American Society of Nephrology

February 27, 2024

The Honorable Jason Smith
1011 Longworth House Office Building
Washington, DC 20515-2508

The Honorable Richard Neal
372 Cannon House Office Building
Washington, DC 20515-2101

Dear Chairman Smith and Ranking Member Neal,

On behalf of the more than 21,000 physicians, scientists, and kidney health professionals who comprise the American Society of Nephrology, thank you for your work to improve the health of all Americans, particularly the 37 million Americans living with kidney diseases. The society urges you to promote access to care by retaining current policy excluding oral only medications from the End Stage Renal Disease (ESRD) bundle.

More than 800,000 Americans are living with kidney failure, including more than 500,000 people who undergo dialysis to manage their life-threatening condition.[i] Dialysis patients comprise a vulnerable population, including many minorities and elderly individuals; hence ensuring the best possible care for dialysis patients is an urgent health equity issue. More than one in three hemodialysis patients identifies as Black while more than 20% identify as Hispanic. Moreover, more than 4,000 people receive dialysis in a skilled nursing facility,[ii] while as many as 10% of hemodialysis patients live in a nursing home at any given time.

All dialysis patients require numerous medications to manage their health, and, for many patients this includes certain oral-only medications, such as phosphate binders. Without access to phosphate binders, patients are at higher risk for vascular problems and bone fractures, which can lead to increased hospitalization and risk of death.[iii]

These oral-only medications are complex to administer and are best dispensed by pharmacies, who have dedicated infrastructure suited to providing these medications. This is particularly important for promoting medication adherence: for example, pharmacies are able to provide patient-specific doses in blister packs in conjunction with the other home medications that a patient takes (on average, 17 to 20 pills per day including 7 pills for phosphate lowering).[iv, v, vi]

To ensure equitable access to oral-only medications, it is vital that these medications continue to be provided in a pharmacy setting and reimbursed through Medicare Part D, which provides coverage to nearly 90% of dialysis patients enrolled in fee-for-service Medicare.[vii]

Requiring these medications to be provided by dialysis facilities has major implications. First, already short-staffed facilities will need to pivot to become high-volume pharmacies, a major logistical challenge. This will be especially challenging for small dialysis providers, who also lack purchasing power to negotiate pricing with drug manufacturers and may not have affiliated pharmacies.

Second, people undergoing dialysis who reside in a skilled nursing facility will face additional barriers to obtaining these medications if pharmacies that the nursing homes contract with are no longer able to supply them to patients. This is true for those patients who receive dialysis onsite in skilled nursing facilities as well as nursing facility residents who travel to dialysis facilities. Skilled nursing facilities typically contract specifically with pharmacies to ensure access for all necessary medications. Requiring dialysis facilities to provide these medications will mean that they are functionally inaccessible to nursing home residents—the most vulnerable dialysis patients. There is no proposed solution for this vulnerable population, which at any given time comprises up to 10% of dialysis patients.

Third, the current proposal to move oral-only medications to the ESRD bundle does not specify which average sales price (ASP) formula would be used, important information to clarify before any process can begin. As Medicare only reimburses 80% of charges within the ESRD bundle, an inadequate ASP formula would mean that dialysis facilities would not only need to absorb the cost of distribution but also, particularly for the most vulnerable patients, lose a significant amount of money providing these medications. For example, in many states, Medicaid does not reimburse the 20% of dialysis charges to a dialysis facility that Medicare does not cover, and the inclusion of oral-only medications in the bundle will substantially increase the total amount of uncovered care. With ongoing limited access issues for patients in multiple states to dialysis, particularly among those with Medicaid as a primary or secondary payer, the proposed oral-only inclusion substantially increases the risk of harming the most vulnerable patients. This is a real risk that threatens health equity.

To maintain equitable access to oral-only medications, the society urges you to continue the current policy of excluding oral-only medications from the ESRD bundle. If oral-only medications are included in the ESRD bundle, patient access to these medications will be hindered, with the most vulnerable patients most affected.

Please do not hesitate to contact ASN Manager of Congressional Affairs Zach Kribs at zkribs@asn-online.org or 202-618-6991 with any questions about achieving equity for people with kidney diseases, access to oral only medications, or this letter.

Sincerely,

Deidra C. Crews, MD, ScM,
FASN President

[i] United States Renal Data System. 2023 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2023.

[ii] The National Forum of ESRD Networks. Quarterly National ESRD Census www.esrdnetworks.org. Date of data release, Dec. 31, 2023. Accessed 2024.

[iii] Lederer E, Ouseph R, Erbeck K. Hyperphosphatemia, eMedicine.com, URL: Hyperphosphatemia: Practice Essentials, Background, Pathophysiology. Accessed 2024.

[iv] Chiu YW, Teitelbaum I, Misra M, de Leon EM, Adzize T, Mehrotra R. Pill burden, adherence, hyperphosphatemia, and quality of life in maintenance dialysis patients. Clin J Am Soc Nephrol. 2009 Jun;4(6):1089-96. doi: 10.2215/CJN.00290109. Epub 2009 May 7. PMID: 19423571; PMCID: PMC2689877.

[v] Marin JG, Beresford L, Lo C, Pai A, Espino-Hernandez G, Beaulieu M. Prescription Patterns in Dialysis Patients: Differences Between Hemodialysis and Peritoneal Dialysis Patients and Opportunities for Deprescription. Can J Kidney Health Dis. 2020 May 1;7:2054358120912652. doi: 10.1177/2054358120912652. PMID: 32426145; PMCID: PMC7218341.

[vi] Fissell RB, Karaboyas A, Bieber BA, Sen A, Li Y, Lopes AA, Akiba T, Bommer J, Ethier J, Jadoul M, Pisoni RL, Robinson BM, Tentori F. Phosphate binder pill burden, patient-reported non-adherence, and mineral bone disorder markers: Findings from the DOPPS. Hemodial Int. 2016 Jan;20(1):38-49. doi: 10.1111/hdi.12315. Epub 2015 May 14. PMID: 25975222; PMCID: PMC4644509.

[vii] United States Renal Data System. 2023 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2023.