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Kansas, Nebraska and
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August 9, 2004

Patrick Nemechek, MD
Nemechek Health Renewal
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Dear Dr. Nemechek:

This letter is to inform you of certain changes that we will be making in our claims processing system in order for claim payments to be consistent with one of our local medical review policies (LMRP.) These changes will take effect on September 1, 2004. This LMRP deals with administration of intravenous immunoglobulin (IVIg). The LMRP can be found on our Website at www.kansasmedicare.com, www.nebraskamedicare.com or www.nwmissourimedicare.com. Select Part B, then LMRP/LCD, select "accept" (to accept the user agreement), then select alphabetical index and scroll to "Intravenous Immune Globulin (IVIg)". Double click on the policy title and the current policy will be displayed. We will explain the need for the changes below.

Data analysis on claims with dates of service between July 1, 2003 and December 31, 2003 shows that Kansas, Kansas City, and Nebraska have a higher utilization than national rates for certain specialties for the use of IVIg. When comparing utilization by allowed charges per 1000 Medicare beneficiaries for all specialties combined:

Kansas City ranks 2nd

Kansas ranks 17th

Nebraska ranks 22nd

In trying to explain this data, we found that our edits have not been consistent with the requirements outlined in our Local Medical Review Policy entitled "Intravenous Immune Globulin (IVIg)".

What will be the actual change?

Beginning September 1, 2004, claims with the ICD-9-CM diagnosis code 279.00 Hypogammaglobulinemia, unspecified, as the only diagnosis on the claim will be denied as not medically necessary.

Clinical rationale for the decision to implement the change:

Diagnosis 279.00 – *Hypogammaglobulinemia, unspecified* is a non-specific diagnosis and is not sufficient to describe any of the 5 covered diseases listed in section 2 of the LMRP under Primary Humoral Immunodeficiencies. ICD-9-CM states that these "unspecified" or "not otherwise specified" codes should be used when documentation does not provide enough information to submit a more specified diagnosis code.¹ If IVIg is being used, there should be enough documentation to show that one of the five primary immunodeficiency diseases listed in the policy exists.

For coverage under this section of the LMRP the hypogammaglobulinemia must be from a primary deficiency, and not due to secondary causes such as medications that interfere with production of IgG, systemic diseases such as renal or gastrointestinal, and certain types of malignancies, or viruses such as Epstein-Barr, Cytomegalovirus and HIV.²

Under **Documentation Requirements** the LMRP states the medical records must document not only clinical assessments but also all laboratory data that led to a specific diagnosis qualifying for IVIg therapy. Several leading researchers in primary immunodeficiencies agree that a low immunoglobulin level alone is not an indication for IVIg therapy. We will cite a few reviews here.

Buckley (1991) states "the only clear indication for replacement therapy with immune globulin is severe impairment in the antibody-forming capacity."³

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Ballow (2002) points out "there is controversy over the clinical significance of the laboratory findings of low levels of serum IgG subclasses." He further states that in addition to a careful history and physical exam, to determine the clinical significance of an IgG subclass abnormality, measurement of functional or specific antibodies is critically important.⁴

Busse (2002) and Park (2004) describe three diagnostic criteria for Common variable immunodeficiency (CVID): 1) Decreased (but not absent) IgG levels with decreased IgA or IgM levels (or both) by at least 2 standard deviations below normal for age, 2) A proven deficiency of antibodies, and 3) Exclusion of other known causes of antibody deficiency.^{5,6,7} All of the primary humoral immunodeficiencies listed in the LMRP require more than just hypogammaglobulinemia to make a definitive diagnosis.

The intent for inclusion of ICD 279.00 in the policy:

ICD-9 code 279.00 was included in the LMRP as a covered diagnosis with the intent it would be used as a secondary diagnosis to describe the secondary hypogammaglobulinemia seen in patients with Chronic Lymphocytic Leukemia (see section 4 of the LMRP). If diagnosis codes 204.10 or 204.11 are used, 279.00 must be used as a secondary diagnosis.

We will also implement editing to review on an individual basis those claims for neurological conditions requiring individual case by case consideration as outlined in 1.f. in the Neurological Disorders section. These disease conditions are Multifocal Motor Neuropathy (MMN), Dermatomyositis, Lambert-Eaton myasthenic syndrome, Inclusion Body Myositis (IBM,) and Polymyositis (PM). Once a case has been individually reviewed an edit will be set up to pay claims without further review for a specified period of time.

Intravenous Immune Globulin therapy is very expensive, but it can be beneficial for patients with primary immune deficiencies and other conditions. Our goal is to assure this expensive therapy is being used within the requirements of our current Local Medical Review Policy. Please review the current LMRP and your utilization for individual patients receiving this therapy. If you have questions regarding the LMRP contact your provider representative.

Sincerely,

Dana Edwards ARNP MSN

Dana Edwards, ARNP, MSN
Nurse Data Analyst, Medicare Medical Review

CC: Priscilla Burke, Nurse Education Coordinator for Medicare Part B
Mary Kennedy, Nurse Education Coordinator for Medicare Part B
Doug Klise, Manager, Provider Education and Communication

References

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4. Ballow, M. Primary immunodeficiency disorders: Antibody deficiency. J. Allergy Clin. Immunology. 2002;109:581-91.
5. Busse, PJ, Razvi S, & Cunningham-Rundles, C. Efficacy of intravenous immunoglobulin in the prevention of pneumonia in patients with common variable immunodeficiency. J Allergy Clin. Immunology 2002;109:1001-4.
6. Park, C L. Common Variable Immunodeficiency. Online at <http://www.emedicine.com/ped/topic444.htm> Last updated May 26, 2004.
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