FORUM OF END STAGE RENAL DISEASE NETWORKS

November 8, 2017

Noridian Healthcare Solutions, LLC JF Part B
Contractor Medical Director
Attn: Draft LCD Comments
PO Box 6781
Fargo, ND 58108-6781

To whom it may concern,

Thank you for allowing us the opportunity to comment on your recent Proposed Local Coverage Determination: Frequency of Hemodialysis (DL37502). Your proposal limits the coverage of hemodialysis to three treatments per week unless there is documentation from the prescribing physician including orders "for each and every additional sessions outside usual 13/14 treatments per month". In addition, your proposal requires documentation in the POC monthly, documenting the need for additional dialysis treatments based on the patient's acute clinical conditions. In your proposal you quote the KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015; Update Guidelines 4.1.1 where it is stated that clinicians should "consider additional hemodialysis sessions or longer hemodialysis treatment times for patients with large weight gains, high ultrafiltration rates, poorly controlled blood pressure, difficulty achieving dry weight, or poor metabolic control (such as hyperphosphatemia, metabolic acidosis, and/or hyperkalemia)." In fact, there are many additional clinical indications where patients can benefit from more frequent hemodialysis, both on an acute and a chronic basis, than the indications you reference.

In addition to acute indications for additional hemodialysis treatments beyond three times per week, there are many patients that currently benefit from more frequent hemodialysis on a chronic basis, including home hemodialysis patients. To deny payment for any additional treatments beyond three times weekly for the care provided to these patients on a chronic basis will very likely lead to these patients no longer receiving the additional treatments, which ultimately can worsen both their health and overall survival. There is substantial Medical Evidence in the peer reviewed Medical Literature demonstrating the benefit of more frequent hemodialysis beyond three times a week. These benefits include improved survival and reduced hospitalizations (1,2), reductions in left ventricular mass, (correlated with improved survival) (3,4), better control of hypertension and reductions in antihypertensive medication use (3,4,5), reductions of post-dialysis recovery time (which improves quality of life) (6,7,8), improved quality of life (4,8,9,10), and

elimination of the two-day gap between dialysis treatments over the "weekend" that patients on thrice weekly dialysis experience (and which is associated with an increased risk of sudden cardiac death and mortality observed in hemodialysis patients on Mondays and Tuesdays) (11). In addition, some larger patients may not be able to achieve adequate dialysis in a standard three times a week schedule, and may require chronic hemodialysis more frequently to achieve adequate dialysis.

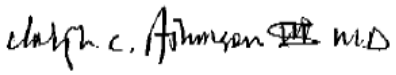
Home hemodialysis patients require more than three times a week dialysis on a chronic basis. Denying payments to dialysis facilities for dialysis treatments in excess of three times a week on a chronic basis, as you are proposing, will very likely lead to a marked decrease in the number of patients on home hemodialysis throughout your region. Decreasing the number of patients on home hemodialysis directly contradicts current CMS initiatives to increase the number of patients on home dialysis modalities. The medical evidence described above on the benefits of more frequent hemodialysis beyond three times a week especially apply to home hemodialysis patients, including improved survival and reduced hospitalizations(1,2). Your proposed changes will likely lead to increased hospitalizations and worsening survival of patients that are currently on Home hemodialysis including patients who end-up returning to in-Center thrice weekly dialysis due to facilities being unable to obtain adequate reimbursed chronically for dialysis treatments in excess of three times per week.

In addition to the Medical reasons for which our patients may benefit from more frequent hemodialysis, there are also many other psychosocial benefits. For many patients this includes being able to maintain a work schedule allowing them to remain in the workforce. Some patients have psychiatric illnesses or anxiety that preclude them from being able to stay on dialysis long enough to achieve adequate dialysis with a three times per week schedule, and therefore require more frequent hemodialysis. Other patients may suffer severe chronic back pain that limits their ability to sit in a dialysis recliner for long enough treatments to achieve adequate dialysis with standard three times a week dialysis. Your proposal would not allow any patients in these frequent real life scenarios to be able to undergo dialysis more than three times a week, since their facilities could not be reimbursed for their chronic additionally needed treatments under your proposals.

Your proposal does include criteria for appropriate acute indications and codes for facilities for payment of more than three times a week hemodialysis. While some patients do have acute indications requiring the need for more than three hemodialysis treatments a week, many more patients have chronic indications requiring the need for more frequent hemodialysis treatment. Documentation to support the chronic need for more frequent hemodialysis should include assessments and orders by physician twice a year. Documentation and orders in excess of biannual for chronic conditions requiring more frequent hemodialysis is unnecessarily burdensome.

We believe that effectively limiting reimbursement to three times a week hemodialysis as a consequence of your proposal will limit the ability of Nephrologists to practice medicine and offer appropriate treatment to many of our most vulnerable patients and places an unnecessary and undue burden on the provider and practitioner. This can ultimately lead to harm to our patients in the form of increased hospitalizations, reduced quality of life, and worsened survival. We urge you to amend your proposal to allow for Nephrologists to prescribe more frequent hemodialysis to any patients that we can justify will benefit from more frequent hemodialysis, either chronically or acutely.

Sincerely,



Ralph Atkinson III, MD

Chair, Medical Advisory Council (MAC)

National Forum of ESRD Networks

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