KIDNEY CARE
PARTNERS

March 30, 2018

Antonietta L. Sculimbrene, MD, MHA
Palmetto GBA (11501 - A and B and HHH MAC, J - M)
Attn: Medical Affairs, AG-275
PO Box 100238
Columbia, SC, 29202-3238

Dear Dr. Sculimbrene:

On behalf of Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the recently published Local Coverage Determination (LCD) Frequency of Hemodialysis (DL34575). KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD).

As we have noted in previous letters to CMS, KCP continues to believe that when there is an individualized plan of care for a patient and medical justification with appropriate documentation, it is necessary and consistent with national policy to reimburse a dialysis facility for more than three treatments a week. We also agree that it is inappropriate for facilities to seek such an additional payment in a blanket manner for all patients receiving hemodialysis whether it be in-center, at home, or using a common therapy room for home dialysis.

While we are pleased that the LCD recognizes the numerous and complex comorbidities that may require a patient to need more than three treatments per week, we are concerned that the LCD limits these conditions to "acute" clinical conditions, which is inconsistent with the clinical literature. As conditions such as "Chronic systolic [or diastolic] (congestive) heart failure" indicate in their title, as well as others without the modifier "chronic" suggest, not all of these conditions are acute in nature. Moreover, evidence-based medicine does not support a practice of treating a patient who is experiencing an acute episode and then stopping an effective treatment until it leads to another acute episode. This would be analogous to treating a diabetic patient with insulin and then stopping the insulin when the blood sugar returned toward normal.

In addition, we are concerned that the LCD indicates that "[Plan of Care] POC number of sessions above 3 times per week (for example the POC states 5 times per week)-those above 3 times per week are not medically justified for additional payment." This sentence is inconsistent with the current CMS policies, as described

below. We also ask that the MACs work with the community to identify other potential codes that are also clinically appropriate to include on the list.

Further, we are concerned that the LCD references "planned inadequate" treatment, which is inconsistent with medical ethics and physician practice. Simply put, physicians do not write prescriptions in which they plan to provide treatment that does not meet the patient's needs.

Thus, we ask before the LCD is finalized that the MAC:

(1) clarify the following statement to include the language in red:

> Modifier KX will be appended to CPT 90999 to signify an additional session was needed for an acute **or chronic** clinical condition **or to prevent the recurrence of acute symptoms**. It will be appended on each line for each additional session within the claim for each month billed.

(2) clarify that a POC that includes more than three treatments a week does not result in an automatic denial of a claim if there is other documentation of medical justification. The POC would not take the place of other medical justification, as outlined in the LCD, but an accurate POC that listed more than three treatments per week as medically necessary would not trigger an automatic denial of a claim; and

(3) remove the reference to "planned inadequate" treatments.

These changes would be consistent with the intent of CMS as expressed in the CY 2017 ESRD PPS Final Rule and ensure that patients will continue to be able to access additional treatments when medically necessary. We again reiterate that medical justification must be determined by both the physician prescribing it and the MAC evaluating its appropriateness at the individual patient level. KCP looks forward to working with the MAC to ensure that the final LCD provides the appropriate balance to prevent inappropriate billing while protecting access to medically necessary treatments.

## I. The LCD Language Must Conform with the Current CMS Policies Regarding Medical Justification for More Than Three Treatments per Week.

The current ESRD PPS reimburses dialysis facilities on a per treatment basis for up to three treatments per week, unless there is documented medical justification for additional treatment(s). The Agency summarized this policy most recently in the CY 2017 ESRD PPS Final Rule.

> [W]e have always recognized that some patient conditions benefit from more than 3 HD sessions per week and as such, we developed a policy for payment of medically necessary dialysis treatments beyond the 3-treatments-per-week payment limit. Under this policy, the MACs determine whether additional treatments furnished during a month are medically necessary and when the MACs determine that the additional treatments are medically justified, we pay the full base rate for the additional treatments. While Medicare does not define specific patient conditions that meet the requirements of medical necessity, the MACs consider appropriate patient conditions that would result in a patient's medical need for additional dialysis treatments (for example, excess fluid). When such patient conditions are indicated on the claim, we instruct MACs to consider medical justification and the appropriateness of payment for the additional sessions.[1]

Nothing in this reiteration of the policy limits medical justification to acute conditions or rejects claims with more than three treatments per week if the POC indicates more than three treatments per week are medically necessary.

> The Medicare ESRD Benefits Policy Manual reiterates this policy:
>
> If the ESRD facility bills for any treatments in excess of this frequency, medical justification is required to be furnished to the A/B MAC (A) and **must be based upon an individual patient's need**.[2]

As the LCD clearly indicates, the role of a MAC is not to "replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for additional hemodialysis sessions." As currently drafted the LCD appears to change the unit of payment. Specifically, the draft LCD would change existing policy in two critical ways.

First it would seem to eliminate the medical justification option for <u>chronic</u> diseases and symptoms. The draft LCD states:

> Those treatment sessions established in the POC are paid by Medicare as 3 X per week. Establishment of more sessions in the POC, such as 4 - 6 sessions per week, are still reimbursed at the 3 X per week amount.
>
> However, on occasion, acute conditions may require additional sessions during the month outside the POC. These may be considered for additional payment. This LCD provides a list of diagnoses felt to be

[1]81 Fed. Reg. 77843.
[2]ESRD BPM § 50.A.1 (Emphasis added).

> consistent with such clinical conditions that could establish medical justification for payment. Use of these diagnoses should be verified in the medical records to support any payment made.

The reference to "acute conditions" indicates that a patient with chronic symptoms may never require more than three treatments per week on an ongoing basis. Again, the language in the preamble to the CY 2017 ESRD PPS and other CMS guidance do not limit the potential for payment for more than three treatments per week to only acute conditions. A change of this nature would require CMS to initiate notice-and-comment rulemaking under the Administrative Procedures Act.[3] Thus, in using the language set forth in the LCD and allowing the medical justification to apply only to acute conditions, the LCD exceeds the authority of the MAC to implement existing policies.

The draft LCD also appears to indicate through the following language that if a POC includes more than three treatments per week, the claim will be denied without taking into account other documentation.

> The following are considered not reasonable and necessary and therefore will be denied as not medically justified for payments.
> 1. POC number of sessions above 3 times per week (for example the POC states 5 times per week)-those above 3 times per week are not medically justified for additional payment

This language does not correspond with current law or policies. As noted in the draft LCD, CMS regulations require an interdisciplinary team to develop a POC for each patient that is individualized to meet the patient's needs. This POC must be reviewed regularly to ensure, among other things, that the patient is receiving adequate dialysis.[4] The regulatory provision regulating the POC further states that:

> The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.[5]

If the necessary care and services to manage the patient's volume status requires more than three treatments per week for a month or potentially longer, the current law requires the POC to indicate that fact.

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[3] *See* 5 U.S.C. § 500 *et seq.*
[4] 42 C.F.R. § 494.80(d).
[5] *Id.* § 494.90(a)(1).

While we understand that the draft LCD is not stating that an interdisciplinary team should not include the number of medically necessary treatments, it appears to automatically deny any claim related to a POC that indicates more than three treatments per week are necessary. This position contradicts the regulatory provision that the POC should contain the accurate dosing of dialysis needed for each individual patient.

This language also seems inconsistent with the remainder of the draft LCD that states:

> POC should be available upon request and should be the annual update or monthly depending on the guidelines above and the stability of the patients. Should a patient require consistent additional dialysis sessions, the POC should show changes in the dialysis prescription or other parameters to address the repeated need for additional sessions. Lack of this documentation will lead to denials.

We agree that a POC alone may not be the only documentation required to establish medical necessity. However, a POC that is reviewed at least monthly and that includes more than three treatments per week as the dose of dialysis also should not automatically trigger a denial, as the language outlining the policy earlier in the LCD seems to state.

Second, the draft LCD would seem to create a new unit of payment for extra hemodialysis sessions ordered under a POC, even when they are medically necessary. The statute provides the Secretary with the authority to establish the unit of payment, which requires the Secretary to initiate notice-and-comment rulemaking to do so.[6] CMS established in the initial rulemaking for the ESRD PPS that the unit of payment would be per treatment.[7] The approach taken in the LCD shifts the payment system from a per treatment unit of payment, which CMS finalized for the ESRD PPS in the CY 2011 ESRD PPS Final Rule and has maintained since its implementation, to a per week unit of payment. Under the draft LCD with the current limitations on chronic conditions and the POC wording, the MAC is focused on the week rather than each individual treatment. This approach is beyond the scope of an LCD. The unit of payment can only be modified through notice-and-comment rulemaking consistent with the Administrative Procedures Act.

In sum, the LCD goes too far in trying to restrict the medical justification. As noted in the ESRD PBM and other CMS rules and guidance, the decision about medical justification must be made on an individual patient basis. The LCD seeks to create a new blanket set of restrictions that is contrary to this current policy and which is beyond the scope of the LCD authority.

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[6] SSA § 1881(b)(14)(C).
[7] *See* 42 C.F.R. § 413.215.

## II. The LCD Language Should Recognize that Patients with Certain Chronic Symptoms/Medical Conditions May Require More Than Three Treatments Per Week.

As CMS wrote in the preamble to the CY 2017 ESRD PPS Final Rule, the Agency has "always recognized that some patient conditions benefit from more than 3 HD sessions per week."[8] Additional treatments are reimbursed "only if there is documented medical justification."[9] The MAC is tasked with determining if "the treatments are medically justified based on a patient condition."[10] This language, as described in Section I, does not limit the patient conditions to "acute" conditions only. The current policy provides medical discretion that allows physicians to account for treating acute and chronic diseases, preventing subsequent acute episodes (*i.e.,* chronic symptoms from recurring), and addressing an individual patient's ability to tolerate the treatment. This decision must be made on an individual case-by-case basis, taking into account the specific needs of an individual patient.

KCP agrees that current policy does not permit a blanket request that all patients in a given setting, receiving more than three treatments a week should be deemed to have medical justification. However, the LCD seems to swing the pendulum in the opposite direction and would create a blanket policy that eliminates the very individualized physician medical judgment that is at the heart of CMS's current policy.

Clinical literature, as well as recognized standards of care and international guidelines, reflect that some patients with chronic diseases that are considered on an individualized basis based on their physician's medical judgment may require more than three treatments per week on an ongoing basis. An American Journal of Kidney Diseases Supplement on Intensive Hemodialysis published in November 2016[11] catalogs the peer-reviewed literature supporting the prescription of additional hemodialysis sessions for the treatment of a number of different chronic patient conditions. Studies report that patients prescribed to receive more than three treatments per week have been able to achieve reductions in, among other things, left ventricular hypertrophy, hypertension (using fewer medications), hyperphosphatemia, depression, long post-treatment recovery times, sleep disturbances, and restless leg syndrome.

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[8] 81 Fed. Reg. 77843.
[9] *Id.* at 77842.
[10] *Id.*
[11] http://www.ajkd.org/issue/S0272-6386(16)X0004-2

The KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update Guidelines 4.1.1 recommends physicians, on an individual, patient-by-patient basis, to "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)." The workgroup that drafted the NKF-KDOQI guidelines noted that "considerations for initiating high-frequency hemodialysis include: sleep apnea, pregnancy, metabolic derangements, uncontrolled hypertension and left ventricle hypertrophy and/or congestive heart failure."[12] While an acute episode may be the initial trigger for a physician's prescribing more than three treatments per week for a particular patient, the success of a higher treatment frequency in preventing additional chronic symptoms from recurring may justify it on an ongoing basis.

It is unclear from the draft LCD why the decision was made to limit medical justification to acute conditions only. Clinical literature suggests strongly that a one time additional treatment is insufficient to address the chronic symptoms that warranted the additional treatment in the first place. We have speculated that the intent may be to require a review of the patient on a regular basis to protect against a blanket assumption that the patient will require more than three dialysis treatments per week on an indefinite basis. While we agree that such a practice should be avoided, the draft LCD is too broad and seems to eliminate the option of paying for more than three treatments per week when a chronic condition/symptom is the underlying medical justification.

As the draft LCD notes, interdisciplinary teams must review the POC for unstable patients on a regular basis. This policy acts as a safeguard by requiring physicians to reassess the appropriateness of the dose of dialysis among other things. The documentation requirements that extend to documents outside the POC also serve to protect against abuse of the system. If these documents do not support the POC, then the MAC would be justified in not granting the additional payment.

It may also be that the MAC seeks to require physicians to reassess the dose of dialysis on a weekly basis and write new prescriptions each week for additional treatments. This requirement is not only unduly burdensome, but also is inconsistent with the Physician Fee Schedule's Monthly Capitated Payment system, which indicates that physicians may see a patient four times a month, but recognizes that it is not always necessary to do so. It also would mean that beneficiaries would be required to pay additional co-insurance obligations if their physician were required to see them each week. There is no evidence to suggest that the current standards are inadequate in terms of the quality of care being provided and the accuracy of the prescriptions being written.

[12] https://www.kidney.org/news/nkf-releases-update-clinical-practice-guideline-hemodialysis

The literature, as well as the recommendations from clinical experts within KCP, also supports shifting away from a targeted Kt/V and toward improved fluid management. In our work to identify areas of treatment that could benefit from new quality measures, the clear consensus within the Kidney Care Quality Alliance (KCQA) was to develop an ultrafiltration measure. The National Quality Forum has endorsed the KCQA ultrafiltration measure and CMS has now adopted a version for the ESRD Quality Incentive Program.

## III. The LCD Language Should Promote the Doctor-Patient Relationship, as well as Accuracy and Transparency in the POC.

The draft LCD also appears to establish a new blanket denial policy for any claim that is linked to a POC that includes a dose of dialysis of more than three treatments per week. KCP is deeply troubled by this new policy, which, as described in Section I, is inconsistent with current law. It also inappropriately interferes with the physician-patient relationship and the proper management of patients with chronic illnesses.

Under current law, physicians are required to engage with their patients on a regular, albeit not necessarily weekly, basis. They discuss the right modality for patients, as well as the appropriate management of the kidney disease and other comorbidities, many of which are chronic. The POC is one place where the appropriate dose of dialysis should be documented. If a number greater than three is included, it should be part of the evidence that a patient requires more than three treatments a week, not a trigger for an automatic denial of a claim seeking payment for the additional treatment.

We agree that additional documentation beyond the POC should be made available to a MAC reviewing a claim for medical justification of more than three treatments per week. However, the draft LCD could result in physicians not updating the POC to accurately reflect the needed treatments. Thus, any other health care provider working with the patient and the POC would not have an accurate or transparent view of the actual medical needs of that patient.

Additionally, while we agree that the codes listed in the LCD include some of the conditions that are appropriate for additional dialysis sessions, there are other conditions, most notably chronic conditions, that are not included. KCP and our members would welcome the opportunity to work with you and the other MACs to review clinical scenarios that are appropriate for more frequent dialysis sessions. In doing so, we could work together to avoid additional administrative burden that would only serve to create barriers to optimal patient care and adversely impact the ability of physicians to prescribe medically appropriate treatments.

Further, the language in the draft LCD that references “planned inadequate” treatments is problematic because it implies that physicians are not meeting their

ethical obligations to patients. We do not agree that a physician who prescribes a therapy for ESRD would write a prescription that was designed to deliver an inadequate weekly Standardized Kt/V. Any decision to regularly perform more than three treatments per week is a direct result of shared decision-making resulting in a chronic plan of care that meets the patient's documented medical needs. As with the POC, the physician uses his/her best judgment to prescribe the course of dialysis treatment. What constitutes the dialysis prescription is the practice of medicine and should remain in the hands of the prescribing physician.

## IV. The LCD Process Should Be More Transparent

KCP appreciates the opportunity to provide comments on the Proposed LCD. Yet, we are concerned that stakeholders were not included in a more comprehensive manner as the MACs developed the current language. If representatives from the various stakeholder groups within the kidney care community were included in a meaningful way, we believe that the Proposed LCD would have not only addressed the concerns that have resulted in its publication, but also recognized the needs of some patients with other chronic clinical conditions/symptoms to receive more than three treatments per week, rather than only on an acute basis. It is also likely that the concerns related to POCs that include more than three treatments per week would have been addressed in a more appropriate manner that would protect the doctor-patient relationship and incentivize accuracy and transparency. We are particularly concerned that there have been conference calls in which only a few selected individuals were asked to participate, rather than allowing all interested stakeholders to be part of the process.

As we have noted elsewhere, we agree that MACs must ensure the fiscal integrity of the program and that part of that job is limiting payment for treatments beyond three per week to those that are medically necessary. Thus, we ask that as you review these comments, as well as those from other stakeholders, you engage in a dialogue with the community as well so that the final LCD presents a workable solution that aligns federal payment policy with appropriate clinical care.

## V. Conclusion

We agree that medical justification for additional treatments under current federal policy is limited to instances when a physician on an individual patient-by-patient basis determines that it is medically justified and documentation beyond the POC supports the additional treatment(s). However, we believe that the LCD should be refined to avoid broad language that would likely result in these patients no longer being able to access these treatments. Thus, we ask that before the LCD is finalized, the text be clarified as follows:

> Modifier KX will be appended to CPT 90999 to signify an additional session was needed for an acute **or chronic** clinical condition **or to prevent the recurrence of an acute symptoms**. It will be appended on each line for each additional session within the claim for each month billed.

We also ask that you clarify that a POC that includes more than three treatments a week does not result in an automatic denial of a claim if there is other documentation of medical justification. Finally, we ask that you remove the reference to "planned inadequate treatment."

Again, KCP appreciates the opportunity to review the draft LCD. We would welcome the chance to work with you to address any concerns that our recommendations may not address. We, too, are committed to being good stewards of federal dollars, while making sure that patients have access to the medically necessary care that they need. Please do not hesitate to contact our counsel, Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions or would like to set up a meeting to discuss our recommendations.

Sincerely,

Allen Nissenson
Chairman
Kidney Care Partners

cc: Laurence Wilson, Director, Chornic Care Policy
Tamara Syrek Jensen, Director, Coverage and Analysis Group
Marie Casey, Coverage and Analysis Group
Karen Reinhardt, Coverage and Analysis Group

**Appendix A: KCP Members**

AbbVie
Akebia Therapeutics, Inc
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners Inc.
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medicare Care Renal Therapies Group
Greenfield Health Systems
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Nephrology Nursing Certification Commission
NxStage Medical, Inc.
Renal Physicians Association
Renal Support Network
Rogosin Institute
Sanofi
Satellite Health Care
U.S. Renal Care