November 2, 2017

Novitas Solutions Jurisdiction H
Novitas Solutions Medical Policy Department
Union Trust Building Suite 600
501 Grant Street
Pittsburgh, PA 15219-4407

RE: Frequency of Hemodialysis Local Coverage Determination DL35014

To whom it may concern:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide comments on the proposed Local Coverage Determination (LCD) Frequency of Hemodialysis DL35014.

The Alliance is a coalition of kidney dialysis stakeholders representing patients, clinicians, providers, and industry. We have come together to promote activities and policies to facilitate treatment choice in dialysis care, while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis. Patients who require more than thrice weekly hemodialysis for more than acute episodes are often referred to home hemodialysis. In the home setting, physicians have more flexibility to tailor the prescription frequency to meet individual patient needs.

Home dialysis is an important treatment option that offers patients clinically meaningful improvements in physical and mental health. Federal policymakers have been strong in their support for the modality. When Congress created the End Stage Renal Disease (ESRD) benefit under Medicare, they were clear that “the maximum practicable number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated.”[1] In the final rule implementing the new ESRD Prospective Payment System on January 1, 2011, the Centers for Medicare and Medicaid Services (CMS) indicated that the new bundled payment would “encourage patient access to home dialysis,”[2] and “make home dialysis economically feasible and available to the ESRD patient population.”[3]

This congressional support is strongly rooted in the evidence behind home dialysis as a lifesaver for appropriate patients. One type of home dialysis, home hemodialysis (HHD), is often prescribed more

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[1] Section 1881(c)(6) of the Social Security Act.
[2] 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).
[3] *Id*. at 49,060.

than thrice weekly, to manage individual patients' clinical needs. More frequent dialysis makes a significant tangible clinical difference for patients, and has been cited in clinical evidence as the cause for many health-related quality of life improvements. Studies have demonstrated that more frequent hemodialysis results in faster recovery time after treatment and fewer side effects[4]; improved cardiac status[5] and survival rates[6]; and increased opportunity for rehabilitation.[7] Importantly, these benefits are seen in ESRD patients with both acute and chronic conditions. As a result, the Alliance strongly believes that in establishing a treatment plan for a complex patient, whether with chronic or acute conditions, the physician and patient should work together to establish the most clinically effective regimen to manage the comorbidities and attain optimal health for every patient. Often this mutually agreed upon treatment plan includes more frequent dialysis in the home, based on medical justification and the substantial clinical benefits seen in patients with a range of chronic and acute conditions.

Given the clinical evidence and strong community wide support for access to home dialysis, the Alliance strongly believes that reimbursement for medically justified more frequent dialysis is a critical element of the ESRD benefit. Moreover, we believe such coverage is in accordance with national reimbursement policy. Although CMS policy empowers MACs to determine the definition of medical justification, an inappropriately narrow definition as reflected in the recent LCD defies CMS guidance and, certainly, the Medicare law's original intent.

While the Alliance appreciates that the recent LCD makes some positive changes, such as the recognition of some of the comorbidities that may require more frequent dialysis, we are very concerned that the LCD unnecessarily limits the definition of medical justification. Such limitation may have a disproportionate impact on home dialysis patients for whom more frequent dialysis is strongly medically justified.

Therefore, the Alliance respectfully requests the following changes to the LCD:

1. **Novitas Solutions Jurisdiction H should recognize that clinical evidence has demonstrated the benefits of More Frequent Dialysis and should be reimbursed accordingly.**

More frequent dialysis is appropriate and necessary for many patients with chronic conditions that do not necessarily present in an acute fashion. As currently drafted, the LCD would limit payment for this treatment option. On the whole, MACs have traditionally honored Medicare policy along with the provider-patient relationship and covered additional sessions of dialysis when prescribed by the nephrologist and supported by clinical documentation of necessity. However, Novitas Solutions Jurisdiction H 's recent LCD deviates from this longstanding policy by inappropriately restricting medical justification to only "acute conditions" and to automatically deny additional payments if the Plan of Care includes more than three treatments per week. We are concerned that only covering more frequent dialysis for acute presentations of underlying chronic conditions creates a dangerous clinical imbalance

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[4] Heidenheim AP, Muirhead N, Moist L, et al. Patient Quality of Life on Quotidian Hemodialysis. *Am J Kidney Dis.* 2003 Jul; 42(1 Suppl):36-41.
[5] Culleton, B et al. Effect of Frequent NHD vs.CHD on Left Ventricular Mass and Quality of Life. *JAMA 2007;*11
[6] Foley, R.N, D.T. Gilbertson et al. Long interdialytic interval and mortality among patients receiving hemodialysis. *New England Journal of Medicine. 2011* 365, no.12:1099-1107
[7] Blagg, Christopher. "It's Time to Look at Home Hemodialysis in a New Light." Hemodialysis Horizons: Patient Safety & Approaches to Reducing Errors. (2006): 22- 28. Web. 12 Apr 2012. http://www.aami.org/publications/HH/Home.Blagg.pdf.

for vulnerable patients. Further, limiting the justification to only "acute" instances inappropriately interferes with the ability of a physician to appropriately manage his/her patient.

Published clinical literature shows that more frequent dialysis can be beneficial to patients. For example, the Frequent Hemodialysis Network Trial published in the *New England Journal of Medicine,* showed significant benefits associated with short more frequent HD in reduction of left ventricular mass and physical health composite score, important surrogate endpoints selected for their historical correlation with mortality and hospitalization outcomes. Short frequent HD was also associated with improved control of hypertension and hyperphosphatemia, and in a subsequent publication was shown to significantly reduce post-dialysis recovery time and improve survival.[8] Further, we'd like to offer for reference that the field lacks profound clinical evidence to support the 3 times per week schedule, especially with certain co-morbidities.[9]

The LCD quotes the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, which clearly outline certain conditions that should prompt consideration of additional dialysis sessions or longer treatment times, including 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). It is critical to note that these guidelines were *not* meant to imply a limiting list, and were never intended to replace and set limits on the clinical assessment of a nephrologist and his or her individual patient. The list of "ICD10s that Support Medical Necessity" included in the draft policy is a good start to recognizing the clinical evidence for the use of more frequent treatments. Importantly, this list must be recognized as not an exhaustive representation of clinical benefit, to allow for providers and clinicians to appeal any treatments not paid under the current draft language.

The Alliance urges Novitas Solutions Jurisdiction H to reconsider this decision and allow patients with chronic conditions to continue receiving more frequent dialysis.

2. **Novitas Solutions Jurisdiction H should revise the draft LCD to allow inclusion of more frequent dialysis in the patient Plan of Care to be considered as medical justification.**

For those patients who are dialyzing at home, and on a more frequent dialysis schedule based on the medical recommendation of their physician, it is expected that such treatment details are included in a Patient's Plan of Care. As outlined earlier in these comments, such patients often experience long term clinical benefit, not simply limited to the treatment of acute conditions. Therefore, inclusion of this treatment regimen in a Plan of Care should not be automatically disallowed from consideration as medical justification.

In addition, the Alliance believes that the relationship between nephrologist and patient is the foundation of quality medical care. Dialysis patients are often some of the most complex beneficiaries in Medicare, requiring physicians to consider the multiple comorbidities that many of them present and leading to a

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

[9] Bleyer, AJ, et. al., Characteristics of Sudden Death in Hemodialysis. *International Society of Nephrology- Kidney International*. 2006

close, individualized relationship between physician and patient. Often, these complex patient conditions, as well as physician goals of optimizing health outcomes and reducing hospitalizations, demand the prescription of dialysis more than three times per week. The Alliance is concerned that the current LCD needlessly interferes in this physician patient relationship by proposing to limit dialysis to only three times per week. The Alliance believes that it is of the utmost importance for nephrologists to be able to properly manage the care of all patients- including by prescribing more frequent dialysis when appropriate.

Furthermore, the Alliance asks that the final LCD remove all reference to "short" and "planned inadequate" dialysis, which implies that physicians are inappropriately prescribing a dose of dialysis contrary to medical standards and ethical behavior. This is simply untrue. Patients who receive more frequent dialysis do so because this schedule was created to best serve their individual clinical needs by their nephrologist. More frequent dialysis is therefore not a misunderstanding of KDOQI guidelines, which as stated above do not serve as a limiting list, or the science of hemodialysis, but instead is prescribed in order to achieve and maintain optimal outcomes in complex patients. Therefore, the Alliance urges Novitas Solutions Jurisdiction H to remove these inappropriate references in its LCD.

Finally, the Alliance is concerned that by removing the option of including more frequent dialysis in the patient's plan of care, the LCD could inadvertently increase the documentation burden on nephrologists. CMS Administrator Seema Verma stated that CMS must make it easier for clinicians 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."[10] This LCD's new documentation burden does not comport with this stated goal.

For all of these reasons, the Alliance urges Novitas Solutions Jurisdiction H to remove any reference to a patient's plan of care and to recognize the importance clinical decision making in determining the best prescription to meet the acute and chronic needs of complex renal patients.

3. **Any LCD put forth by Novitas Solutions Jurisdiction H should accord with CMS's longstanding payment policy, which allows for more than three hemodialysis treatments per week when medically justified.**

CMS has had a longstanding policy of covering three payments for hemodialysis per week, and more if they are "medically justified." Specifically, the CY 2017 ESRD PPS Final Rule states, "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."[11] Of note, the Medicare manuals establish no limitation on chronic or acute conditions that may result in payment. The recently published LCD seemingly ignores this CMS policy, stating instead that more frequent dialysis sessions

[10] https://blog.cms.gov/
[11] 81 Fed. Reg. 77843.

will still be reimbursed at the 3 times per week amount, with exceptions for only acute conditions listed in the draft policy. The Alliance urges Novitas Solutions Jurisdiction H to reconsider this new policy and continue to allow for reimbursement of more frequent dialysis when medically justified. Specifically, we ask that the proposed LCD be edited to ensure that additional sessions that a physician determines are needed to address acute or chronic conditions and/or to prevent the recurrence of an acute symptom linked to an acute or chronic condition may with appropriate documentation be reimbursed. Leaving the language as Proposed would change the underlying policy CMS has implemented, which is beyond the implementation authority of the MACs.

The Alliance appreciates the opportunity to provide comments on these important and urgent issues. For any questions you may have, please contact Michelle Seger at michelle@homedialysisalliance.org or 202.466.8700.

Sincerely,

Stephanie Silverman
Executive Director

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