Medicare Local Coverage Determinations Limit Access to IVIG

By Melissa Schweitzer and Michelle Vogel

Many IG Living readers are contacting the magazine to report problems acquiring their intravenous immune globulin (IVIG) treatments, and the reasons they report are varying:

- Patients' IVIG dosing is being reduced at hospitals by an average of 50%, contrary to physicians' orders.
- Medicare will not cover their IVIG therapy.
- Their trough levels are too high to warrant IVIG.
- Hospitals are requiring patients to sign documents (Advance Beneficiary Notices or ABNs) indicating that they will assume financial responsibility for their IVIG treatments, in the event that Medicare refuses to cover them.
- Their IVIG treatment is being terminated temporarily until medical necessity is determined.

Our reimbursement consultants have investigated these cases and discovered that the majority of Medicare carriers (these are private insurance companies that implement Medicare benefits at the local level) are implementing "Local Coverage Determinations"[1] that are reducing patient access to IVIG therapy in states across the country. These determinations vary by state and carrier, and are not based on accepted medical guidelines for treatment and dosing.

According to Jordan Orange, MD, PhD, assistant professor of pediatrics at the University of Pennsylvania School of Medicine and attending physician in immunology at Children's Hospital of Philadelphia, "The randomness that underlies the differences in these determinations is truly idiosyncratic and unscientific, and thus the criteria are detrimental to patient care."

We encourage you to read this article, become informed about Local Coverage Determinations, learn how to appeal such determinations, and advocate against this challenge to quality patient care.

[1] Additionally, many private insurance companies have adopted the Milliman Care Guidelines, which have limitations in coverage similar to Local Coverage Determinations and seem to be outdated, arbitrarily applied, and not necessarily based on sound medical evidence. In a subsequent article, we will review the Milliman Care Guidelines.

Local Coverage Determinations

Although Medicare is a federal program, it contracts with private insurance companies (carriers) and fiscal intermediaries (FIs) to pay healthcare bills at the local level. Each Medicare carrier and FI has the discretion to determine which services are reasonable and necessary and, therefore, covered as a Medicare benefit. These coverage policies are issued in a document called a Local Coverage Determination (LCD).

LCDs are drafted by individual Medicare carriers in individual states; consequently, there are distinct differences in them, carrier-to-carrier and state-to-state, rather than having a single set of coverage guidelines defined at the federal level. This creates confusion about coverage and payment policies for providers and patients. Also of concern, the soundness of the individual LCD criteria depends on the capabilities of the local Medicare carrier's medical director and the expertise of the Carrier Advisory Committee members, who provide insurance claims and medical determination review and advice. Clinical expertise is essential when determinations involve conditions that are rare or otherwise difficult to diagnose and/or difficult to treat.

In the February-March 2007 IG Living, Reimbursement Q&A section, we briefly discussed a Rhode Island case in which Linda, a Medicare patient with a primary immune deficiency disease (PIDD), was having trouble accessing her IVIG treatment due to an LCD denial, despite PIDD being an on-label use for IVIG. Specifically, her LCD stated the following reasons in its explanation of the denial of IVIG coverage:

> *Documentation provided does not adequately support the medical need for the services rendered. Medicare guidelines require that the services provided are supported by a covered diagnosis that would justify the medical need for treatment of the patient's illness or injury. The medical documentation submitted indicates the laboratory level is 1030; dosage to be adjusted to keep levels between 400–600. There was no evidence of infection or dosage adjustment. We will therefore hold the provider liable.*

Linda's provider, the hospital where she had been regularly receiving her infusions prior to the LCD, was suddenly refusing to treat her unless she signed an Advance Beneficiary Notice.

An Advance Beneficiary Notice (ABN) is a document that providers can require a Medicare beneficiary to sign. The ABN holds the beneficiary responsible for the cost of the treatment, if Medicare does not cover it.

In Linda's case, if she signed the ABN, she would be assuming financial ➢

responsibility for the cost of her IVIG infusions, because the LCD had already indicated Medicare would not cover them. However, Linda is appealing the Local Coverage Determination, so she refused to sign the ABN, to avoid becoming responsible for the cost of her treatments if her appeal fails. Consequently, Linda is going without treatment for her PIDD, and her health is deteriorating.

It is important to note some key elements in the explanation of the carrier's decision: Even though Linda's physician prescribed IVIG to be administered on a monthly basis, and even though Linda's PIDD is normally covered by Medicare, the local carrier can deny coverage, because Linda's serum trough levels do not meet the carrier's lower trough level guidelines.

Linda was prescribed the number of grams of IVIG and the frequency of treatment necessary to keep her as close to infection free as reasonably possible. Her local Medicare carrier is requesting that she have infections in order to be eligible for IVIG, instead of preventing the infections.

In another case, Carol, a Georgia resident, contacted IG Living for assistance. She had been admitted to a hospital and diagnosed with chronic inflammatory demyelinating polyneuropathy (CIDP), normally a covered indication for IVIG. She received her first infusions as an inpatient, and did well. Her physician subsequently prescribed IVIG infusions in the hospital's outpatient clinic. Carol went to the clinic and was told that Medicare did not cover IVIG.

According to Carol's carrier's LCD:

> *IVIG is not covered as an initial therapy for patients with newly diagnosed CIDP nor as a maintenance therapy in patients failing to respond to an initial course of IVIG following therapies with other agents; exception to this rule would be in patients with severe CIDP and in patients who have contraindications for immunosuppressive drugs.*

Carol has not been able to receive her IVIG, and her condition continues to deteriorate even though she showed improvement when she received her infusion as an inpatient. Unfortunately, it is likely that Carol will indeed be determined to be eligible for IVIG by the time this article is published, because her health is deteriorating to the point that she will be admitted to the hospital as an inpatient.

The Effect of LCDs Across the Country

The following chart shows examples of current provisions by local Medicare contractors that may limit coverage for IVIG.

Primary Immune Deficiency Diseases (PIDD)

Limitation of Coverage	States Affected
The following limitations are made on patient serum IgG trough levels to qualify for IVIG coverage: • Serum IgG trough levels must fall within the range of 400-600 mg/dl; this applies to any individual with a primary immune deficiency disease, with no specification on the particular type of PIDD • Serum IgG trough levels must be tested every 3 months.	AK, AL, AZ, AR, CA, CO, CT, DE, FL, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NY, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
The following limitations are made on dosage of IVIG: • IVIG loading dose ranged from 100 mg/kg to 600 mg/kg body weight and maintenance doses ranged from 100 mg/kg to 400 mg/kg body weight administered approximately once per month by intravenous infusion. Maintenance doses exceeding 200 mg/kg may be covered, but only if the desired clinical response to 200 mg/kg is clearly documented as inadequate.	AK, AL, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MA, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
After a period of 1–2 years and at similar intervals thereafter, attempt must be made to stop IVIG infusion to identify specific immunochemical abnormality; requires periodic monitoring to justify need for continued infusion.	KS, NE

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Limitation of Coverage	States Affected
IVIG not covered as initial therapy for patients with newly diagnosed CIDP nor as maintenance therapy in patients failing to respond to an initial course of IVIG following therapies with other agents; exception to this rule would be in patients with severe CIDP (Rankin scores of 4 or 5) in whom rapid therapeutic response is deemed medically desirable and in patients who have contraindications for immunosuppressive drugs.	CO, DC, DE, GA, ID, MT, NC, NJ, NM, TN, TX, VA
Covered if intolerant of prednisone or azathioprine over at least 3 months or neurologic function assessment score of at least 3 or greater on Rankin Scale. Covered when difficulty with venous access for plasmapheresis or other therapy has failed or is contraindicated, or for rapidly progressive forms.	AK, AL, AZ, CA, CO, CT, DE, FL, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NY, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY, Puerto Rico, and Virgin Islands
Dosage guidelines: Initial therapy 400 mg/kg body weight for 5 days. Maintenance therapy 250–400 mg/kg body weight no more frequently than every 2 weeks.	AK, AL, AZ, CA, CO, CT, DE, FL, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
An attempt must be made to wean the dosage when improvement has occurred. Must be an attempt to stop IVIG if improvement is sustained with dosage reduction.	AZ, AR, KS, LA, MO, MT, NE, NM, ND, OK, RI, SD, UT, WY

Guillain-Barré Syndrome (GBS)

Limitation of Coverage	States Affected
IVIG therapy is covered as equivalent to plasmapheresis for the treatment of GBS if patient has paralysis that precludes from walking 30 feet without assistance and is within the first 2 weeks of illness.	AK, AL, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
Covered when difficulty with venous access for plasmapheresis or other therapy has failed or is contraindicated, or for rapidly progressive forms.	CT, IL, IN, KY, NY, OH, Puerto Rico, Virgin Islands
At 6 month intervals after therapy has begun, the following elements must be documented in medical records for chronic use of IVIG: clinical summary of functional status, a recent physical exam, copies of objective tests including nerve conduction studies and pulmonary function tests, an assessment of long-term prognosis and anticipated future treatment courses.	CA, MA, ME, NH, VT
Dosage guidelines: 1000 mg/kg body weight daily for 2 days or 400 mg/kg body weight daily for 5 days. In some states, dosage can only be repeated if evidence of continued clinical progression after initial infusion is completed, but not if patient has ongoing, but stable weakness.	AK, AL, AZ, CA, CO, CT, DE, FL, GA, HI, IA ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

Myositis

Limitation of Coverage	States Affected
Individual coverage determination required for coverage of IVIG in dermatomyositis (DM), polymyositis (PM), and inclusive body myositis (IBM); also includes multifocal motor neuropathy (MMN) and Lambert-Eaton in this category.	AK, AL, AZ, CA, CO, CT, DE, FL, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
DM is covered when difficulty with venous access for plasmapheresis or other therapy has failed or is contraindicated (second-line agent) and for rapidly progressive forms.	AL, CT, IL, IN, IA, KY, NY, OH, SD
IVIG covered for PM and DM if the following criteria are met: • Biopsy-proven disease • Have had at least a 4–6 month trial of prednisone or prednisone combination therapies • May be covered at less than 4 month trial if profound, rapidly progressive and/or potentially life-threatening muscular weakness and is refractory or intolerant to previous therapy • Lack of response to other therapies as reflected by persistently elevated CK (creatine kinase) levels and/or lack of improvement on muscle strength improvement scales.	CO, DC, DE, GA, ID, MT, NC, NM, TN, TX, VA
Patient's record must show that there was a measurable response within 6 months of use of IVIG or its use will no longer be considered medically necessary.	CT, NY
Dosage guidelines: Suggested doses of IVIG range from 1000 mg/kg body weight daily for 2 days every 4 weeks or 400 mg/kg body weight for 5 days every 4 weeks in patients intolerant of high dose therapy, to 2000 mg/kg, as a common initial empirical dose, with the division of the dosage left up to the physician.	AR, GA, ID, IL, IN, KS, MO, NC, NE

Myasthenia Gravis

Limitation of Coverage	States Affected
IVIG is covered when difficulty with venous access for plasmapheresis, if patient is intolerant of or refractory to cholinesterase inhibitors, corticosteroids and azathioprine, and/or if patient has profound rapidly progressive and/or potentially life-threatening muscular weakness.	AK, AL, AZ, AR, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NY, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY, Puerto Rico, Virgin Islands
Hospitalization is required for coverage. IVIG can be used in patients with chronic, severe, MG with a vital capacity of less than 1 litre, dysphagia associated with aspiration and inability to ambulate 100 ft without assistance. Documentation must be submitted after 2 treatments and should record significant improvement in order for continued coverage to be allowed.	LA, MO, MS; MA, ME, NH, VT: Also states that documentation of medical necessity and efficacy of treatment must be provided at each 6-month interval after treatment has started and include: clinical summary of functional status, physical exam, copies of objective tests, and assessment of long-term prognosis and anticipated future treatment courses
Dosage guidelines: No clearly established regimen, although studies have reported success with dose of 400 mg/kg body weight per day for 5 days.	AK, AL, AZ, CA, CO, CT, DE, FL, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

Idiopathic Thrombocytopenic Purpura (ITP)	
Limitation of Coverage	**States Affected**
For acute ITP, IVIG can be recommended in the following situations: • 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) • In patients with severe thrombocytopenia (platelet counts less than 20,000/mm3) considered to be at risk for intracerebral hemorrhage. For chronic refractory ITP, IVIG can be recommended in the following situations: • Prior treatment with corticosteroids and splenectomy • Age of 10 years or older • Platelet counts persistently at or below 20,000/mm3 • Duration of illness less than 6 months • No concurrent illness/disease explaining thrombocytopenia	AL, AK, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
For ITP in pregnancy, IVIG can be recommended for 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 3. Pregnant women with past history of splenectomy.	AR, AZ, GA, IL, IN, KY, LA, MO, MT, ND, NJ, NM, OH, OK, RI, SD, TN, UT, WY
There is good scientific evidence that supports this use in a few of the neurological disorders; in others, however, the evidence is either poor or lacking. The literature shows that not all patients with the following diseases need treatment with IVIG: • Acute and chronic inflammatory demyelinating polyradiculoneuropathy • Guillain-Barré syndrome • Immune Thrombocytopenic Purpura in pregnancy • Myasthenia gravis When administered for the above conditions, the medical record must document one of the following situations to constitute appropriate IVIG infusions: • Other therapy has failed or is contraindicated • Rapidly progressive forms of these diseases The beneficiary is not liable for services denied as not reasonable and necessary unless a valid waiver of liability (advance beneficiary notice or ABN) has been signed.	AZ
Reimbursement can be allowed for chronic use as long as the drug is effective in the immunodeficiency states. The usual treatment for ITP should not exceed 90 days. Dosage should range between 100 to 500 mg/kg, I.V., every month.	LA, MO, MS
Dosage guidelines for Acute ITP: a. 1,000 mg/kg body weight given on 1 or 2 consecutive days b. 400 mg/kg body weight given on each of 2–5 consecutive days. Dosage for chronic refractory ITP: a. Initial—1 or 2g/kg body weight (total cumulative dose) given in equal amounts over 2–5 days b. Maintenance—800–1,000 mg/kg body weight administered no more frequently than every 2–6 weeks as determined by serial platelet counts	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY

Appealing LCDs

If your IVIG therapy is denied based on a Medicare LCD, you probably have the right to appeal the denial—and you should.

You can appeal the LCD denial, if you meet the following criteria:

1. If you are entitled to benefits under Medicare Part A, are enrolled under Medicare Part B, or both.
2. If your physician says that you need the denied item(s) or service(s) or if you have already received the item(s) or service(s).

You will know if your IVIG treatment coverage has been denied if you receive a Medicare Summary Notice (MSN), including a Notice of Denial. An MSN indicating a denial will include the following:

1. Explanation of Benefits (EOB): The EOB explains the services you received; the amount billed; any amount covered; and what you owe.
2. Notice of Denial: This explains what service(s) was denied; why it was denied; how much time you have to appeal the denial; and how to file the appeal.
3. Local Coverage Determination: The LCD explains what limitations your local carrier imposes on coverage for your IVIG therapy for your disease state (along with all other disease states for which IVIG coverage is available).

When can you file an LCD appeal?

If you have not yet received the item or service, you must file your appeal request within six months of the date of the treating physician's written statement that you need the item or service.

If you have already received the item or service, you must file your appeal request within 120 days of the date of the initial denial notice.

Mail your LCD appeal request to:
Departmental Appeals Board
Civil Remedies Division, Mail Stop 6132
Cohen Building, Room G-644
330 Independence Avenue, S.W.
Washington, DC 20201

What information must you include in your LCD appeal request?

When you file an LCD appeal request, include:

1. Name of the Medicare beneficiary
2. His or her address
3. Telephone number
4. Health insurance claim number, if applicable

Current Medical Guidelines

To understand the differences between the LCD guidelines and quality patient care, it is helpful to review current medical guidelines for IVIG therapy by disease state.

Primary Immune Deficiency Diseases[2]

Dosage Guidelines	Current Medical Guidelines on Serum IgG Trough Levels
According to American Academy of Asthma, Allergy and Immunology (AAAAI), the usual initial dose of IVIG for antibody replacement is 400–600 mg/kg delivered every 3–4 weeks. However, this may vary with the particular PIDD in question, i.e., patients with extremely low IgG levels at presentation may benefit from a larger loading dose before the initiation of regular maintenance dosing. AAAAI states that an acceptable starting point for maintenance dosing is 400 mg/kg for many patients, which should be adjusted to achieve the optimal clinical result.	According to the AAAAI, the trough level for patients with agammaglobulinemia should be at least greater than 500 mg/dl and preferably greater than 800 mg/dL. Trough levels for patients with common variable immune deficiency disease (CVID) should be equal to pretreatment levels of IgG plus 300 mg/dl. Higher trough levels (>800 mg/dl) have the potential of improving pulmonary outcome. Additionally, IgG trough levels can be unreliable in patients with CVID and should not be used as primary benchmarks for guiding therapy. AAAAI recommends monitoring trough levels at no greater than every 3 months and preferably no greater than every 6 months.

Neurological Disorders[3]

Dosage Guidelines
A standard loading dose of 2 g/kg is usually administered over several days, depending on tolerance and convenience. It is then followed by booster doses of 0.5 to 1 g/kg every 2 weeks, or 1 to 2/kg every month, for a total of 2 to 3 months, at which time the neuropathy is re-evaluated. Improvement may be seen at 2 weeks to 3 months after beginning therapy, but if there is no improvement in 2 to 3 months, the IVIG is discontinued. Maintenance therapy is usually continued until there is maximal improvement, and then discontinued or tapered to see if it is still needed. In approximately one-third of cases, the disease is monophasic, and the improvement persists. In the other two-thirds, however, the disease relapses so that maintenance therapy is needed. The dose is then adjusted as needed. In such cases, the IVIG therapy can be considered a holding action, until a cure is found.

Idiopathic (Autoimmune) Thrombocytopenia Purpura

Dosage Guidelines	Current Medical Guidelines	
Recommend initial dose of 1.0 g/kg for 1–2 days	**Use of IVIG in pregnancy:**[4] Generally, corticosteroids are used as the initial therapy in ITP, but this can induce or exacerbate gestational diabetes, bone loss, hypertension, and abruption and prematurity. Therefore, in pregnancy, IVIG together with low-dose prednisone is the treatment of choice. Splenectomy should be avoided if possible to avoid abortion.	**Use of IVIG in Rh-patients:**[5] IVIG is the preferred treatment for Rh- ITP patients, and anti-D represents a frontline treatment option for Rh+ ITP patients.

5. Title of the LCD that is being challenged
6. Specific provision(s) of the LCD affecting the Medicare beneficiary
7. Name of the private company (carrier or FI) that used the LCD

In addition to this, the request should explain:

1. What item or service is needed
2. Why the LCD is incorrect
3. Why the appeal request is being made

Include with your LCD appeal request a letter from the doctor treating you that states:

1. Item or service that you need
2. Any medical literature that supports the treatment of IVIG for your diagnosis, and any treatment guidelines available.

Now, It's Time for Action!

It is critically important to keep your elected representatives informed of your LCD appeal—and to seek their help. Send them copies of your appeal packet, including a cover letter asking the representatives to support your appeal. Then follow up with phone calls to them. Remember to keep copies of everything for yourself!

The more frequently patients report such problems, the more likely the negative effects of LCDs on patient care will be reduced. Like the rest of us, many of our representatives are unaware of LCDs, and they would be shocked to know how LCDs inhibit quality patient care.

To find your elected representatives' contact information and to download a sample cover letter, visit www.igliving.com and click on Take Action.

If you have a question or need assistance, please email us at editor@igliving.com.

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[2] *The Journal of Allergy and Clinical Immunology, Volume 117, Number 4, April 2006: Use of Intravenous Immunoglobulin in Human Disease: A Review of Evidence by Members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology.*

[3] *American Academy of Neurology Press, Demos Publications, New York 2006: Peripheral Neuropathy; When the numbness, weakness and pain won't stop. Norman Latov, MD, PhD.*

[4] *Blood, The American Society of Hematology; October 1, 2005; Volume 106, Number 7: How I treat idiopathic thrombocytopenic purpura (ITP); Douglas B. Cines and James B. Bussel.*

[5] *B Journal of Thrombosis and Haemostasis 2005; Volume 3, Supplement 1: Anti-D Compared to IVIG for the Treatment of Immune Thrombocytopenic Purpura: A Systematic Review. Bussel JB, Provan D, Sinclair CJ, Genereux MG.*