ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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Dear Dr. Noel:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the recently published Local Coverage Determination (LCD) Frequency of Hemodialysis. ASN represents nearly 17,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of patients. ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney diseases. Foremost among the society's concerns are the preservation of equitable patient access to optimal quality care for kidney diseases and kidney failure (including transplantation) and the integrity of the patient-physician relationship.

ASN is deeply troubled by Wisconsin Physicians Service's (WPS) proposed new policy, which, as described below, the society believes interferes with the patient-physician relationship, creates unnecessary administrative burden, and is inconsistent with current law.

ASN respectfully requests that WPS revise the LCD to:

- Protect the physician-patient relationship
- Encourage medically-justified individualized care
- Recognize both acute and chronic conditions and care needs
- Avoid undue administrative burden on physicians
- Conform to current CMS policy

Protecting the physician-patient relationship

ASN firmly believes that the physician-patient relationship is a cornerstone of ensuring quality medical care for patients. Patients with kidney failure have a variety of often serious comorbidities that impact requirements for dialysis therapy. As such, their physicians must approach and design their care with meticulous attention to individual healthcare needs to optimize outcomes, reduce hospitalizations, and control symptoms. These complex patient conditions sometimes demand prescription of dialysis more than three times a week.

As currently written, the draft LCD interferes with the patient-physician relationship in concerning ways. By proposing to establish a blanket denial policy for any claim that is linked to a Plan of Care (POC) that includes a dose of dialysis of more than three treatments per week, and by limiting the conditions that qualify as "medical justification"

for more than three treatments per week to only a few acute conditions while excluding chronic conditions, WPS inappropriately infringes upon the physician-patient relationship, establishing substantial barriers to our ability to prescribe what we think is the optimal treatment for individual patients and our ability to prevent future, more severe complications for these already vulnerable patients.

Encouraging medically-justified individualized care

Care that is individualized must also be medically appropriate. ASN agrees that the acute conditions listed in the draft LCD all constitute valid reasons a patient experiencing them may warrant dialysis more than three times per week. However, limiting dialysis more than three times per week to only patients with the acute conditions listed in the draft LCD is shortsighted, and simplifies what is a very complicated procedure done for very complicated and unique medical problems.

Under current law, physicians are required to engage with their dialysis patients on a regular basis, typically at least monthly. In care plans, which are performed annually for most dialysis patients and more frequently for sicker patients, physicians, patients, and other members of the care team discuss the right modality for patients, as well as the appropriate management of kidney disease and other comorbidities, many of which are chronic.

The POC is one place where the clinically indicated dose of dialysis should be documented. If more than three treatments per week are included in the POC, it should be accompanied by evidence that a patient requires more than three treatments a week; this indication however should not serve as a trigger for an automatic denial of a claim seeking payment for treatments in excess of three per week. ASN agrees 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, as discussed in more detail elsewhere, ASN believes that documentation of a chronic need for additional treatments in the POC should also be sufficient.

Clinical literature, as well as best practices and international guidelines, recognize that some patients with kidney failure may require more than three treatments per week on an ongoing basis in order to achieve and maintain optimal health; this treatment requirement is identified by the medical judgment of the treating physician. A peer-reviewed *American Journal of Kidney Diseases* Supplement on Intensive Hemodialysis published in November 2016[1] catalogs the literature supporting the prescription of additional hemodialysis sessions for the treatment of a number of different chronic conditions. Studies report that patients prescribed more than three treatments per week have been able to achieve improvements in, among other things, left ventricular hypertrophy, hypertension (using fewer medications), hyperphosphatemia, depression, post-treatment recovery time, sleep disturbances, and restless legs syndrome. The society raises this not to suggest that *all* patients with these conditions always need more frequent dialysis, but rather to underscore the imperative for physicians to individualize patient care based on a number of factors, including that patient's other chronic conditions.

[1] http://www.ajkd.org/issue/S0272-6386(16)X0004-2

Further supporting the concept that chronic, more frequent hemodialysis may be needed by individual patients, the KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update (recommendation 4.1.1) instructs 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)." Substantial evidence, including that discussed above, suggests clinical benefits associated with more frequent hemodialysis.

Two notable articles include a 2011 New England Journal of Medicine publication demonstrating that there was increased risk of mortality for hemodialysis patients as the interval between dialysis grew from 48 to 72 hours; this likely reflects volume accumulation and/or solute accumulation over the extended time period without dialysis. More importantly, the Frequent Hemodialysis Network Daily Trial, published in 2010 in the New England Journal of Medicine demonstrated an improvement in the composite outcome of all-cause death and change in left ventricle mass associated with more frequent hemodialysis, suggesting that there are important health benefits to this treatment approach.[2] An LCD that automatically denies a POC prescribing more than three dialysis treatments a week interferes with a physician's responsibility to appropriately prescribe care, ignores existing clinical data and pathophysiology, and undermines best clinical practices for some patients. While the LCD does recognize some of the conditions that may cause a patient to require more than three treatments per week, it appears to only do so on an acute basis. ASN urges WPS to revise the proposal to also account for dialysis more than three times per week on a chronic/maintenance basis as a part of a plan of care.

ASN noted with concern that the proposed LCD suggests that physicians are deliberately prescribing planned 'inadequate' dialysis treatments. Dialysis patients who regularly receive more than three hemodialysis treatments per week are among the most health literate and engaged of dialysis patients; 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 individualized needs. As discussed, more frequent hemodialysis is generally performed to maintain optimal volume status. Current practice is directed at achieving safe and sufficient volume clearance as well as a weekly standardized solute clearance rather than simply individual session small solute clearance. The suggestion that these are 'planned inadequate' treatments reflects a poor understanding of hemodialysis, particularly as relates to factors affecting volume management like vascular refill and hemodynamics, as well as a misinterpretation of the KDOQI guidelines. ASN's nearly 17,000 members would be pleased to discuss the interplay between volume status and small molecule kinetics with WPS to reinforce that adequate dialysis requires both solute and volume control, and that, while these are not entirely independent of each other, they are approached differently.

Recognizing both acute and chronic symptoms as indications for more frequent hemodialysis

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[2] FHN Trial Group. In-center hemodialysis six times per week versus three times per week. N Engl J Med. 2010;363(24):2287-300.

ASN is concerned that the LCD limits the conditions for more than three dialysis treatments per week to "acute" clinical conditions, a limitation that is not consistent with the clinical literature. As reflected in the names of conditions such as "Chronic systolic [or diastolic] (congestive) heart failure", as well as others without the modifier "chronic" many conditions where more frequent hemodialysis is beneficial are chronic rather than acute in nature. Moreover, it is contrary to best practices to treat patients when they have an acute episode, then stop the treatment approach that addressed the issue; such a shortsighted strategy will, predictably, lead to another acute episode for many patients, and risk re-hospitalization and resource use requirements that far exceeds that of an additional weekly dialysis session.

If the proposed LCD is finalized as drafted, the society believes it would result in increased hospitalizations and lengths of stays. As the second case study illustrates, if nephrologists are not able to schedule additional outpatient sessions then some patients will inevitably end up in the hospital for those additional sessions, and as a consequence of not receiving them in their normal dialysis care environment. Permitting outpatient treatments for most patients who require them will result in lower inpatient costs (the latter of which are of course more expensive) than a policy that restricts more than three sessions per week for all but a limited patient population.

Current CMS policy allows for medical discretion that permits physicians to account for treating both acute and chronic conditions, preventing subsequent acute episodes (*i.e.,* clinical deterioration related to chronic conditions from recurring). This medical judgment incorporates the physician's assessment of an individual patient's ability to tolerate hemodialysis sessions, recognizing that many patients have heart disease or autonomic dysfunction that makes more frequent hemodialysis the best modality for that individual. This decision must be made on an individual case-by-case basis, taking into account the specific needs of an individual patient and shared decision-making with that patient.

In the preamble to the CY 2017 ESRD PPS Final Rule, CMS wrote that the Agency has "always recognized that some patient conditions benefit from more than 3 HD sessions per week."[3] Additional treatments are reimbursed "only if there is documented medical justification."[4] It is the responsibility of the MAC to determine if "the treatments are medically justified based on a patient condition."[5] Notably, this language does not limit the patient conditions that qualify for dialysis more than three times per week to only "acute" conditions. Additionally, it does not revisit the conditions for coverage and require more frequent care planning for those who are stably treated with more frequent hemodialysis. By restricting the draft proposal to acute conditions, WPS inappropriately interferes with the physician's duty to provide appropriate, patient-centered care. ASN offers vignettes from practicing nephrologists illustrating several cases in which this LCD could prevent the appropriate care that is currently offered from being covered.

- ***Case Study # 1***

Patient: A 30-year-old man with primary hyperoxaluria complicated by kidney failure.

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[3] 81 Fed. Reg. 77843.
[4] *Id.* at 77842.
[5] *Id.*

Prescribed Treatment: To control his hyperoxalosis and prevent other end-organ damage, he required hemodialysis six times per week; he elected to perform this in-center.

Results: The patient was otherwise well, and he worked part-time as allowed by his dialysis schedule. He had no hospitalizations while receiving dialysis and ultimately received a successful liver-kidney transplant. This is a good example of someone with a chronic condition (hyperoxaluria) that is controlled by more frequent dialysis, with the plan of care (POC) calling for frequent dialysis. He was stable, and, therefore, more frequent care-planning would have not had value justifying its resource cost. He was seen most weeks by his physician, but not every week – and this was appropriate for his clinical state.

- ***Case Study #2***

Patient: An 80-year-old man treated with hemodialysis for more than 10 years with three hospitalizations in a six-week period due to fluid overload in the setting of heart failure with preserved ejection fraction. Despite aggressive education, he continued to gain substantial weight between sessions; this weight gain was in part due to chronic odynophagia, making fluids easier for him to swallow than solids. Each hospitalization came towards the end of the long interdialytic interval (Mondays, given that he was typically treated on a Tuesday/Thursday/Saturday schedule). His spKt/V at dialysis was ~1.8, consistent with adequate dialysis. He does not tolerate more than 2.5 to 3 kg of ultrafiltration per session, developing hypotension.

Prescribed Treatment: To control volume overload, he agreed to a fourth weekly dialysis treatment on Mondays.

Results: The fourth regularly-scheduled session was documented in his POC. Following this prescription change, he had no further emergency department visits of hospitalizations for fluid overload. Given prior trends, if more than thrice-weekly dialysis was not provided routinely, he would be virtually certain to experience re-hospitalization; accordingly, integrating this into his POC (as opposed to writing weekly revisions to his dialysis prescription) was the most prudent course of action.

- ***Case Study Discussion***

In the above case studies, the provision of more than thrice-weekly dialysis was critical to the patient's health in the long-term (chronic need), not just in the short-term (acute need). Also, in both cases, the proposed new requirement that the patient's nephrologist file an acute order with medical justification for the additional dialysis session every week—as would be necessary under the proposed LCD—would make provision of optimal care more challenging for nephrologists, creating administrative burden with no clinical utility. It would also create uncertainty and increased risks for the patient, and may increase tensions among physicians, patients, and dialysis facilities, with facilities objecting to medically indicated and prescribed additional treatments due to inappropriately strict criteria and resulting uncertainty of payment as delineated in this proposed LCD.

Avoiding undue physician burden

CMS Administrator Seema Verma recently said that the agency must make it easier for providers to "focus on doing the work that patients and families need them to do without causing them to be subject to excessive regulatory and administrative burden." [6] Simultaneously, there is an increased—and appropriate—emphasis within the agency on providing patient-centered care, a goal that cannot be met if health professionals spend their time saddled with excess paperwork instead of interfacing with their patients.

ASN is dismayed that by prohibiting nephrologists from developing a POC prescribing (and documenting the medical justification for) more than thrice-weekly dialysis, this proposed LCD runs directly contrary to the agency's stated goal. By eliminating the existing option to document the need and medical justification for more than thrice-weekly dialysis in the POC, this proposal inherently *increases* the documentation burden on nephrologists to achieve the same care goals that are currently achieved with less paperwork. Nephrologists provide optimal care when they can dedicate their time to patients, not paperwork.

Furthermore, ASN believes that, if finalized, this proposal will create an unnecessary and unhelpful dynamic wherein dialysis facilities will begin to feel pressured to "push back" on physician-prescribed appropriate and optimal care due to reimbursement concerns at the facility. The resultant dynamic will devalue nephrologists' expertise and harm patients, resulting in less patient-centered care and greater risk of hospitalization, emergency department utilization, pulmonary edema/fluid overload and death. The sum impact of the proposed LCD is substantial and unnecessary strain on the patient-physician relationship through the establishment of marked administrative and regulatory barriers to the prescription of appropriate and individualized medical care that will result in fewer medically indicated dialysis sessions being delivered to patients who need them.

Conforming to CMS policy

When an individualized plan of care POC for a patient and medical justification (with appropriate documentation) exists, it is appropriate and consistent with national policy to reimburse a dialysis facility for more than three treatments a 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

[6] https://blog.cms.gov/ August 22, 2017.

> 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.[7]

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.

This proposed LCD exceeds the bounds of WPS's authority in trying to restrict what conditions can be covered for more than thrice-weekly dialysis with medical justification. As CMS rules and guidance have made clear, the decision regarding medical justification must be made on an individual patient basis. The LCD seeks to create a new coverage decision based on a set of restrictions that are contrary to current CMS policy. For such a change to occur, CMS would have to rely upon notice-and-comment rulemaking, which is beyond the scope of the LCD authority

Again, thank you for the opportunity to provide comment on this proposed LCD. ASN would be pleased to discuss these comments with CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at rmeyer@asn-online.org.

Sincerely,

Eleanor D. Lederer, MD, FASN
President

[7] 81 Fed. Reg. 77843.