

REVISED LCD REQUIRING COMMENT/NOTICE PERIOD
(changes to current language)

Contractor Name	BC Kansas
Contractor Number	00150
Contractor Type	Fiscal Intermediary
LCD Database ID Number	L2541
LCD Title	Intravenous Immunoglobulin (IVIg)
Contractor's Determination Number	
AMA CPT / ADA CDT Copyright Statement	CPT codes, descriptions and other data only are copyright 2004 American Medical Association (or such other data of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. CDT-4 codes and descriptions are © 2002 American Dental Association. All rights reserved.
CMS National Coverage Policy	<ul style="list-style-type: none"> • 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. • Medicare Benefit Policy Manual, Pub.100-2, Chapter 15, §50.6 for Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home • Program Memorandum A-02-076, CR#2298, dated August 7, 2002 for October 2002 OPPS updates. • Program Memorandum AB-02-093, CR# 2192, dated July 2, 2002 for Coverage and billing for intravenous immune globulin (IVIg) for the treatment of autoimmune mucocutaneous blistering diseases. • Program Memorandum A-03-020, CR#2671, dated April 2, 2003 for April 2003 OPPS updates • Transmittal 6, CR#3059, dated January 23, 2004 for coverage of intravenous immune globulin in the home for the treatment of primary immune deficiency diseases.
Primary Geographic Jurisdiction	Kansas
Oversight Region	Region VII
CMS Consortium	Midwest
Original Policy Effective Date	09/16/1999
Original Policy Ending Date	
Revision Effective Date	12/02/2004
Revision Ending Date	
Indications and Limitations of Coverage and/or Medical Necessity	Intravenous Immunoglobulin is made by cold ethanol fractionation of human plasma derived from 3000 to 10,000 donors. Further purification, fractionation and chromatography result in a product that is stabilized variously for human use. These procedures remove protein and other contaminants; minimize the concentration of IgG aggregates that increase the risk of an anaphylactoid and other adverse reactions in recipients. Also, they deactivate potential viral contaminants, such as HBV, HCV and HIV. The final product containing more than 95% IgG carries approximately 40% as dimers and the rest as

monomers. The pooled product probably exerts its beneficial effect through neutralization of pathogenic autoantibodies, suppression of pathogenic cytokines, acceleration of the rate of IgG catabolism, inhibition of complement binding and blockade of Fc (stem region) receptors.^{1,3,5}

All United States licensed IVIg products are labeled for use as replacement therapy in patients with primary immunodeficiencies. Individual products carry additional labeled indications (see table in Reference Section). There are several "off-label" uses for IVIg, especially in neurological disorders.^{1,2} There is good scientific evidence that supports this use in a few of the disorders; in others, however, the evidence is either poor or lacking. A shortage of IVIg has been noted in the US. At least a part of this shortage has been attributed to unapproved ("off label") use, and an indefinite duration of use, particularly in neurological illnesses.⁴ This policy places emphasis on neurological uses of IVIg since off label use is common in this field.

1. Neurological Disorders

In many neurological illnesses, IVIg has been of benefit although such use is "off-label" from FDA approved indications. Studies with acceptable or sound methodological bases have shown that IVIg can halt and reverse progression in Myasthenia Gravis, Guillain-Barré Syndrome, and Chronic Inflammatory Demyelinating Neuropathy (CIDP). In a few neurological conditions as Multifocal Motor Neuropathy (MMN), Dermatomyositis and Lambert-Eaton myasthenic syndrome IVIg may be of benefit. It is well to remember that recently defined entities do not carry a specific ICD number. We find that there is potential for misunderstanding and lack of clarity with regard to IVIg usage in neurological diseases. Therefore, before undertaking this therapy, please direct attention to the following requirements.

- a) The diagnosis of the disorder must be unequivocal. There must be clinical (history, quantitative examination) electrophysiological motor-sensory nerve conductions, (EMG), CSF, ancillary (ex: serum immunoprotein), and where necessary biopsy (muscle-nerve) data to support the diagnosis. Clear diagnostic criteria exist for making a diagnosis in the above disorders. The reason for choosing IVIg as a treatment must be transparent on review of records. Previous treatment failures with alternative agents require documentation.
- b) Once treatment is initiated, we expect meticulous documentation of progress. If there is initial improvement, and continued treatment is necessary, then some type of quantitative assessment to monitor the progress is required. Quantitative monitoring may use any accepted metric as MRC scale and ADL measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is insufficient to either continue IVIg or to expect coverage.
- c) Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory monitoring solely to guide IVIg therapy will not be medically necessary.
- d) There must be an attempt made to wean the dosage when improvement has occurred. There must be an attempt to stop the IVIg infusion if improvement is sustained with dosage reduction. If improvement does not occur with IVIg, then infusion should not continue.
- e) We will not cover the use of IVIg for the following disorders: Multiple Sclerosis, epilepsy, Amyotrophic Lateral Sclerosis (ALS), paraneoplastic neurological syndromes, undiagnosed neuropathy or weakness, malignancies with no causal link to coexisting neurological dysfunctions.
- f) In cases of Multifocal Motor Neuropathy (MMN), Dermatomyositis, Lambert-Eaton myasthenic syndrome, Inclusion Body Myositis (IBM) and Polymyositis

(PM) coverage determination will require individual consideration. The merits of the situation will require a review. **Dosage Guidelines in neurological disorders:** 2g/kg is a common initial empirical dose. We leave the choice of division of total initial dosage and rate of infusion to the treating physician. A decision to provide maintenance infusions must be justified through clear documentation as delineated in 1b, 1c and 1d above. We do not advocate a particular maintenance dosage schedule, but we do require literature support for a specific schedule chosen for each patient.

2. Primary Humoral Immunodeficiencies

A primary B-cell dysfunction results in primary humoral immunodeficiencies. We cover IVIg replacement for patients with primary immunodeficiencies and severe impairment of antibody capacity. Covered diseases include congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked immunodeficiency with hyper-IgM, and severe combined immunodeficiencies.

To demonstrate the existence of medical necessity for IVIg, it is vital to establish the initial diagnosis unequivocally. The following criteria establish the diagnosis of primary immunodeficiency:

1. Recurrent sinopulmonary, gastrointestinal and other sepsis, and
2. Laboratory tests demonstrating defective humoral immunity. The defects include: (i) low absolute IgG levels (ii) low IgG₂ or IgG₃ subclass levels (iii) a failure to produce antigen-appropriate antibodies when immunized with specific test antigens, and
3. The absence of a disorder, other than primary immunodeficiency, that could explain the clinical and laboratory presentations.

To merit the label of recurrent infections there should be evidence of several infections, many confirmed by imaging changes and growth in cultures, and most requiring antibiotics for resolution. In this clinical setting, absolute levels of immunoglobulin beyond 2 SDs of normal, or a failure to increase antigen-induced antibodies above 2 to 4 times the pre-challenge levels have been regarded as indicative of primary immunodeficiency. We accept these general ranges and metrics for establishing a diagnosis of primary humoral immunodeficiency. Fulfillment of the above criteria for primary humoral immunodeficiency is necessary for commencing IVIg infusions.

Dosage Guidelines: IVIg loading dose of 200-400 mg/kg body weight and maintenance doses of approximately 400 mg/kg body weight administered approximately once per month by intravenous infusion. Infusions are usually given every 4 weeks, but the interval should be adjusted, depending on the serum trough IgG concentrations and the patient's clinical condition. If no clinical improvement occurs while receiving on-going infusions, then the infusions should not continue.

Once treatment is initiated, we expect meticulous documentation of progress. Some type of quantitative assessment to monitor the clinical course is required. There should be clinical evidence that the patient is benefiting from IVIg. Some suggested criteria for measurement include: 1) number of infections, 2) frequency and duration of antibiotic use 3) number of febrile episodes, 4) number of health provider visits, 5) number of absences from work or school 6) ADLs and/or other measures specific to the patient's clinical condition. Subjective or experiential improvement alone is insufficient to either continue IVIg or to expect coverage.

After a period of 1-2 years and at similar intervals thereafter, there must be an

attempt made to wean or stop the IVIg infusion. It is important to identify the specific immunochemical abnormality that led to the initial establishment of a diagnosis of primary immunodeficiency. This abnormality, be it serum IgG, subclass IgG or post-immunization changes, requires periodic monitoring to justify the need for continued infusion.

Determination of what constitutes (i) failure of conventional therapy, (ii) contraindications to conventional to conventional therapy and, (iii) the duration of short-term therapy are subject to review by the contractor, pre or post-payment.

Limitations:

Secondary Immunodeficiencies:

Low immunoglobulin levels or failure of antibodies to rise to an antigen challenge occurs sometimes in patients who do not have primary B-cell disorders. These changes may be the result of several systemic illnesses, malignancies, viral infections or drugs. In these disorders a state of secondary immunodeficiency exists. This state may also lead to recurrent infections and laboratory immunoglobulin abnormalities.

Secondary immunodeficiencies or hypogammaglobulinemia, in isolation, will not be covered unless the immunodeficiency is the result of chronic lymphocytic leukemia or childhood Human Immunodeficiency Virus (HIV) Infection.

3. Idiopathic Thrombocytopenic Purpura (ITP):

ACUTE ITP - We will cover IVIg for (a) management of acute bleeding, due to severe thrombocytopenia (platelet counts usually less than 30,000/ul); b) to increase platelet counts prior to invasive surgical procedures, e.g. splenectomy, c) in patients with severe thrombocytopenia (platelet counts less than 20,000/ul) considered to be at risk for intracerebral hemorrhage. **Dosage Guidelines:** (i) 1,000 mg/kg body weight given on one or two consecutive days, or (ii) 400 mg/kg body weight given on each of two to five consecutive days.

CHRONIC REFRACTORY ITP - To be eligible for IVIg coverage patients must fulfill these criteria: a) prior treatment with corticosteroids and splenectomy; b) duration of illness of greater than six months; c) age of 10 years or older; d) no concurrent illness/disease explaining thrombocytopenia and e) platelet counts persistently at or below 20,000/ul. **Dosage Guidelines:** (i) Initial - 1 or 2 g/kg body weight (total cumulative dose) given in equal amounts over two to five days; (ii) Maintenance - 800-1,000 mg/kg body weight, usually administered no more frequently than every two to six weeks, as determined by serial platelet counts.

4. Chronic Lymphocytic Leukemia (CLL)

Coverage will be for prevention of recurrent bacterial infections in patients with B-cell chronic lymphocytic leukemia. Patients eligible for treatment must have unequivocally documented CLL, an immunoglobulin G (IgG) level of less than 600 mg/dl, and a recent history of serious bacterial infection(s) requiring either oral or parenteral antibiotic therapy. **Dosage Guidelines:** 400 mg/kg body weight given every 3-4 weeks.

5. Kawasaki disease

We will cover IVIg if begun within 10 days of onset of fever, and when oral aspirin is used concurrently as follows: oral aspirin 100 mg/kg daily orally until the 14th day of illness, then 3-5 mg/kg for a period of five weeks. **Dosage Guidelines:** 400 mg/kg body weight for four consecutive days or a single infusion of 2,000 mg/kg body weight.

6. Bone Marrow Transplantation (BMT)

IVIg will be covered for use in BMT recipients to reduce the incidence of infections and acute graft versus host disease. Two conditions for coverage must be met: a) the graft recipient must be 21 years of age or older and b) the BMT must be a covered Medicare procedure, as defined in the Coverage Issues Appendix, 35-30.

Dosage Guidelines: 500 mg/kg body weight given on days -7 and -2 pre-transplantation, then weekly through day 90 post-transplantation.

7. Human Immunodeficiency Virus (HIV) Infection

IVIg will be covered for patients infected with HIV to reduce significant bacterial infection when **all** of the following coverage indicators are present: a) age less than 13 years old; b) evidence of either qualitative or quantitative humoral immunologic defects and c) current bacterial infections, despite appropriate antimicrobial prophylaxis. **Dosage Guidelines:** 400 mg/kg body weight given every 28 days.

8. Pemphigus

Effective for services performed on or after October 1, 2002, IVIg is covered for treatment of the following biopsy-proven conditions:

- Pemphigus Vulgaris,
- Pemphigus Foliaceus,
- Bullous Pemphigoid,
- Mucous Membrane Pemphigoid (aka, Cicatricial Pemphigoid), with or without ocular involvement,
- Other specified bullous dermatoses.

Coverage will be available when patients 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.
- 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. Again, contractors have the discretion to decide what constitutes short-term therapy.

Determination of to what constitutes (i) failure of conventional therapy, (ii) contraindications to conventional to conventional therapy and, (iii) the duration of short-term therapy are subject to review by the contractor, pre or post-payment.

Coverage Topic	Prescription Drugs	
Type of Bill Code	13X, 85X	
Revenue Codes	0636	
CPT/HCPCS Codes	J1563 Injection, immune globulin, intravenous, 1g	
ICD-9 Codes that Support Medical Necessity	<i>**Italicized words within this section are not a part of the ICD-9-CM description; but rather are additional coverage requirements.</i>	
	042	Human immunodeficiency virus [HIV] disease
	204.10-204.11	Lymphoid leukemia, chronic <i>(Mention secondary diagnoses as Hypogammaglobulinemia and recurrent bacterial infections using appropriate codes.)</i>

279.00	Hypogammaglobulinemia, unspecified <i>(Do not use 279.00 as a stand-alone diagnosis. Instead use it as a secondary diagnosis when describing secondary hypogammaglobulinemia of Chronic Lymphocytic Leukemia (204.10 or 204.11.))</i>
279.03	Other selective immunoglobulin deficiencies (selective deficiency of IgG)
279.04	Congenital hypogammaglobulinemia
279.05	Immunodeficiency with increased IgM
279.06	Common variable immunodeficiency
279.12	Wiskott-Aldrich syndrome
279.2	Combined immunity deficiency
287.3	Primary thrombocytopenia <i>(use 287.3 for ITP)</i>
357.0	Acute infective polyneuritis (Guillain-Barré Syndrome)
357.81	Chronic inflammatory demyelinating polyneuritis <i>(use 357.81 for CIDP)</i>
357.9	Unspecified inflammatory and toxic neuropathy <i>(use 357.9 for Multifocal Motor Neuropathy)</i>
358.01	Myasthenia gravis with (acute) exacerbation
358.1	Myasthenic syndromes in diseases classified elsewhere (Eaton-Lambert Syndrome)
446.1	Acute febrile mucocutaneous lymph node syndrome [MCLS] <i>(Kawasaki disease)</i>
694.4	Pemphigus
694.5	Pemphigoid
694.60	Benign mucous membrane pemphigoid without mention of ocular involvement
694.61	Benign mucous membrane pemphigoid with ocular involvement
694.8	Other specified bullous dermatoses
710.3	Dermatomyositis
710.4	Polymyositis
728.89	Other disorders of muscle, ligament, and fascia <i>(use 728.89 for Inclusion Body Myositis)</i>
V42.81	Organ or tissue replaced by transplant; bone marrow
V42.82	Organ or tissue replaced by transplant; peripheral stem cells
Diagnoses that Support Medical Necessity	
ICD-9 Codes that DO NOT Support Medical Necessity	
ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation	
Diagnoses that DO NOT Support Medical Necessity	All ICD-9-CM codes not listed in section: ICD-9 Codes that Support Medical Necessity.
Documentation Requirements	Medical records need not accompany routine electronic claim submissions. The chart, however, must carry the following documentation. 1. Each claim must be submitted with ICD-9-CM codes that reflect the condition of

	<p>the patient, and indicate the reason(s) for which the service was performed.</p> <ol style="list-style-type: none"> 2. Medical records must document not only clinical assessments but also all laboratory data that led to a specific diagnosis qualifying for IVIg therapy. This requirement cannot be waived. Medical records maintained by the treating physician must clearly document the medical necessity for both initiation and continuation of IVIg therapy. Required documentation of medical necessity include: <ul style="list-style-type: none"> -- history and physical examination -- office/progress notes(s); -- test results with written interpretation; -- accurate weight in kilograms should be documented prior to each infusion, since the dosage is based on a mg/kg dosage; -- documentation of prior treatments -evidence of laboratory results demonstrating a significant deficiency in immunoglobulin levels prior to initial treatment (where appropriate or referenced by this policy); -- history of recurrent and severe infections; -- current effectiveness of IVIG therapy; and -- goals and/or treatment plan 3. In addition, for specific diagnoses we require fulfillment of criteria listed under the appropriate item of the, "Indications and Limitations" section. 4. Please pay attention to the requirements for off label uses. <p>Physicians or other providers administering IVIg at the request of another provider assume full responsibility as to the medical necessity for IVIg under the terms and conditions of this policy. These providers must also be able to meet the documentation requirements given above, either directly through their own medical records, or indirectly through records obtained from the referring physician.</p>
<p>Appendices</p>	<p>Note that there is no specific ICD-CM listing for a few neurological syndromes. We have listed the closest alternative that is available.</p> <p>Cytomegalovirus (CMV): In seronegative recipients who receive lung, liver, pancreas or heart transplants from donors seropositive for CMV, specific IVIg prophylaxis with CMV antibody may be necessary. This policy, however, does not address cytomegalovirus immune globulin (HCPCS code J0850.)</p> <p>All United States licensed IVIg products are labeled for use as replacement therapy in patients with primary immunodeficiencies. Individual products may carry additional labeled indications. The FDA (Food and Drug Administration) web site (http://www.fda.gov, search as, "immune globulin intravenous") carries current information about product specifics, withdrawals and introductions. There are several "off-label" uses for IVIg, especially in neurological disorders.^{1,2} There is good scientific evidence that supports this use in a few of the disorders; in others, however, the evidence is either poor or lacking. There was a shortage of IVIg in the past in the US. At least a part of this shortage had been attributed to unapproved ("off label") use, and an indefinite duration of use, particularly in neurological illnesses.⁴</p>
<p>Utilization Guidelines</p>	
<p>Sources of Information and Basis for Decision</p>	<ol style="list-style-type: none"> 1. Dalakas, M. (1998). "The Use of Intravenous Immunoglobulin for Neurologic Diseases." <i>Neurology</i> 51, supplement 5: S1-S45. <i>This is an excellent 45 page review supplement to the "green journal" (Neurology). It deals with many aspects of neurological use, from theory to practice. There are original data and evaluations.</i> 2. Ratko, T. A., D. A. Burnett, et al. (1995). "Recommendations for off-label use of intravenously administered immunoglobulin preparations. University Hospital

	<p>Consortium Expert Panel for Off-Label Use of Polyvalent Intravenously Administered Immunoglobulin Preparations [see comments]." <i>Jama</i> 273(23): 1865-70. <i>A well-quoted review paper on general off-label uses; it has a very useful reference table.</i></p> <p>3. Yu, Z. and V. A. Lennon (1999). "Mechanism of intravenous immune globulin therapy in antibody-mediated autoimmune diseases." <i>N Engl J Med</i> 340(3): 227-8. <i>A proposed mechanism that may differ from traditional explanations of how IV-Ig works. The second author is a respected neuroimmunologist.</i></p> <p>4. (1999). "Availability of immune globulin intravenous for treatment of immune deficient patients--United States, 1997-1998." <i>MMWR Morb Mortal Wkly Rep</i> 48(8): 159-62. <i>A CDC statement detailing their views on IV-Ig shortage.</i></p> <p>5. Rosa, T. (1998). "Primary Immunodeficiencies." <i>Mayo Clin Proc</i> 73(September): 865-872. <i>This paper details every accepted use of IV-Ig in primary immunodeficiencies.</i></p> <p>6. Ballow, M. Primary immunodeficiency disorders: Antibody deficiency. <i>J. Allergy Clint. Immunol.</i> 2002;109:581-91.</p> <p>7. Jaffe EF SECONDARY HYPOGAMMAGLOBULINEMIA - <i>Immunol Allergy Clin North Am</i> - 2001 Feb; 21(1); 141-163</p>
Advisory Committee Notes	<p>This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from the medical community.</p> <p>Advisory Committee meeting date: June 9,10, 1999, November 3, 2004</p>
Start Date of Comment Period	05/17/1999
End Date of Comment Period	05/17/1999
Start Date of Notice Period	05/17/1999
Related Documents	
LCD Attachments	

Revision History		
Update Number	Date	Changes
10	12/02/2004	We are extending the Comment Period to 01/10/2005 to allow additional comments to be submitted on this policy.
9	10/27/2004	This policy is subject to language changes and is going through the comment/notice process. The comment process begins 10/27/2004 and ends 12/10/2004.
8	02/18/2004	CMS' National Policy Added: Transmittal 6, CR#3059, dated January 23, 2004 for coverage of intravenous immune globulin in the home for the treatment of primary immune deficiency diseases.
7	08/13/2003	Covered Diagnosis Codes Deleted as this code is invalid and needs a 5 th digit effective 12/31/2003: 358.0 Myasthenia gravis Added effective for services on or after 10/01/2003: 358.01 Myasthenia gravis with (acute) exacerbation
6	06/18/2003	CMS' National Policy Added:

		<ul style="list-style-type: none"> Program Memorandum A-03-020, CR#2671, dated April 2, 2003 for April 2003 OPPS updates.
5	02/12/2003	<p>HCPCS/CPT Codes</p> <p>Deleted per the YR2003 HCPCS code updates:</p> <p>J1561 Injection, immune globulin, intravenous, 500 mg</p>
4	12/31/2002	<p>HCPCS/CPT Codes</p> <p>Added for dates of service on or after 10/01/2002:</p> <p>J1563 Injection, immune globulin, intravenous, 1g</p> <p>CMS' National Policy (formerly known as HCFA's National Policy)</p> <p>Added:</p> <ul style="list-style-type: none"> Program Memorandum AB-02-093, CR# 2192, dated July 2, 2002 for Coverage and billing for intravenous immune globulin (IVIg) for the treatment of autoimmune mucocutaneous blistering diseases. Program Memorandum A-02-076, CR#2298, dated August 7, 2002 for October 2002 OPPS updates. <p>CMS' National Policy (formerly known as HCFA's National Policy)</p> <p>Added:</p> <p>Program Memorandum AB-02-093, CR# 2192, dated July 2, 2002 for Coverage and billing for intravenous immune globulin (IVIg) for the treatment of autoimmune mucocutaneous blistering diseases.</p> <p>Indications and Limitations</p> <p>Added new bullet #8:</p> <p>8. Pemphigus</p> <p>Effective for services performed on or after October 1, 2002, IVIg is covered for treatment of the following biopsy-proven conditions:</p> <ul style="list-style-type: none"> Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous Membrane Pemphigoid (aka, Cicatrical Pemphigoid), with or without ocular involvement, Other specified bullous dermatoses. <p>Coverage will be available when patients meet at least one of the following criteria</p> <ul style="list-style-type: none"> 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. 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. Again, contractors have the discretion to decide what constitutes short-term therapy. <p>Determination of to what constitutes (i) failure of conventional therapy, (ii) contraindications to conventional therapy and, (iii) the duration of short-term therapy are subject to review by the contractor, pre or post-payment.</p> <p>Covered Diagnosis Codes</p> <p>Deleted as this code is invalid and needs a 5th digit due to year 2003 ICD-9 updates:</p>

		<p>357.8 Other inflammatory and toxic neuropathy</p> <p>Added effective for services on or after 10/01/2002:</p> <p>357.81 Chronic inflammatory demyelinating polyneuropathy</p> <p>694.4 Pemphigus</p> <p>694.5 Pemphigoid</p> <p>694.60 Benign mucous membrane pemphigoid without mention of ocular involvement</p> <p>694.61 Benign mucous membrane pemphigoid with ocular involvement</p> <p>694.8 Other specified bullous dermatoses</p>
3	03/31/2001	<p>*This section now required based on new HCFA guidelines*</p> <p>AMA CPT Copyright Statement CPT codes, descriptions, and other data only are copyright 1999 American Medical Association. All rights reserved. Applicable FARS/DFARS Clauses Apply.</p> <p>HCPCS/CPT Codes</p> <p>Added:</p> <p>J1561 Injection, immune globulin, intravenous, 500 mg</p> <p>Revenue Code This section changed from Revenue Code 0259 to 0636 – Drugs requiring specific identification</p> <p>Indications and Limitations “Dosage Guidelines in Neurological Disorders” located under bullet 1. “Neurological Disorders” information changed to the following: <i>Dosage Guidelines in neurological disorders:</i> 2g/kg is a common initial empirical dose. We leave the choice of division of total initial dosage and rate of infusion to the treating physician. A decision to provide maintenance infusions must be justified through clear documentation as delineated in 1b, 1c and 1d above. We do not advocate a particular maintenance dosage schedule, but we do require literature support for a specific schedule chosen for each patient.</p> <p>Covered Diagnosis Codes The following statement added to the top of this section: <i>*The following italicized words are not a part of the ICD-9 description; but rather are additional policy coding guidelines/requirements</i></p> <p>☒ This policy reprinted in its entirety due to the changes made. ☒</p>
2	05/31/2000	<p>Covered Diagnosis Codes The descriptions of the following codes were corrected to read as follows:</p> <p>204.10- Lymphoid leukemia, chronic</p> <p>204.11 <i>Mention secondary diagnoses as Hypogammaglobulinemia and recurrent bacterial infections using appropriate codes</i></p> <p>287.3 Primary thrombocytopenia (use for ITP)</p> <p>357.8 Other inflammatory and toxic neuropathy (use for CIDP)</p> <p>357.9 Unspecified inflammatory and toxic neuropathy (use for Multifocal Motor Neuropathy)</p> <p>358.1 Myasthenic syndromes in diseases classified elsewhere (Eaton-Lambert syndrome)</p> <p>446.1 Acute febrile mucocutaneous lymph node syndrome [MCLS] (Kawasaki's disease)</p> <p>728.89 Other disorders of muscle, ligament, and fascia (use for Inclusion Body Myositis)</p> <p>V42.81 Organ or tissue replaced by transplant; bone marrow</p> <p>V42.82 Organ or tissue replaced by transplant; peripheral stem cells</p>
1	11/30/1999	<p>Please note Covered Diagnosis Code 279.2 is not in the correct numerical order and should be located after Covered Diagnosis Code 279.12 on the</p>

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E-mail and postal address to which comments should be sent:

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