquired immuno-deficiency states, which describes recurrent infections or diarrhea in association with hypogammaglobulinemia.

### **Documentation Requirements**

- Documentation supporting the medical necessity for this procedure should be legible, maintained in the patient's medical record, and available to Medicare upon request. All supporting documentation should be supplied when medical records are requested.
- To report these services, use the appropriate HCPCS code.
- An appropriate diagnosis code must be submitted on the claim. The patient's medical record should indicate the signs/symptoms supporting the diagnosis and functional impairment.

### **Utilization Guidelines**

Medicare would expect to see Intravenous Immunoglobulin used only for the indications listed within this policy.

### **Other Comments**

Physicians should avoid prescribing Intravenous Immunoglobulin, except for patients with severe immune deficiency who have low antibody level, or for those who have other well-established indications for therapy with Intravenous Immunoglobulin, as described within this policy.

### **Sources of Information**

TrailBlazer Health Enterprises, Inc., Part B Newsletter, July 12, 2000.

### **Advisory Committee Notes**

This policy does not reflect the sole opinion of the carrier, intermediary, or Carrier/Intermediary Medical Directors. Although the final decision rests with the carrier/intermediary, this policy was developed in cooperation with the Carrier Advisory Committee (CAC), which includes representatives from the appropriate specialties.

Advisory Committee meeting date: N/A

**Start Date of Comment Period**

N/A

**End Date of Comment Period**

N/A

**Start Date of Notice Period**

08/01/01

**Revision History**

<u>Number</u>	<u>Date</u>	<u>Changes</u>
96-01-R1	08/01/2001	Expanded the policy with ICD-9 codes for existing and new indications. Added HCPCS code J1563, per HCPCS Level II Codes. Update will make policy consistent with TrailBlazer Part B Policy.

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