National Kidney Foundation®

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November 3, 2017

Laurence Wilson
Director, Chronic Care Policy Group
Centers for Medicare & Medicaid Services
7500 Security Blvd
Mail stop: C5-02-23
Baltimore, MD 21244
Via email: laurence.wilson@cms.hhs.gov

Re: Local Coverage Determinations for Frequency of Hemodialysis

Dear Mr. Wilson,

The National Kidney Foundation is very concerned about the coordinated draft Local Coverage Determinations (LCD): Frequency of Hemodialysis issued for comment by the Medicare Administrative Contractors and requests that CMS not allow the policies to be implemented as written. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

The KDOQI guidelines are intended to help guide practitioner decision making and promote improvements in care delivery by providing recommendations based on a rigorous and thorough review of the available evidence.

> *This Clinical Practice Guideline document is based upon the best information available as of June 2015. It is designed to provide information and assist decision making. It is not intended to define a standard of care, and should not be construed as one, nor should it be interpreted as prescribing an exclusive course of management. Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of*

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practice.[1]

The guidelines are not intended to be used to drive policy that significantly limits the shared decision making between practitioners and patients. In fact, the 2015 updated Hemodialysis Adequacy Guideline, cited as the basis for this LCD, promote shared-decision making more than ever before as many of the recommendations call for considering different durations of dialysis, including more frequent dialysis, and informing patients of the risks and benefits of the different types of dialysis available.

Engaging patients in their care and developing care plans is a key goal that that CMS has championed and that this LCD would undermine. Care planning should begin with patients' individual life goals and values in mind and treatment options available to best help patients meet those goals. This should not simply be dismissed as unnecessary care, in fact it may be vital for patients to achieve optimal outcomes. However, we also recognize that reasonable limitations are needed to ensure appropriate payments are made, but this draft LCD goes too far in implementing restrictions making it less likely that patients will truly have the opportunity to participate in shared decision making when it comes to frequency of dialysis treatments. For these reasons we highlight the overburdensome barriers that this policy creates in achieving individualized, patient-centered care and suggest that CMS work with patients and health care practitioners to develop a more reasonable policy.

KDOQI Clinical Practice Guideline for Hemodialysis Adequacy

First, the KDOQI guidelines are misquoted in this LCD. This LCD states, "Efforts to increase the dose of dialysis administration above 3 times per week have not improved survival, indicating that something else needs to be addressed."

The word "above" has been added to the actual quote from the KDOQI Clinical Practice Guideline for Hemodialysis Adequacy 2015 Update, which is found in the Executive summary and actually reads, "Efforts to increase the dose of dialysis administered 3 times weekly have not improved survival, indicating that something else needs to be addressed."[2]

The KDOQI statement is referring to the dose of dialysis delivered during a traditional dialysis schedule of 3 times per week. It is not referring to the number of treatments delivered as this LCD implies. Furthermore, the KDOQI Hemodialysis Adequacy workgroup notes a paucity of research conducted on outcomes related to more frequent dialysis, particularly for home

[1] KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update (Section I: Use of the Clinical Practice Guidelines) Am J Kidney Dis. 2015;66(5):884-930.
[2] ibid

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hemodialysis. This is not to say that there is not clinical benefit of additional dialysis sessions, but instead highlights a lack of significantly powered randomized control trial studies. The guideline recommends consideration of additional treatments for specific acute and chronic conditions based on observational data and practitioner judgement in conjunction with patients' individual goals.

Acute and Chronic Conditions

There are far more reasons that more frequent dialysis may be necessary than the current list of 7 acute conditions in this LCD.

> *Clinicians should be alert to subtle symptoms and signs of kidney failure that may indicate a need for more dialysis or a different dialysis modality.*

Patients may benefit from additional dialysis for both acute and **chronic conditions** as is highlighted in the KDOQI guidelines. Furthermore, while a patient may receive more frequent dialysis because of an acute condition continuing extra dialysis treatments to prevent a reoccurrence of the acute condition should also be viewed as reasonable and necessary and not require weekly review and justification. We are concerned that this LCD will lead to changes in practice and patients who are stable receiving more than three times per week dialysis to become unstable – potentially resulting in an increase in hospitalization rates and thus increasing Medicare spending and putting patients' lives at risk. As a result, we recommend that the LCD be modified to allow for additional dialysis treatments to be reimbursed for acute and chronic conditions and the ongoing receipt of extra dialysis to avoid reoccurrence of acute conditions. The National Kidney Foundation and the KDOQI steering committee would be happy to work with you to help define reasonable parameters around conditions where reimbursement for extra treatments is warranted.

Plan of Care

The LCD states that claims will be denied if more than three treatments per week are in the Plan of Care (POC). We believe this is contradictory to CMS policy as the POC should accurately reflect the care delivered to patients including documenting additional treatments prescribed for acute conditions or chronic conditions. Therefore, if additional treatments are noted in the POC they should not be automatically denied when appropriate medical justification for those conditions has been provided to the MAC. Additionally, the KDOQI Hemodialysis Adequacy guideline recommends:

> *…that all HD prescriptions specify the duration of the individual dialysis session, the number of treatments per week, blood and dialysate flow rates, the location for HD treatment, and the level of assistance. A proposed nomenclature is summarized in Table 6.*

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Table 6. Descriptive Nomenclature for Various HD Prescriptions

Proposed Name	Time of Day	Duration (h/session)	Frequency (sessions/wk)
Conventional HD	Daytime	3-5	3-4
Frequent HD[a]			
Short	Daytime	<3	5-7
Standard	Daytime	3-5	5-7
Long	Nighttime	>5	5-7
Long HD[b]			
Long thrice weekly	Nighttime or daytime	>5	3
Long every other night	Nighttime	>5	3.5
Long frequent	Nighttime	>5	5-7
Treatment Location			
In-center	Outpatient treatment in a hospital or dialysis facility		
Home	HD treatment in the patient's home		
Level of Assistance			
Fully assisted	HD treatment is performed entirely by a health care provider		
Partially assisted	The patient performs some (but not all) aspects of the HD treatment him or herself (eg, cannulation of fistula, connection/disconnection, setting machine, monitoring blood pressures), while other aspects are performed by a health care provider		
Self-care (with or without an unpaid caregiver)	The patient performs all aspects of the HD treatment him or herself, with no assistance from a health care provider; this may be done with or without the assistance of an unpaid caregiver		
Blood flow rate			
Standard	≥300 mL/min		
Low flow	<300 mL/min		
Dialysate flow rate			
Standard	≥500 mL/min		
Low flow	<500 mL/min		

Abbreviation: HD, hemodialysis.
[a]Short and standard daily HD are usually delivered in-center, while long-nocturnal HD is usually delivered at home.
[b]Long–thrice weekly HD may be delivered in-center or at home, while long every other night and frequent HD are usually delivered at home.

The National Kidney Foundation is submitting comments to each MAC in response to the draft LCD. However, we urge CMS to not allow the MACs to move forward with this policy as written. The National Kidney Foundation and our KDOQI steering committee is happy to have further conversations with you and the MACs to help shape a more reasonable policy that achieves both the goals of appropriate and necessary reimbursement and optimal patient outcomes.

Sincerely,

Kevin Longino
Kevin Longino
CEO
Kidney Transplant Recipient

Michael Choi
Michael Choi, MD
President

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