



Jonathan Blum
Principle Deputy Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

10 July 2023

Dear Mr. Blum:

On behalf of the Alliance for Home Dialysis, thank you to you and your staff for meeting with us last week to talk about the state of home dialysis in the US, including a pathway home for acute kidney injury (AKI) patients. We very much appreciated your time, attention, and thoughtful questions.

While AKI began to get more attention during the COVID-19 pandemic, the range of patients who experience it is broad. The risk of AKI generally is 2-5 percent, but as high as 19-23 percent for hospitalized or critically ill patients. Home dialysis became extra important during the pandemic, when patients needed to isolate at home, however it remains an important modality today. Clinical experience and data support expanding this option for AKI patients beyond the pandemic. However, once an AKI patient is discharged, the rules of the Medicare program will not reimburse for these patients, because by regulation the reimbursement is limited to in-center dialysis. The decision for individuals with AKI to select home dialysis should be a shared decision with the individual and the prescribing physician, instead of being subject to a blanket prohibition. We ask that CMS reimburse providers for patients with AKI who are placed on home dialysis. These patients would receive the standard training necessary for receiving home dialysis.

Given that CMS raised this issue for comment in the CY22 rule, we believe that CMS can address this issue in the CY24 rule by removing the prohibition on payment for home dialysis for AKI patients subject to clinician and patient shared decision making.

Attached to this letter you will find a packet of materials covering the following issues, among others that we discussed at the meeting:

- Why a pathway to home dialysis is critical for AKI patients, including information on preservation of remaining kidney function
- Patient safety mechanisms, including education, telehealth, and more

- Home dialysis nursing
- Operationalizing an AKI to home program

In addition, we wanted to take the time to respond to your question: *How fast would you expect impact if the care system offers more flexible payment?*

Overall, we believe the impact would be fairly immediate. There are many nephrologists that would be ready and willing to make the required changes, as they have been asking for this update for some time. In addition, in facilities, the care pathways for AKI are in many places already developed; turning them into pathways to home therapy would be relatively straightforward as PD and HHD training materials already exist.

In order to provide an illustration, we conducted research into a similar situation from 2017. Beginning January 2017, ESRD facilities were able to furnish dialysis services to AKI patients. Adoption of outpatient dialysis procedures for these AKI patients increased rapidly following implementation of this policy.

Specifically, outpatient dialysis claims among patients with AKI increased by 49% from 820 in January 2017 to 1,222 in February 2017, and approximately 34% to 1,633 in March 2017. The growth rate levelled off by May of 2017, with 1,945 AKI patients receiving dialysis in the outpatient setting. Over time, more AKI patients continue to receive dialysis in ESRD facilities, with 3,207 AKI patients receiving dialysis through an ESRD facility in December of 2019.

Therefore, based on our clinical experts' opinions and this analogous situation, we believe that the impact of covering home dialysis for AKI patients would be rapid.

Thank you again for your willingness to discuss these important issues with us. We look forward to continued discussions and appreciate your offer to talk again. We'd very much like to do that once you have had the opportunity to review the follow-up documents. We are also happy to respond to any questions you may have. Please don't hesitate to contact us at mseger@vennstrategies.com.

Sincerely,



Michelle Seger
Managing Director
Alliance for Home Dialysis