



November 4, 2013

Debra Patterson, M.D.
Contractor Medical Director
Novitas Solutions, LLC
Suite 1200
9330 Lyndon B Johnson Freeway
Dallas, TX 75243-1213

Re: Frequency of Dialysis LCD (DL32755 and DL34388)

Dear Dr. Patterson:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to comment on the draft local coverage determination entitled “Frequency of Dialysis” (“draft LCD”).

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.

Congress and the Centers for Medicare and Medicaid Services (CMS) have consistently acknowledged the importance of ensuring beneficiaries with access to home dialysis.¹ In fact, one of the Agency’s stated goals in the implementation of the new ESRD payment system was to “encourage patient access to home dialysis”² and to “make home dialysis economically feasible and available to the ESRD patient population.”³ However, today only 10% of U.S. dialysis patients receive treatment at home, with approximately 2% of patients receiving home hemodialysis (HHD).⁴

Daily hemodialysis, particularly at home, is an important treatment option that offers significant clinical benefits because it allows for more frequent and/or longer lasting dialysis sessions. For instance, studies have demonstrated that more frequent hemodialysis results in faster recovery time after treatment with fewer side effects;⁵ improved cardiac status⁶ and survival rates;⁷ and increased likelihood for transplantation⁸ and opportunity for rehabilitation.⁹

¹The ESRD Program Amendments of 1978 (P.L. 95 - 292)

² 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).

³ Id. at 49,060.

⁴ U S Renal Data System, USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012.

⁵ 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.

⁶ Culleton, B et al. Effect of Frequent NHD vs.CHD on Left Ventricular Mass and Quality of Life. JAMA 2007;11

⁷ Pauley, R.P. Survival comparison between intensive hemodialysis and transplantation in the context of the existing literature surrounding nocturnal and short-daily hemodialysis. Nephrol Dial Transplant. 2013 28: 44-47.

⁸ ibid

The Alliance believes the draft LCD should be modified to expand coverage for dialysis patients treating more frequently. Limiting reimbursement for more frequent hemodialysis to four treatments per week and restricting the coverage to a small group of medical conditions will not properly provide coverage for most patients on HHD. The Alliance believes the proposed LCD should be expanded to be consistent with stated federal policy to increase access to home dialysis and with current clinical evidence. The Alliance supports developing a policy that provides more frequent dialysis (up to 6 treatments per week) for patients receiving HHD and would ask that additional chronic diagnosis codes be considered.

While studies and surveys have reported that physicians believe 10-14% of patients are ideally clinically suited for more frequent home hemodialysis, the current utilization of this therapy option, as previously stated, is only about 2% of dialysis patients.¹⁰ If the draft LCD moves forward in its current form, physicians and patients would be less likely to choose this modality knowing that coverage beyond the fourth treatment would be denied. In fact, the University of Michigan Kidney Epidemiology and Cost Center's analysis of 2009 Medicare claims data found an association suggesting lower prevalence of HHD in Medicare Area Contractor (MAC) regions that have more restrictive HHD payment policies with regard to frequency of treatment.¹¹

A more recent review of Medicare claims data by Avalere confirms low utilization of HHD within the Novitas' jurisdiction that currently has the draft LCD in place. For example, in Texas, the utilization of HHD is only 1.5%, while the national average demonstrated in claims data is 2.3%.¹² Stated another way, in Texas, patients are 35% less likely to use HHD as compared to the national average use of HHD. While the Avalere data does not directly measure the connection between the LCD policy and utilization, it is clear that Texas already lags behind the national average, and any policies that would create additional barriers to HHD would only serve to further discourage its use, instead of incentivizing it as Congress and CMS intended.

To preserve clinically appropriate patient choice and promote quality outcomes, **the Alliance supports revisions to the draft policy to allow for payment of additional dialysis sessions with the inclusion of the following acute and/or chronic conditions** to the section of the draft titled "diagnoses that support medical necessity."¹³ These additions will align the codes that support medical necessity with current clinical literature:

- 275.3 Disorders of Phosphorus Metabolism
- 458.8 Other Specified Hypotension
- 429.3 Left Ventricular Hypertrophy (LVH)
- 588.89 Other specified disorders resulting from impaired renal function
- 780.57 Sleep Apnea
- 300.4 Depression
- 333.94 Restless legs
- V62.29 Other occupational circumstances
- V63.3 Educational circumstances

⁹ 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>.

¹⁰ Mendelssohn D, et al. What Do American Nephrologists Think About Dialysis Modality Selection?: American Journal of Kidney Disease 37:22–29, 2001.

¹¹ Hirth et al, Frequency of payment for more than thrice weekly dialysis for home hemodialysis (HHD) University of Michigan Kidney Epidemiology and Cost Center analysis for CMS. Presented at ASN 2011

¹² Dialysis Heat Maps, Distribution of Patients on PD and HHD by Race and State, Avalere Report prepared for Baxter, April 2013. Accessed at the following website:

http://homedialysisalliance.org/userfiles/Updated%20Avalere%20Heat%20Map_Distribution%20of%20Dialysis%20Patients%20Utilizing%20Home%20Modalities%20by%20State%20in%202011.pdf

¹³ See Alliance attachment one

- V60.8 Economic or housing

Please find attached clinical literature providing evidence in support of these codes. In addition, we urge you to review the clinical justification and documentation submitted by Alliance members individually. It is important to note that data in support of these codes comes from both randomized, controlled clinical trials (RCT) and from data published in studies where RCTs are unavailable, which is preponderant in the case of kidney disease. As you know, clinical practice is informed by consistently positive evidence in peer-reviewed publications demonstrating the clinical benefits of more frequent dialysis.

Additionally, the Alliance believes that **the draft LCD should be further revised to strike the current paragraph, found in the section titled “Utilization Guidelines,” stating that “in general, only a fourth treatment will be covered [...].”** In its place, we recommend stating “Patient records with claims for more than three treatments per week must support that additional dialysis sessions are for treatment of an acute or chronic condition in accordance with the criteria of this LCD.”

The Alliance also urges the **removal of the “five pounds per day” threshold from the definition of fluid overload in the draft LCD.** We believe it is an arbitrary level not supported in clinical literature that would not account for many dialysis patients who will become fluid overloaded at a lesser figure.

Finally, we request that **the words “and peritoneal dialysis” be stricken** from the following statement on page two: “Hemodialysis *and peritoneal dialysis* performed or billed more than three times per week is reasonable and medically necessary [only for the following conditions...].” Consistent with CMS policy, peritoneal dialysis or “PD” (e.g. Continuous Ambulatory Peritoneal Dialysis and Continuous Cycler Peritoneal Dialysis) is paid at a daily rate equivalent to thrice weekly incenter hemodialysis treatment without the need for additional documentation of medical necessity.

Thank you for the opportunity to comment on this important draft LCD and please feel free to contact Lindsay Punzenberger at 202-466-8700 if you have any questions or would like additional details.

Sincerely,



Stephanie Silverman
Executive Director



Signing Alliance Members

American Association of Kidney Patients

American Kidney Fund

American Nephrology Nurses Association

American Society of Nephrology

American Society of Pediatric Nephrology

Baxter

Dialysis Patient Citizens

Greenfield Health Systems

Home Dialyzors United

Hortense and Louis Rubin Dialysis Center, Inc.

Medical Education Institute

N.A. Chapter International Society for Peritoneal Dialysis

National Kidney Foundation

National Renal Administrators Association

Northwest Kidney Centers

NxStage Medical

Renal Physicians Association

Renal Support Network

Satellite Healthcare

Southwest Kidney Institute

TNT Moborg International Ltd.

Washington University School of Medicine, Renal Division



Attachment One

Clinical Study References

275.3 Disorders of Phosphorus Metabolism

1. Ayus A, Mizani M, Achinger A, Thadhani R, Go A, Lee S: Effects of Short Daily versus Conventional Hemodialysis on Left Ventricular Hypertrophy and Inflammatory Markers: A Prospective, Controlled Study. JASN September 1, 2005 vol. 16 no. 9 2778-2788.
2. The FHN Trial Group; In-Center Hemodialysis Six Times per Week versus Three Times per Week. N Engl J Med 2010; 363: 2287-2300.
3. Kooienga L. Phosphorus Metabolism and Management in Chronic Kidney Disease: Phosphorus Balance with Daily Dialysis. Seminars in Dialysis 2007; 20: 342-345.
4. Pierratos A: NHD 9 years later. Hemo Int. 8:44-50, 2004.
5. Block GA, Port FK: Re-Evaluation of Risks Associated With Hyperphosphatemia and Hyperparathyroidism in Dialysis Patients: Recommendations for a Change in Management. J Am Kid Dis. 35(6): 1226-37, 2000.
6. Mucsi I, Hercz G, Uldall R, Ouwendyk M, et al: Control of Serum Phosphate without any phosphate binders in patients treated with Nocturnal Hemodialysis. Kidney International. 53(5): 1399-1404, 1998.
7. Achinger et al. Journal of the American Society of Nephrology, 2006.
8. Reynolds et al. International Urology and Nephrology, 2010.
9. Van Biesen et al. Hemo Int., January 2003.

458.8 Other Specified Hypotension

1. Movilli, E., Gaggia, P., Zubani, R., Camerini, C., Vizzarda, V., Parrinello, G., Savoldi, S., et al. (2007). Association between high ultrafiltration rates and mortality in uraemic patients on regular haemodialysis: A 5-year prospective observational multicentre study. Nephrology, dialysis, transplantation 22(12), 3547-52.
2. Burton, J. O., Jefferies, H. J., Selby, N. M., & McIntyre, C. W. (2009). Hemodialysis-induced cardiac injury: determinants and associated outcomes. Clinical journal of the American Society of Nephrology 4(5), 914-20.

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4. Murashima M, Kumar D, Doyle A, Glickman J: Comparison of intradialytic blood pressure variability between conventional thrice-weekly hemodialysis and short daily hemodialysis. *Hemodialysis International* Volume 14, Issue 3, pages 270–277, July 2010.

429.3 Left Ventricular Hypertrophy (LVH)

1. Culleton B, Walsh M, Klarenbach S, et al: Effect of Frequent Nocturnal Hemodialysis vs Conventional Hemodialysis on Left Ventricular Mass and Quality of Life. *JAMA*. 298(11): 1291-1299, Sept 2007.
2. The FHN Trial Group; In-Center Hemodialysis Six Times per Week versus Three Times per Week. *N Engl J Med* 2010; 363:2287-2300.
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4. Ayus A, Mizani M, Achinger A, Thadhani R, Go A, Lee S: Effects of Short Daily versus Conventional Hemodialysis on Left Ventricular Hypertrophy and Inflammatory Markers: A Prospective, Controlled Study. *JASN* September 1, 2005 vol. 16 no. 9 2778-2788.
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8. Kalantar-Zadeh K, et al. *Circulation*, 2009.
9. Goldfarb-Rumantzev et al. *Nephron Clinical Practice*, 2009.
10. Hanna et al. Abstract from HFSA Annual Scientific Meeting, 2008.
11. Movilli et al. *Nephrology Dialysis and Transplantation*, 2007.
12. Traeger et al. *Hemodialysis International*, 2004.

Sleep Apnea 780.57 and Restless Legs 333.94

1. Jaber B, Schiller B, Burkart J, Daoui R, Kraus M, Lee Y, Miller B, Teitelbaum I, Williams A, Finkelstein F: Impact of At-Home Short Daily Hemodialysis on Restless Legs Symptoms and Sleep Disturbances. *Clinical Journal of the American Society of Nephrology* March 2011CJN.10451110.
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3. KDOQI Adequacy Work Group: Guidelines for Hemodialysis Adequacy, *American Journal of Kidney Diseases*, Vol 48, No 1, Suppl 1 (July), 2006: pp S53-S62; S53.

4. Unruh M, et al. Restless legs symptoms among incident dialysis patients: Association with lower quality of life and shorter survival. *Am J Kidney Disease* 2004; 43:900-909.

300.4 Depression

1. Jaber B, et al: Effect of Daily Hemodialysis on Depressive Symptoms and Postdialysis Recovery Time: Interim Report from the FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study. *American Journal of Kidney Diseases* Volume 56, Issue 3, Pages 531-539, September 2010.
2. Boulware LE, Yongmei L, Fink NE, Coresh J, Ford DE, Klag MJ, Powe NR: Temporal Relation among Depression Symptoms, Cardiovascular Disease Events, and Mortality in End-Stage Renal Disease: Contribution of Reverse Causality. *Clinical Journal of the American Society of Nephrology*. 1: 496-504, 2006.
3. Lopes AA, et al: Depression as a predictor of mortality and hospitalization among hemodialysis patients in the United States and Europe. *Kidney International*. 62:199-207, 2002.

V62.29 Other Occupational Circumstances; V.63.3 Educational Circumstances; V.60.8 Economic or Housing

As reported in the Dialysis Outcomes and Practice Patterns Study (DOPPS), lower health related quality of life scores in dialysis patients have been strongly associated with significantly higher risk of death and hospitalizations. More frequent hemodialysis may improve mental and physical health and has been shown to improve recovery time and post-dialysis fatigue. Patients treated with more frequent dialysis are significantly more likely than their peers to continue or resume employment. Similarly, patients treated with more frequent dialysis are more likely to attend and complete school.

1. The FHN Trial Group. In-center hemodialysis six times per week versus three times per week. *New England Journal of Medicine* 2010; 363:2287-2300.
2. Punal J, Varela Lema L, Sanchez-Guisande D, Ruano-Ravina A: Clinical effectiveness and quality of life of conventional haemodialysis versus short daily haemodialysis: a systematic review. *Nephrology Dialysis Transplantation* (2008) 23 (8): 2634-2646. (DOI: 10.1093/ndt/gfn010).
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4. Ting G, Kjellstrand C, Freitas T, Carrie B, Zarghamee S: Long-term study of high-comorbidity ESRD patients converted from conventional to short daily hemodialysis *American Journal of Kidney Diseases* Volume 42, Issue 5 , Pages 1020-1035, November 2003.
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8. Mapes D, et al. Health-related quality of life as a predictor of mortality and hospitalization: The Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney International* 2003; 64; 339–349.