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September 13, 2007

Fiserv Health
Claim Appeal Unit
PO Box 8086
Wausau, WI 54402-8086

RE: Patient
ID No.
Dates of service:
Type of service: IVIg

Dear Sir or Madam:

I am writing to appeal the noncoverage decision of IVIg for your insured, Patient. My HIPAA release is enclosed.

Fiserv denied coverage on the ground that "the use of IVIG is not allowable except in cases where the diagnosis is firm." You have then quoted your policy exclusions, stating that services must be medically necessary. However, there is nothing in the quoted policy language that informs us of what support you would require in order to find that a diagnosis is "firm." Thus, you have failed to state the reasons for your denial with sufficient particularity to allow us to respond. Further, in fact, the diagnosis is entirely sufficient to support the use of IVIg. For these reasons, your noncoverage decision should be reversed.

Fiserv claims that the diagnosis of CIDP is not supported by the medical evidence. This is false.

First, it must be stated unequivocally that Fiserv's claim that Dr. Mathews did not return your physician reviewer's phone calls is patently false. Dr. Mathews called 712-251-1207 on June 18, 19 and 20, 1007 and left messages for your reviewer, Dr. Nitz.

Second, you have been provided with a nerve conduction study that showed "moderate to severe demyelinating sensorimotor polyneuropathy with secondary axonal loss." As set forth in Dr. Mathews's July 26, 2007 letter, enclosed herein, the nerve conduction study:

revealed evidence of conduction block in the right tibial and the left median motor responses as well as temporal dispersion in the left median motor response. There was significant prolongation of the distal latencies along with

marked reduction in the conduction velocities as well as significant prolongation of the F-wave responses. . . .

As Dr. Mathews states, these criteria meet the standard set by the American Academy of Neurology (copy enclosed).

In addition, we are enclosing the report of a brain MRI that shows "nonspecific white matter disease." Although this could be attributable to other problems, when taken together with the other test results, this confirms a demyelinating disorder like CIDP.

Dr. Mathews's view that the EMG establishes the diagnosis of CIDP is confirmed by other sources. As the attached article by Richard A. Lewis, M.D., et al., states, an EMG is a "critical test" to determine whether a patient has CIDP. Dr. Lewis lists four results that should be shown in an EMG to make a diagnosis of CIDP. They are:

- Multifocal conduction block or temporal dispersion of compound muscle action potential;
- Prolonged distal latencies and dispersion of the distal compound motor action potential;
- Variable conduction slowing to less than 70% of normal;
- Absent or prolonged F wave Latencies.

Dr. Lewis states that, "as the disease progresses, patients tend to develop secondary axonal degeneration."

Here, these criteria are met. There is evidence of conduction block. There is temporal dispersion in the left median motor response. There is "significant prolongation of the distal latencies." There is marked reduction in the conduction velocities. And there is significant prolongation of the F-wave responses. Since all of the criteria are met, it would seem that the diagnosis is, in a word, "firm."

The fact that Ms. Patient has diabetes strengthens, rather than undermining, this diagnosis. Dr. Mathews cites *Chronic inflammatory demyelinating polyneuropathy in diabetic patients, Muscle Nerve 2003, April 27 (4); 465-70* for the proposition that diabetics are predisposed to have CIDP. I enclose an article that reports similar results of a study that was published in the May 2002 issue of *Archives of Neurology*. There, University of Miami researchers found that "CIDP is a sufficiently common occurrence in patients with diabetes mellitus (DM) that it should be considered in the differential diagnosis of any diabetic patient with a worsening, relatively severe neuropathy, particularly where there is major motor involvement." In this study, "[t]he incidence of DM-CIDP was 11 times higher in diabetic than in nondiabetic patients." 80.8% of patients who were treated with IVIg showed significant improvement.

Finally, we know that IVIg has worked in this case. The medical literature states that, in cases of suspected CIDP, the fact that treatment works confirms the diagnosis. Dr. Latov of Weill Medical College of Cornell University states that "patients with neuropathy of otherwise unknown etiology are more likely to have CIDP . . . and warrant a trial of therapy if they have nerve conduction velocities below the lower limits of normal, prolongation of F-waves beyond the normal range, **or** presence of conduction block or temporal dispersion." Latov, N. Diagnosis of CIDP, *Neurology*. 2002 Dec. 23; 59 (12 Suppl 6): S2-6 (emphasis added). According to Dr. Latov, any one of these would be sufficient to warrant a trial of therapy.

Further, and most significantly here, Dr. Latov states that **"[a] favorable response to therapy, consisting of stabilization or improvement of the neuropathy, would confirm the diagnosis."** *Ibid.* Here, there can be no question that Ms. Patient has a favorable response to therapy and, thus, her diagnosis of CIDP is confirmed.

Dr. Latov's position is borne out by other studies. One such study showed that "[c]urrent electrodiagnostic criteria for CIDP are insensitive and may fail to diagnose the condition in a substantial number of patients." Magda, et al., Comparison of Electrodiagnostic Abnormalities and Criteria in a Cohort of Patients with Chronic Inflammatory Demyelinating Polyneuropathy, *Arch Neurol*, 2003 December; vol. 60, no. 12. Another study found that "the AAN electrophysiologic criteria are the most restrictive and fit only a subset of patients with CIDP." Sander, H., et al., Research criteria for defining patients with CIDP, *Neurology* 2003; 60: S8-S15. "Regardless of which criteria are chosen for use in clinical trials, patients who fall outside these criteria may also have CIDP and may benefit from treatment. Unfortunately, because of the lack of clarity with regard to diagnostic criteria for CIDP, many patients remain untreated. . . . Therefore, although patients may not meet the diagnostic criteria for inclusion in clinical trials of CIDP, they may still benefit from current and future treatments used in CIDP." *Ibid.*

Ms. Patient presented with progressive muscle weakness worsening at the end of the day. She had difficulty swallowing, droopiness in right eyelid, and occasional double vision. She also had trouble climbing stairs and some spells of confusion and thinking. Dr. Mathews ruled out other ailments, as set forth in the enclosed records.

Since commencing IVIg treatment, Ms. Patient has had no progressive weakness. She has no further falls and improved strength. In short, Ms. Patient's symptoms are alleviated by the IVIg, but they return roughly ten days after an infusion. There is a clear causal connection between the IVIg and the improvement of Ms. Patient's symptoms.

I. Conclusion

In sum, Fiserv's noncoverage decision is so lacking in specific reasons as to render it inadequate under state and federal law. Saying that a diagnosis is not "firm" without indicating what a "firm" diagnosis would look like makes it impossible for us to properly focus our appeal. Nor is there any policy language that requires a "firm" diagnosis, or informs us of what a "firm" diagnosis would entail.

However, here, the diagnosis is, in fact, firm. Ms. Patient meets all of the criteria for CIDP, as established by objective test results. We also know that CIDP is common in diabetics. Finally, we know that IVIg alleviates her symptoms. It is difficult for us to imagine how much firmer a diagnosis Fiserv could require.

For all of these reasons, we urge you to reverse your noncoverage decision. Thank you.

Sincerely,

Jennifer C. Jaff*

* Admitted to practice law in Connecticut, New York and the District of Columbia. Advocacy for Patients is a 501(c)(3) tax-exempt organization and does not charge patients for its services. Advocacy for Patients is funded by, among other sources, grants from foundations and companies that engage in health care-related advocacy, manufacturing, delivery and financing. A list of grantors will be furnished upon request.