

National Government Services, Inc
Medical Policy Unit
P. O. Box 7108
Indianapolis IN 46207-7108

10 September 2023

To whom it may concern,

This communication is part of a long-standing effort to submit an LCD reconsideration for the clinical off-label use of infliximab in the treatment of refractory microscopic colitis, which affects approximately one % of patients with microscopic colitis, a condition poorly understood and difficult to diagnose.

My first submission was sent to the Medical Policy Unit via UPS and USPS on May 16, 2022 and a receipt signed by Ron Lang, IC courier at the post office in Indianapolis on May 18, 2022.

A reply, dated August 24, 2022 from CMS addressed to my wife, Marilou Angevine, signed by S. McGee, acknowledged receipt of the letter received on May 18. In my reply of September 6, I expressed concern that my letter of May 18 accompanied by a large packet of references, was to request an LCD reconsideration for infliximab. It had no connection with an event that had occurred in November 2020.

There was no response to my letter and no reply to several FAXed inquiries. I finally contacted the e-mail address of the Medical Policy Unit and was informed that they had no record of receiving the material of May 18, or the follow-up inquiries. The Mail Room also was not able to find the UPS packet which weighed approximately 1 ½ pounds!

After several weeks of e-mail exchanges I was informed in mid-August 2023 that the submitted material had been discovered and it was returned to me electronically. It apparently had not been considered by the Policy Group.

I was advised to resubmit the request for amendment to Article A52423 Billing and Coding: infliximab and biosimilars (see our letter of May 11, 2022).

A brief review of more recent literature since the initial submission did not add significant information. Of note is the mention of infliximab treatment for refractory microscopic colitis to be found in the web sites of both the Mayo and Cleveland Clinics.

Sincerely,

James M. Angevine, MD, Honorary Staff
Saint Mary's Hospital, Madison WI 53715
Clinical adjunct asst. professor of Pathology
University of Wisconsin School of Medicine and Public Health
jmangevine@gmail.com