



**MEDICARE  
PART A INTERMEDIARY**  
Kansas

**MEDICARE  
PART B CARRIER**  
Kansas, Nebraska and  
Northwest Missouri

August 26, 2004

Patrick M Nemecek, MD  
Nemecek Health Renewal  
4010 Washington St #500  
Kansas City, MO 64111-2610

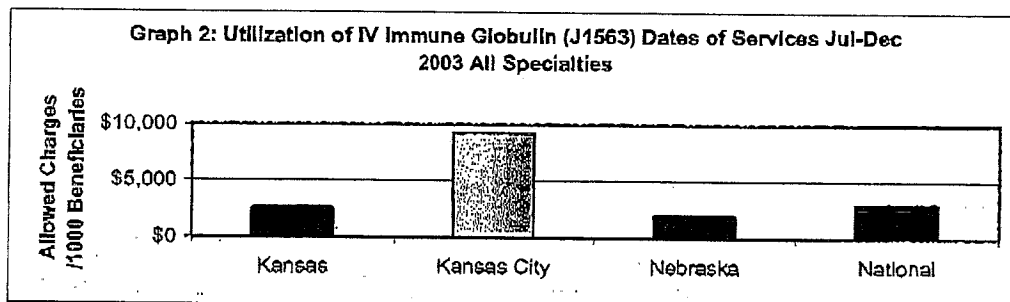
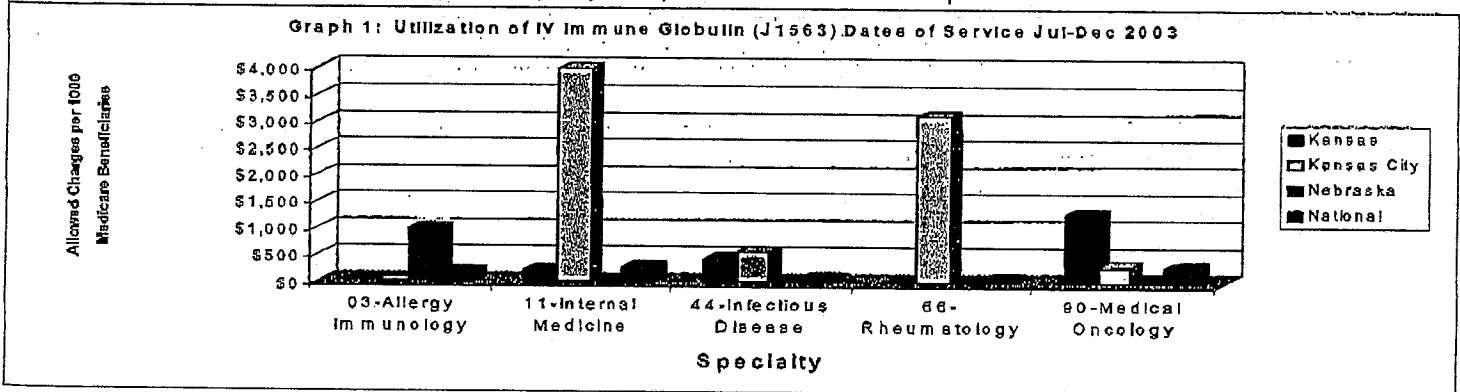
UPIN: E56236  
PIN: P830754

Dear Dr. Nemecek:

As a Medicare Part B Carrier, Blue Cross Blue Shield of Kansas performs medical review to assure the goals of CMS are met. The purpose of the Medicare Medical Review unit is to provide education to providers so we can reach CMS's ultimate goal of paying claims right the first time.

**GENERAL DATA**

Data analysis was done on claims paid July 1, 2003 through March 31, 2004 and with dates of service July 1, 2003 through December 31, 2003 for all providers in Kansas, Kansas City, and Nebraska billing HCPCS (Healthcare Common Procedural Coding System, 2004) code J1563 - Injection, immune globulin, intravenous, 1 gram. Data shows Nebraska specialty 03 (Allergy Immunology), Kansas specialties 44 (Infectious Disease) and 90 (Medical Oncology), and Kansas City specialties 11 (Internal Medicine), 44 (Infectious Disease), and 66 (Rheumatology) to be over twice the national average in allowed charges per 1000 Medicare beneficiaries for utilization of Intravenous Immune globulin (IVIg) when compared to others in their specialty (see Graph 1). Graph 2 shows data for all specialties combined.



**MEDICARE PART A & PART B**  
A CMS CONTRACTED INTERMEDIARY/CARRIER

**KANSAS**  
Claims/Inquiries  
PO Box 3543  
Topcka, Kansas 66601-3543  
www.kansasmedicare.com

**KANSAS CITY AREA**  
Claims/Inquiries  
PO Box 3537  
Topcka, Kansas 66601-3537  
www.nwmissourimedicare.com

**NEBRASKA**  
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PO Box 3541  
Topeka, Kansas 66601-3541  
www.nebraskamedicare.com

Exhibit 2

**PROVIDER DATA**

There were 27 providers in Kansas City who had allowed services for J1563 for July-December 2003 dates of service. Of these, seven were internal medicine specialists. You ranked highest of all providers in your specialty in allowed services, allowed dollars and number of patients receiving IVIg. You ranked second for all Kansas City providers giving IVIg. Because there is such a wide variation in the specialties billing IVIg, comparison data was difficult to validate. However, it appears you may specialize in treatment of patients with conditions requiring treatment with IVIg. We will be conducting medical review on a small sample of your patients' claims to determine if your utilization is in compliance with the guidelines in our Local Medical Review Policy. These patients were selected by choosing those with the highest utilization between January 1, 2004 and July 31, 2004. See section below on **Medical Review** for additional details.

**EDUCATION**

Our Local Medical Review Policy (LMRP) entitled "Intravenous Immune Globulin (IVIg)" is available on our website at [www.nwmissouri.com](http://www.nwmissouri.com) select Part B, then LMRP/LCD, select "accept", then select alphabetical index and scroll to Intravenous Immune Globulin (IVIg). Double click on the policy title and the current policy will appear.

It appears from data, you are treating patients with **Primary Humoral Immunodeficiencies**. The policy states:

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. Patients must have deficient qualitative and/or quantitative antibody production and recurrent bacterial infections directly attributable to this deficiency.

**Dosage Guidelines:** IVIg loading dose of 200-400 mg/kg body weight and maintenance doses of 100-200 mg/kg body weight administered approximately once per month by intravenous infusion.

Under **Documentation Requirements** the policy states:

The chart...must carry the following documentation.

1. 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.
2. In addition, for specific diagnoses, we require fulfillment of criteria listed under the appropriate item of the Indications and Limitations section.
3. Please pay attention to the requirements for off label uses.

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.

**MEDICAL REVIEW**

The documentation we require in order to review the use of IVIg and determine if it is in compliance with the LMRP can be quite large, therefore we have limited this review to a small number of patients. Some of the information we are requesting is not specifically outlined in the current LMRP but will be used to determine if clarifications or revisions are needed. We have chosen ten of your current IVIg patients for which we will review claims for J1563 on a prepayment basis. These patients are:

Rank	Patient Name	Medicare Number	Diagnosis
20			279.00 Hypogammaglobulinemia, unspecified
21			279.00 Hypogammaglobulinemia, unspecified
22			279.00 Hypogammaglobulinemia, unspecified
23			279.00 Hypogammaglobulinemia, unspecified
26			279.00 Hypogammaglobulinemia, unspecified
32			279.00 Hypogammaglobulinemia, unspecified
34			279.00 Hypogammaglobulinemia, unspecified
35			279.00 Hypogammaglobulinemia, unspecified
36			279.00 Hypogammaglobulinemia, unspecified
37			279.00 Hypogammaglobulinemia, unspecified

Diagnosis 279.00 – Hypogammaglobulinemia, unspecified is a non-specific diagnosis and is not sufficient to describe any of the 5 covered diseases. This non-specific diagnosis is intended to describe the secondary hypogammaglobulinemia

seen in patients with chronic lymphocytic leukemia. If diagnosis 279.00 has been submitted, please submit additional information relating the hypogammaglobulinemia to the primary immunodeficiency disease state being treated with IVIg.

Submit clinical and laboratory data supporting the presence of a quantitative and/or qualitative immunoglobulin deficiency and history of recurrent bacterial infections directly attributable to the deficiency. Submit dates of bacterial infections and laboratory evidence of positive cultures of a bacterial pathogen(s). Submit pre- and post- vaccination serum titer levels to support qualitative deficiencies (including references on interpretation of "non-responder" status). Submit Immune globulin levels (IgG, IgA, IgM etc.) and IgG subclass levels to support a quantitative deficiency. Clinical findings should accompany laboratory data to support the significance (severity) of the deficiency(ies) identified. Submit IgG serum trough levels used to adjust dosages and frequency of treatment. If IVIg is being used at higher or more frequent doses than the guidelines given, or if IVIg is being used off-label for conditions not addressed in the LMRP, please submit documentation to support such use. This should include scientific data or research studies (random clinical trials or other definitive studies) published in peer-reviewed medical journals.

Please note that beginning September 1, 2004, this carrier will no longer pay for claims with 279.00 as the primary or only diagnosis on the claim. You should have received a letter under separate cover regarding this change. There is also an article on our website about this change. It can be found at [http://www.kansasmedicare.com/part\\_B/med\\_review/articles/081004IVIg.htm](http://www.kansasmedicare.com/part_B/med_review/articles/081004IVIg.htm).

For all disease conditions, submit clinical and laboratory data to support compliance with LMRP requirements. This may include but is not limited to history and physical reports, signed and dated physicians' orders, progress notes, infusion records, nursing notes, consultation reports, laboratory reports, diagnostic testing reports, surgical reports, Immunization records, or other medical records that would support medical necessity of all services billed on the claim.

#### REVIEW PROCESS

When we receive a claim for code J1563 for one of the above patients, you will receive a letter requesting patient records. **DO NOT SUBMIT ANY DOCUMENTATION/RECORDS UNTIL YOU RECEIVE A LETTER REQUESTING RECORDS FOR A SPECIFIC CLAIM.**

Records **must** be received within **45 days** of the date on the request. Failure to comply with the request will result in denial of the claim. If a claim is denied or reduced, you will have the right to appeal the decision.

To expedite your claims review, please send records requested to **PO Box 30, Topeka, KS 66601.**

Following the conclusion of the review, you will be provided with an assessment of our results and any additional education that is deemed appropriate. If you have questions regarding the reason for selection or the process of this review, please contact me at (785) 291-8406 or Priscilla Burke at (785) 291-6958.

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  
Doug Klise, Manager, Provider Education and Communication