

Local Coverage Determination (LCD): Immune Globulin Intravenous (IVIg) (L34314)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

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Original Effective Date

L34314

For services performed on or after 10/01/2015

LCD Title

Immune Globulin Intravenous (IVIg)

Revision Effective Date

For services performed on or after 02/01/2020

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

N/A

Retirement Date

N/A

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CMS National Coverage Policy

Title XVIII of the Social security Act; Section 1862(a)(1)(A) section allows coverage and payment for only those

services that are considered to be reasonable and necessary.

Title XVIII of the Social Security Act; Section 1833(e). This section prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

CMS Manual, Pub.100-2, Chapter 15, section 50.4 and section 50.4.2. This section addresses coverage of drugs and biologicals.

CMS Manual, Pub.100-3, Chapter 1, Section 250.3. This section describes coverage for IVIg for treatment of Autoimmune Mucocutaneous Blistering Diseases.

CMS Manual, Pub. 100-2, Chapter 15, Section 50.6. This section describes coverage of IVIg for the treatment of Primary Autoimmune Deficiency Disease in the home.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Note: Providers should seek information related to National Coverage Determinations (NCD) and other Centers for Medicare & Medicaid Services (CMS) instructions in CMS Manuals. This LCD only pertains to the contractor's discretionary coverage related to this drug.

IVIg is a solution of human immunoglobulins specifically prepared for intravenous infusion. Immunoglobulin contains a broad range of antibodies that specifically act against bacterial and viral antigens.

There may be acceptable off-label uses for IVIg in rare patient populations or in rare individual patient clinical scenarios which are not covered by this LCD. In such instances, a request for an individual patient consideration by the Medical Director should accompany the appeal of any denied claim.

There are several off-label uses for IVIg, especially in neurological disorders. There is good scientific evidence that supports use in a few of the disorders; in others, however, the evidence is either poor or absent. This policy addresses the off-label uses of IVIg in certain neurological conditions, and idiopathic thrombocytopenic purpura (ITP) in pregnancy. It also clarifies the conditions under which certain FDA-approved uses may be covered. [This policy does not address the use of IVIg in any condition covered by a National Coverage Determination \(NCD\) or CMS manual instruction. \(See attached article\)](#)

Idiopathic Thrombocytopenic Purpura (ITP) in Pregnancy:

Pregnant women with this disease are at risk for delivering thrombocytopenic infants. Protection of the fetus becomes an important consideration in management of a pregnant woman with immune thrombocytopenic purpura. IVIg may be recommended in the following:

1. Pregnant women who have previously delivered infants with autoimmune thrombocytopenia;
2. Pregnant women who have platelet counts less than 75,000/mm³ during the current pregnancy; or
3. Pregnant women with past history of splenectomy

In the presence of one of the above indications, the use of IVIg may be covered if one of the following situations is present:

- Failure of or contraindications to other therapy; and/or

- Rapidly progressive form of the disease;

All the conditions listed below (see Neurological Disorders) for Medicare coverage are met.

Neurological Disorders:

The use of IVIg in some neurological conditions has been associated with demonstrable clinical benefit. Studies with acceptable methodological bases have shown that IVIg may halt and/or reverse disease progression in Myasthenia Gravis, Guillain-Barre Syndrome and Chronic Inflammatory Demyelinating Neuropathy (CIDP). In a few neurological conditions, such as Polymyositis, Multiple Myeloma, Multifocal Motor Neuropathy (MMN), Dermatomyositis and Lambert-Eaton myasthenic syndrome, IVIg may be of benefit.

Medicare may provide coverage for the use of IVIg use in the above disease conditions if the following requirements are met.

For Guillain-Barre, Myasthenia Gravis, Acute or Chronic Inflammatory Demyelinating Neuropathy (see CIDP below for additional criteria), Dermatomyositis, and Relapsing-Remitting Multiple Sclerosis (MS), the use of IVIg may be covered if one of the following scenarios is present:

- Failure of or contraindications to other therapy (absolute requirement for Dermatomyositis and MS); and/or
- Rapidly progressive form of the disease.

The diagnosis of the disorder must be reasonably certain, based on a thorough history and examination as well as, when necessary, electromyography (EMG), spinal fluid tests, serum tests and biopsy findings.

The clinical record **must document** the medical necessity to initiate IVIg therapy, and the ongoing need as long as treatment continues. The reasons for prescribing IVIg must be clear and include all required information. For example, previous treatment failures must be recorded.

Once treatment is initiated, documentation of progress must be meticulous. If there is initial improvement and continued treatment is necessary, then some type of quantitative assessment to monitor and document the progress is required. Quantitative monitoring may include any accepted metric assessment such as MRC scale and activities of daily living (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.

Clinical monitoring takes precedence over laboratory monitoring. If significant clinical improvement is evident, then laboratory monitoring, solely to guide IVIg therapy, is not medically necessary.

When improvement has occurred, attempts to decrease/wean the dosage must be made and documented. Following dosage reduction, if improvement is sustained, an attempt to discontinue IVIg must be made. If documentable improvement does not occur with IVIg administration, then infusions should not continue.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and its variants (multifocal motor neuropathy, multifocal acquired demyelinating polyneuropathy, multifocal motor neuropathy, pure sensory CIDP).

CIDP is an autoimmune disorder caused by an attack on peripheral nervous system myelin. Clinically CIDP follows a *subacute onset of weakness and/or sensory loss, evolving progressively, or in a stepwise fashion, over several months. Reflexes are usually decreased or absent. Electrodiagnostic testing (EDX) reveals the classic features of demyelination, with prolonged distal latencies, conduction slowing, prolonged F-waves, conduction block, and temporal dispersion in most cases. Most patients have an elevated spinal fluid protein level.* (Jonathan S. Katz, MD, Dept. of Neurology, Stanford University)

Chronic progressive painful peripheral sensory neuropathy, which is common with diabetes mellitus or toxins, may eventually show demyelinating features on electrodiagnostic testing. Typically, these cases have progressed for more than one year prior to electrodiagnostic testing. Many patients with CIDP are not seen until several years into their illness.

In patients with sensory or sensorimotor polyneuropathies, when a CIDP diagnosis is uncertain, a response to a therapeutic trial of prednisone (e.g. 30-60 mg/d or perhaps 50-100 mg/d for 2-4 months with a taper) should be helpful to increase the specificity of the diagnosis in order to help assure that IVIg will be effective. In the absence of other supporting information, a subjective response to a therapeutic trial of IVIg is not sufficient to validate the diagnosis of CIDP. The principal goal of the treatment is to improve motor function in most patients.

If a diagnosis of multifocal motor neuropathy is suspected, a trial of IVIg is recommended since this condition does not respond to prednisone.

Specific diagnostic criteria for CIDP should include:

- **In typical CIDP**, symmetrical muscle weakness affects proximal and distal muscles of all four limbs. Sensory loss may affect the distal limbs and usually involves large fiber modalities. The clinical evolution tends to be gradually progressive, evolving over periods of more than 8 weeks although patients typically present to clinicians within 6 months of onset. Decreased or absent reflexes in affected nerve distributions occur in nearly all CIDP presentations, and develop during the acute phase typically within 8 weeks of symptom onset. The patient should have a neurologic function assessment score of at least 3 or greater on the Rankin Scale at the time of initial therapy. However, IVIg can be used in patients with rapidly worsening weakness regardless of the Rankin score.
- **A multifocal variant of CIDP** (multifocal acquired demyelinating sensory and motor neuropathy or MADSAM) leads to sensory and motor dysfunction in multiple individual nerve distributions (for example, ulnar or median). Weakness may affect the upper or lower limbs, but it most commonly affects distal musculature and is more common in the hands. Progression tends to be step-wise with episodes of weakness compiling over time to cause gradually increasing debility.
- **Multifocal motor neuropathy (MMN)** is a purely motor syndrome that tends to affect the hands. Like MADSAM, the weakness affects the distribution of individual nerves and tends to progress in a step-wise fashion over time. Patients may have subjective sensory complaints but objective sensory findings are not present. The diagnosis is generally made using motor and sensory nerve conduction studies. MMN responds to IVIg but not to Prednisone. Therefore, Prednisone is never indicated in this condition.
- Occasionally, a patient with **CIDP** may have **only sensory symptoms**. The sensory loss may affect the upper or lower limbs and tends to be relatively symmetrical. Like more common sensory-motor CIDP presentations, patients typically seek medical attention within 6-9 months from onset. The sensory loss may begin relatively acutely and progresses in a stepwise or gradual fashion. The sensory distribution is usually not simply limited to the feet or in a stocking distribution, but takes on unusual patterns involving the trunk, arms, or proximal legs. The condition is rare compared with the relatively common purely sensory neuropathies such as distal diabetic, toxic, alcoholic, and idiopathic neuropathies. Pure sensory CIDP also must be distinguished from distal demyelinating neuropathies associated with an IgM paraprotein, which is not responsive to IVIg or prednisone.
- Laboratory evidence of CIDP includes:
 - Conduction block at sites not prone to nerve compression.
 - Motor nerves characteristically show segmental conduction slowing and increased distal latencies consistent with a demyelinating polyneuropathy. This is present in typical CIDP, MADSAM, MMN, and purely sensory CIDP.

- Conduction slowing from a demyelinating neuropathy should be distinguished from conduction slowing secondary to moderate to severe axonal loss.
- Cytoalbuminologic dissociation in more than 90% of cases.
- Serum tests may show:
 - An IgG monoclonal gammopathy (e.g. on immunofixation electrophoresis); however, an IgM monoclonal gammopathy places the diagnosis in question.
 - An elevation of a specific antibody to GM-1 increases the likelihood of MMN. Antibodies to myelin associated glycoprotein (MAG) or sulfatide may occur in patients with demyelinating neuropathies besides CIDP and place the diagnosis in question.
- No other explanation for the diagnosis, such as
 - HIV disease;
 - Distally predominant diabetic neuropathy;
 - Diabetic amyotrophy;
 - Diabetic cachectic neuropathy;
 - Distal acquired demyelinating symmetric neuropathy with an IgM paraprotein; or
- No evidence of another treatable cause of the polyneuropathy;
- No evidence of hereditary demyelinating neuropathy.

Special consultation recommendations for IVIg use for CIDP, CIDP variants, and MMN:

- Before beginning the initial treatment (i.e. the induction dose) for CIDP, or, for patients currently on treatment for CIDP within 3 months of the effective date of this policy, a consultation is expected from a neurologist or rheumatologist who is an expert in the field of CIDP. This will help validate the diagnosis is correct and the IVIg treatment is reasonable and necessary. The consultation should include a comprehensive history and examination as defined in the CPT book, validate the diagnosis of CIDP, and clarify the need for IVIg treatment. The consultation should set forth the recommended treatment regimen, appropriate measures of therapeutic benefit, and any recommendation for follow-up consultation.
- If the indication for IVIg treatment is principally for pain control in a patient with presumed CIDP predominantly affecting the sensory nerves, before beginning the initial treatment (i.e. the induction dose), the patient should have shown a measurable response to a therapeutic trial of prednisone. In addition, the consultation from a neurologist or rheumatologist who is an expert in the field of CIDP is expected. This consultation should help validate the need for IVIg treatment for pain control as opposed to other pain treatment options that do not include IVIg.

IVIg for CIDP following the initial treatment regimen:

- Once treatment is initiated, the benefit of treatment must be measured. Quantitative monitoring may use any accepted metric as MRC scale and activities of daily living (ADL) measurements.
- Subsequent treatment with IVIg will be covered only when the patient demonstrates significant improvement in clinical condition and, when relevant, a reduction in the level of sensory loss. For long-term treatment of stable patients, the dose must be periodically reduced or withdrawn, and the effects measured, in order to validate continued use.

There is no reimbursement for the use of IVIg in the treatment of the following neurological disorders: epilepsy, Amyotrophic Lateral Sclerosis (ALS), paraneoplastic neurological syndromes, undiagnosed neuropathy or weakness

and malignancies with no casual link to coexisting neurological dysfunctions.

The use of IVIg should be reserved for patients with serious defects of antibody function. The goal is to provide immune globulin to those who lack it. The following are certain FDA approved indications for IVIg, which are covered by Noridian.

Acute ITP:

- Management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/mm³);
- To increase platelet counts prior to invasive major surgical procedures (splenectomy); or
- In patients with severe thrombocytopenia (platelet counts less than 20,000/mm³) considered to be at risk for intracerebral hemorrhage.

Chronic Refractory ITP:

First line treatment

- Pediatric ITP;
- In combination with steroids if rapid platelet response justified or to avoid splenectomy; or
- Contraindications to steroids

Second line treatment

- Following treatment with corticosteroids with splenectomy; or
- Platelet counts persistently at or below 20,000/mm³.

Symptomatic Human Immunodeficiency Virus (HIV):

Indications for intravenous immunoglobulin would include:

1. Patients less than 13 years of age;
2. Entry CD4+ lymphocyte counts greater than or equal to 200/mm³; and
3. Clinically symptomatic or asymptomatic, but immunologically abnormal

Other Disorders:

- a. Chronic Lymphocytic Leukemia with associated hypogammaglobulinemia. To initiate IVIg for this disease, the IgG level should be less than 600 mg/dl or there should be evidence of specific antibody deficiency and the presence of repeated bacterial infections.
- b. Bone Marrow/Stem Cell Transplantation
 - Transplantation must have been for a Medicare covered indication;
 - Patients 20 years of age or older;
 - Cytomegalovirus (CMV) seropositive before transplantation; or
 - Cytomegalovirus (CMV) seronegative, had seropositive marrow donors, and were undergoing allogenic transplantation for hematologic neoplasms.

- c. Kawasaki Disease (Mucocutaneous Lymph Node Syndrome)
- d. Transplantation rejection, kidney, stem cell or heart, antibody-mediated.
- e. Desensitization for a pre-kidney or pre-heart transplantation.
- f. Autoimmune retinopathy (limited to three months unless there is improvement on therapy)

Immunoglobulin Deficiencies:

The principal clinical manifestations of humoral immunodeficiency are recurrent bacterial infections of the upper and lower respiratory tract. Immunoglobulin replacement therapy is required in patients with certain immunodeficiency diseases characterized by absent or deficient antibody production and, in most cases, recurrent or unusually severe infection. Individuals with agammaglobulinemia (IgG levels that fall below 200 mg/dl) need lifelong antibody replacement. Those with either a hypogammaglobulinemia or functional deficiency should have a well-documented severe polysaccharide nonresponsiveness and evidence of recurrent infections with a proven requirement for antibiotic therapy.

Summary of Evidence

NA

**Analysis of Evidence
(Rationale for Determination)**

NA

General Information

Associated Information

Medical record documentation maintained by the treating physician must clearly document the medical necessity to initiate IVIg therapy and the continued need thereof. Required documentation of medical necessity could include:

- History and physical;
- Office/progress note(s);
- Test results with written interpretation; and An accurate weight in kilograms should be documented prior to the infusion since the dosage is based mg/kg/dosage.

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
02/01/2020	R12	In <i>Coverage Indications, Limitations and/or Medical Necessity</i> , under <i>Immunoglobulin Deficiencies</i> , agammaglobulinemia indications are clarified.	<ul style="list-style-type: none"> Creation of Uniform LCDs Within a MAC Jurisdiction
10/01/2019	R11	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
10/01/2019	R10	<p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage</p>	<ul style="list-style-type: none"> Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	
08/13/2019	R9	<p>Article is revised to add the following diagnoses, per CR 11295: D80.2, D80.3, D80.4, D80.6, D80.7, D81.5, D82.1, D82.4, D83.1 and G11.3.</p> <p>07/16/19 At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
07/01/2018	R8	<p>Coverage for immunodeficiency is clarified and expanded with additional diagnosis codes (Z86.19, Z87.01) due to provider reconsideration request. Revisions were made to d. and e. under Other Disorders in Indications and Limitations of Coverage and the following diagnoses were added: T86.21, T86.22, T86.298, Z48.21, Z86.19, Z87.01, Z94.1. References were updated.</p> <p>05/24/18 At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> • Reconsideration Request
07/17/2017	R7	<p>Indications and Limitations of Coverage, under Other Disorders, the letter e. is added: Desensitization for a pre-kidney transplantation in patients with a panel reactive antibody (PRA) of 80% or below. Use in patients with a PRA of 81% or higher is considered to be experimental/investigational by this Contractor and is therefore not covered. Post transplantation to prevent rejection remains covered without regard to antibody levels. LCD is revised to add Z76.82. Sources of Information is updated to include multiple recently reviewed sources and moved to the Bibliography.</p> <p>12/11/17 At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore</p>	<ul style="list-style-type: none"> • Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		not all the fields included on the LCD are applicable as noted in this policy.	
10/01/2016	R6	LCD is revised to add diagnosis G61.82, effective 10/1/2016 per the 2016/2017 annual ICD-10 update. The JEA (L36409) LCD is retired and is combined into the JEB L34314 LCD so that both JEA and JEB contract numbers will have the same final MCD LCD number.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction • Revisions Due To ICD-10-CM Code Changes
11/07/2015	R5	The LCD is revised to add diagnoses M33.00, M33.01, M33.02, M33.09, M33.10, M33.11, M33.12, M33.20, M33.90, M33.91, M33.92 and M33.99 effective 11/07/2015.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction
11/07/2015	R4	The LCD is revised to add diagnoses G61.0 and G65.0 effective for dates of service on/after 10/1/15.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction
11/07/2015	R3	This LCD is revised to add ICD-10 D83.9 effective for dates of service on/after 10/1/2015. Due to technical restrictions in the Medicare Coverage Database, the effective date cannot be a date previous to the last revision effective date. In this case that date is 11/7/2015. Noridian will, however, pay diagnosis D83.9 effective 10/1/2015.	<ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes
11/07/2015	R2	This I-10 version is the result of finalizing I-9 DL33532 in I-10.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction
10/01/2015	R1	ICD-10 G25.82 is added to the LCD as payable effective 10/1/2015.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A54641 - Intravenous Immune Globulin (IVIg)-NCD 250.3

A57187 - Billing and Coding: Immune Globulin Intravenous (IVIg)

A54660 - Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home – Medicare Benefit Policy Manual, Chapter 15, 50.6

A54645 - Response to Comments: Immune Globulin Intravenous (IVIg)

Related National Coverage Documents

NCD(s)
250.3 - Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases

Public Version(s)

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Updated on 05/25/2018 with effective dates 07/01/2018 - 08/12/2019

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Keywords

N/A