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## **Capital City Medical Associates**

January 31, 2006

Coverage and Analysis Group Centers For Medicare and Medical Services Mail Stop C1-09-06 7500 Security Boulevard. Baltimore, MD 21244-1850

To Whom It May Concern:

"A Formal Request for Reconsideration"

I am a physician in Internal Medicine and Rheumatology who practices in Jefferson City, Missouri. I have recently learned through a claim denial that restless leg syndrome is not a diagnosis that is considered acceptable for the ordering of iron studies including iron, TIBC, ferritin levels, and iron saturation. Restless leg syndrome is a common pain syndrome that I frequently see in my practice as a rheumatologist. It is widely published that restless leg syndrome may be a manifestation of iron deficiency in the absence of anemia and generally is recommended in medical literature that an iron level with iron binding, iron saturation, and ferritin be measured if a diagnosis of restless leg syndrome is clinically present. Restless leg syndrome may be the sole manifestation of iron deficiency. Iron supplementation is found to be an effective treatment in patients who present in this manner and who are found to be relatively iron deficient. Therefore, I would request that restless leg syndrome be added to the list of acceptable ICD9-CM code for ordering iron and ferritin levels.

I have included two review articles from recent medical journals that advise measurement of iron levels and ferritin levels to assess restless leg syndrome. One of these is from the Mayo Clinic Proceedings in July 2004. The association with iron deficiency was emphasized on page 917-918 in the section under "Comments." The second article is from the New England Journal of Medicine on 5/22/03. The connection with iron deficiency is described on page 2104 on the right hand side under "Strategies and Evidence-Evaluation". These articles are included with this letter.

In addition, two studies investigating the association of iron with restless leg syndrome are included. The first is from Age and Aging in 1994, volume 23:200-203. The first author is S. T. O'Keeffe. In this study, low serum ferritin levels were found to be associated with restless leg syndrome and serum ferritin levels were inversely correlated with the severity of restless leg symptom. Also, patients treated with iron supplementation were found to have improvement in restless leg severity score.

A second article from Sleep, volume 20, #4, 1998 with the first author, Erica R. Sun. This is a blinded study examining the relationship between serum ferritin levels and the severity of restless leg syndrome symptoms. Again, restless leg syndrome was associated with low ferritin level; the lower the level, the more significant the symptoms. These patients were examined with sleep studies as well as symptom reports. The last article I have included is from the Journal of Neuroscience Research, volume 62:623-628. The first author is Christopher J. Earley and this is a review article about the pathophysiology of restless leg syndrome and the association with iron and ferritin levels.

In view of the data and widespread publication of recommendations to measure iron and ferritin levels in patients suspected of restless leg syndrome, I would appreciate a review and reconsideration of the national coverage and determination policies of serum iron studies. It is my request that restless leg syndrome be added to the allowable diagnoses for the measurement of iron, iron binding capacity, ferritin, and transferrin levels. Please notify me of your response to this request.

Respectfully,

Kaun H Bie, 10

Karen H. Rice, M.D. KHR:csr