April 27, 2020 | Insights & Analysis | COVID-19 Intel Center

COVID-19 Poses New Challenges in the Evolving Kidney Care Landscape

Mark Gooding

Matt Kazan

Zach Levine

Summary

The kidney care payment and delivery landscape was poised for change in 2020 due to existing policies and market trends. Given the specific risk COVID-19 poses to these patients, the pandemic is creating new challenges and potentially accelerating existing trends in the kidney care space.

For the 37 million Americans with kidney disease, COVID-19 presents a particularly salient threat. The Centers for Disease Control and Prevention (CDC) notes comorbidities that often cause or are associated with chronic kidney disease (CKD)—such as diabetes, hypertension, and heart failure—are among the underlying conditions that put individuals at greater risk for complications of COVID-19. Further, for the almost 500,000 Americans with end-stage renal disease (ESRD), the nature of facility-based dialysis treatment (typically 3 times weekly) presents additional risks for immunocompromised patients in a time when social-distancing is considered a best practice to mitigate exposure to the virus.

Given the market and policy changes that were expected in the kidney care space in the coming year, the COVID-19 pandemic has created new dynamics and exacerbated existing uncertainties for patients, providers, and the spectrum of stakeholders delivering, coordinating, and financing care.

Avalere Health | An Inovalon Company | © 2020. Avalere Health LLC. All Rights Reserved. www.avalere.com

Government Moving to Create Flexibilities for Providers

The Centers for Medicare & Medicaid Services (CMS) has taken action over the past 2 months to grant flexibilities to providers and offer guidance to dialysis facilities in the wake of COVID-19. In March, the CMS expanded access to telehealth and provided a "toolkit" for providers outlining the types of services covered under Medicare. These changes allow nephrology practices to use telehealth to conduct visits with patients receiving in-facility dialysis treatments for the first time. The CARES Act also waived the face-to-face requirement between home dialysis patients and their managing clinicians. The CMS also issued guidance to dialysis facilities on how to limit transmission of COVID-19, including screening of patients and staff and sanitizing of facilities. A subsequent update to this guidance provided additional flexibilities for home dialysis services and offered clarification on the establishment of special purpose renal dialysis facilities (SPRDFs) to provide dialysis to sick or isolated patients.

COVID Testing Provider Capacity and Manufacturer Supplies

While the focus of hospital capacity in recent weeks has been availability of ventilators, recent reporting from Politico and *The New York Times* has noted the increasing strain the pandemic has placed on hospitals' inpatient dialysis capacity. Hospitals have reported an alarming rate of COVID intensive care unit patients experiencing acute kidney injury, requiring recurring dialysis to filter toxins and waste from patients' blood. Given that COVID has already pushed some hospitals beyond capacity, the increased need for dialysis has created unexpected demands on hospitals in terms of capital equipment, dialysis supplies, and the trained staff to perform the dialysis. Already, providers are beginning to think of contingency planning for potential human and resource capacity shortfalls—presenting yet additional challenges for these providers and manufacturers trying to meet this demand.

Interest in Driving Dialysis Treatment to the Home

With nearly 90% of all ESRD patients receiving dialysis in a facility setting, the COVID pandemic is creating particular challenges for providers seeking to limit the likelihood and risks of transmission to this immunocompromised patient population. While the CMS has created flexibilities for certain telehealth provisions and the creation of SPRDFs in the wake of this crisis, the response to the risks associated with in-facility treatment due to this pandemic align with the Trump administration's broader goals of increasing utilization of home-based dialysis for appropriate candidates. This goal was underscored in last July's "Advancing American Kidney Health" executive order, which introduced a series of voluntary care delivery models and the proposal of the mandatory ESRD Treatment Choices (ETC) Model. Though the voluntary models (whose participants are expected to start their implementation period this year) would not tie

 © 2020. Avalere Health LLC. All Rights Reserved.

payment to home dialysis utilization, the ETC Model (as proposed) would create an immediate up-side payment adjustment for home dialysis and then introduce a 2-sided adjustment for dialysis facilities and managing clinicians based on home dialysis and organ transplant rate performance. Importantly, the ETC Model has not been finalized, although it currently sits at the Office of Management and Budget under review.

Questions remain whether the administration—amid the existing uncertainties created by COVID pandemic for this patient and provider population—will seek to finalize and implement this model in the coming months or utilize the standard ESRD Prospective Payment System rulemaking process to further its goals for increased home dialysis shifts.

Questions Loom Regarding the Role Medicare Advantage Will Play

Under the 21st Century Cures Act, all Medicare fee-for-service (FFS) beneficiaries with ESRD will be able to enroll into Medicare Advantage (MA) plans for the 2021 plan year. Uncertainty remains regarding the extent to which FFS patients will migrate to MA plans during the enrollment period opening this October, but additional supplemental benefits (e.g., vision, transportation), an out of pocket maximum, and low/zero-dollar premiums often associated with these plans could incent these patients to switch. Another consideration for these patients will be the limited access in some states to supplemental insurance (i.e., Medigap) plans for those under the age of 65.

MA plans should monitor the potential shift in ESRD enrollment in light of this policy change. ESRD patients comprised less than 1% of the Medicare population but accounted for 7.2% of Medicare costs in 2017. Avalere has conducted analyses that indicated ESRD FFS costs exceed the MA payment rate in 10 of the top 15 metropolitan statistical areas based on total ESRD patient population. Further, Avalere research has identified demographic differences between FFS and MA ESRD patient populations, which suggest ESRD patients in FFS are more likely to be a racial/ethnic minority and dually eligible for Medicare and Medicaid.

The challenges associated with greater ESRD enrollment may occur simultaneously with COVID-specific challenges. MA plans will need to project 2021 costs by June 2020, which has been complicated by the progression of COVID-19, the magnitude of differed services during widespread social distancing that may now occur in 2021, and the potential recurrence of COVID-19 in late 2020/early 2021. Additionally, for 2021, risk scores will be based in part on diagnoses recorded in 2020. CMS recently announced that MA plans will be permitted to use diagnoses recorded during telehealth visits under certain circumstances for risk adjustment. Despite this new flexibility, however, changes in utilization could impact 2021 risk scores and

Avalere Health | An Inovalon Company | © 2020. Avalere Health LLC. All Rights Reserved.

payment.

MA plans must balance the uncertainties of new ESRD enrollment with the financial, operations, and clinical risks presented by the COVID-19 pandemic. Given that MA penetration is greatest in metropolitan areas—where both the highest number of COVID-19 cases are likely to be and where ESRD patients more typically live—plans must identify opportunities to mitigate financial exposure while utilizing telehealth and enhanced care coordination to balance these patients' kidney health and their risks to exposure.

Looking Ahead

Collectively, the pandemic is creating unprecedented challenges to providers, payers, manufacturers, and—most importantly—CKD and ESRD patients who are at elevated risk of the serious complications of COVID-19. The CMS will likely drive additional policy changes through waivers and guidance in the immediate term, and the ESRD PPS rulemaking and broader market initiatives will reveal broader approaches to cope with the impact of the pandemic. Understanding the opportunities and risks these policy developments and market responses present will be critical for manufacturers, providers, and plans in the coming months.

Avalere is monitoring these developments and will continue to leverage its expertise across policy, market access, data analytics, and quality disciplines to assess how kidney care policy and markets evolve in the coming months. To learn more about the evolving patient support space and how Avalere can help your business drive access and continuity of care in this dynamic time, connect with us.

Check out our COVID-19 Intel Center.

© 2020. Avalere Health LLC. All Rights Reserved.