

HOME DIALYSIS: UNLOCKING NEW OPPORTUNITIES IN AN EVOLVING LANDSCAPE

THE US MARKET OPPORTUNITY FOR KIDNEY DISEASE TREATMENT IS LARGE, WITH AN ESTIMATED 37 MILLION US ADULTS HAVING CHRONIC KIDNEY DISEASE (CKD).¹

End-Stage Renal Disease (ESRD) accounts for approximately 7.2% of traditional Medicare spending or about \$507.9 billion per year.² Several recent policies, including the 2019 Advancing American Kidney Health executive order, aim to accelerate the transition to home dialysis therapies, reducing expenditures for treating this disease. This push for home dialysis dramatically changes the ability of healthcare organizations to gain market share, presenting a growth opportunity for device manufacturers.

How Provider Incentives were Slowing Adoption of Home Dialysis

While home dialysis has been available in the US for the past few decades, only 13% of dialysis patients receive treatment at home. At-home dialysis rates remain low despite the growing medical consensus that home dialysis therapies lead to better patient outcomes.³ Provider incentives play a significant role in this slow adoption.

Historically, the Centers for Medicare & Medicaid Services (CMS) has attempted to engineer provider incentives by establishing reimbursement parity between in-center and more profitable at-home treatments. However, individual nephrologists prescribe therapies to dialysis patients and manage their care under the current system. Most nephrologists don't share in the profits generated by the dialysis corporations they are affiliated with, rendering previous attempts at provider incentives unsuccessful.

To resolve the incentives gap, CMS enacted a new reimbursement policy in 2021, known as the ESRD Treatment Choice (ETC) Model, which includes incentives for both dialysis organizations and individual nephrologists. Under the ETC model, which contains 30% of dialysis facilities, participating providers will receive financial bonuses or penalties based on their rates of home care in relation to their previous performance, as well as the performance of peer facilities. Additionally, we expect the Kidney Care Choices (KCC) Model, which launched in January 2022 and incentivizes providers to delay the onset of dialysis, to have an indirect impact on home dialysis.⁴

¹ <https://www.cdc.gov/kidneydisease/basics.html>

² *USRDS Annual Report, 2020*

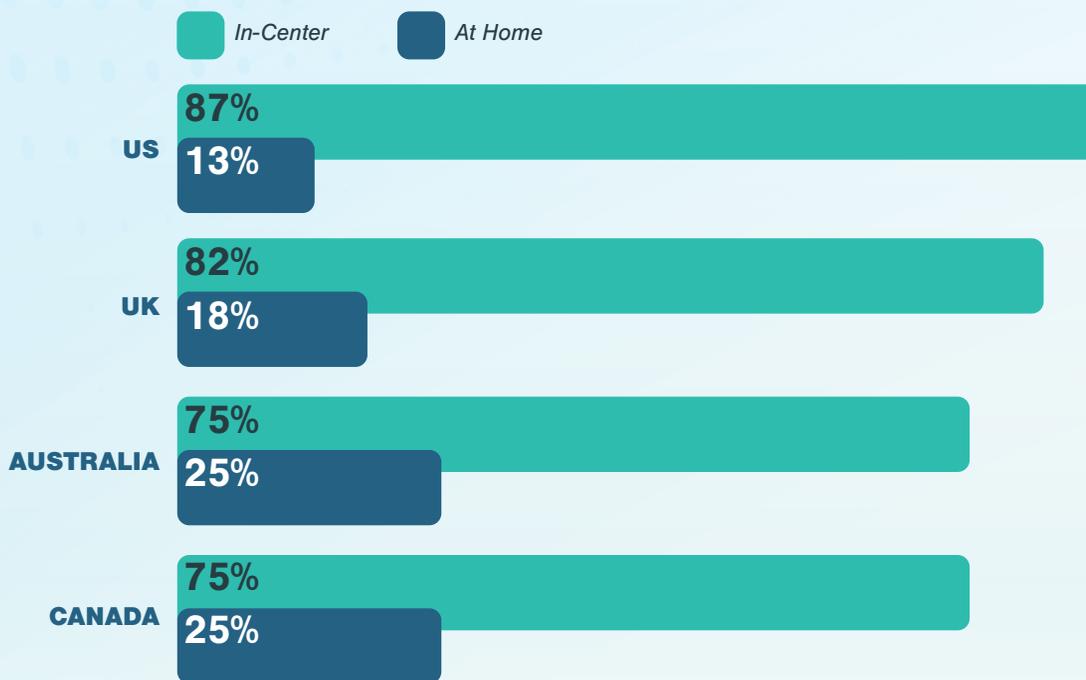
³ <https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model>

⁴ <https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model>

New Opportunity as a Result of the ETC Model

We predict that home dialysis adoption and increased demand for innovative home therapy technologies will accelerate because of the ETC Model, creating growth opportunities for device manufacturers. Compared to other developed countries, US home dialysis adoption is far slower. This lag signals substantial room for growth over the long term. We expect the US home dialysis market to represent an opportunity of \$3 billion by 2030.

Market Share (%) of ESRD Modalities in Developed Countries (2020)



With the ETC Model addressing the near-term constraint of nephrologist prescription behavior, we anticipate a shift in the US treatment mix to better reflect home care rates of peer countries in the coming years. The US dialysis market is on the brink of a transformational change, and home dialysis device manufacturers must position themselves to capture the upcoming opportunity.



Evolving Dialysis Treatment Landscape

The US dialysis market is highly concentrated among a small number of large providers. Fresenius and DaVita, the two largest dialysis organizations, provide treatments for 70% of dialysis patients in the US.⁵ A large-scale transition to home therapies can disrupt the existing market dynamics, reducing competitive barriers to entry.

Cost Reduction of Home Dialysis

Home dialysis reduces providers' dependence on in-center treatment infrastructure, dramatically reducing entry costs of the treatment centers and the associated equipment.

In-center treatments require a higher capital investment than home dialysis; over the last several decades, US market leaders have spent billions building out the necessary dialysis treatment infrastructure to provide in-center treatment at scale. This level of capital investment is essential because in-center treatments scale locally; a center in Chicago doesn't serve patients in Miami. Patients favor shorter commute times when selecting a dialysis facility, so the key to dominating the market is to build a hyper-dense network of treatment facilities. The only way to expand market share with this method is to develop and acquire new treatment facilities closer to patients' homes.

Home care providers can scale much more efficiently with home dialysis without geographical constraints. Once a patient is adequately trained and has a dialysis machine in their home, providers can monitor treatments remotely. Patients will still need to see their local nephrologist for regular visits. Still, much of the care, including daily monitoring, troubleshooting, patient support networks, and claims management, can be carried out remotely by a provider like Cricket Health or Strive Health. Because the infrastructure for this new treatment paradigm will be primarily software enabled, providers will be able to scale their patient care globally. For example, the same software and staff used to manage patients in Chicago can also support patients in Miami or anywhere else in the world.

This cost reduction is the main factor driving the transformation of the dialysis market by enabling fresh competition, spurring novel innovations, and creating new opportunities for industry participants.



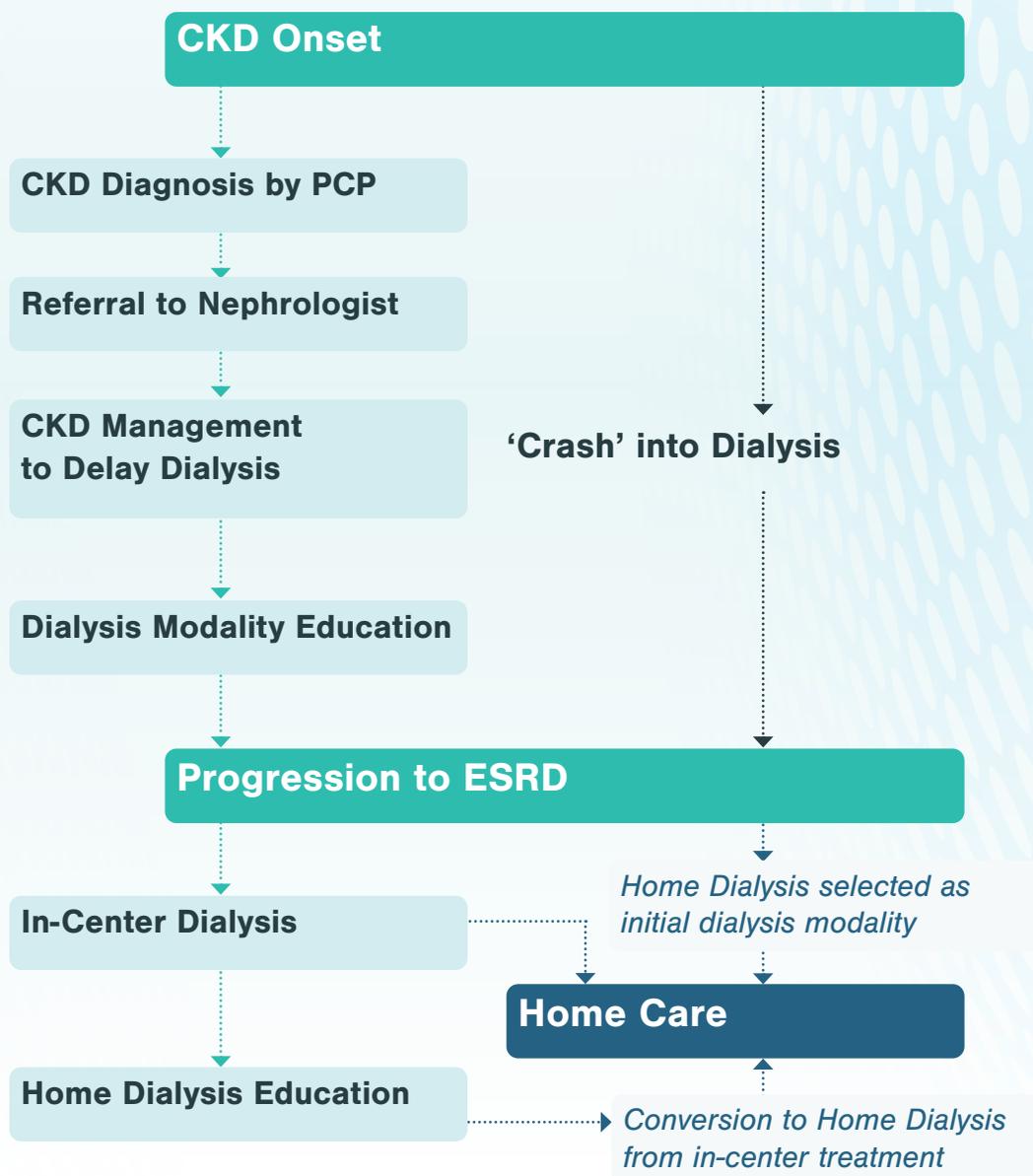
⁵ *Nephrology News & Issues*

Transforming the Patient Care Pathway

As lower entry costs lead to greater market fragmentation, innovative new care providers are beginning to capture patient share earlier in the patient care pathway, circumventing competitive barriers imposed by incumbents. Major dialysis organizations rely on close ties with nephrologists to capture a steady stream of patient referrals in the conventional pathway. Most chronic kidney disease (CKD) patients are diagnosed by their primary care provider. These primary care providers then refer those patients to a nephrologist who helps them manage their CKD, educates them about dialysis modalities, and, if necessary, guides them on their transition to chronic dialysis treatment. While some nephrologists operate independent dialysis treatment programs, most refer patients to their affiliated dialysis organization.

The Dialysis Pathway

■ Required step
 ■ Step included in most common patient pathway
 ■ Step not included in most common patient pathway



Identifying patients at risk of developing ESRD is the best way to grow the patient population and make space for home dialysis. Accelerated home care adoption, combined with a growing emphasis on building holistic patient care models, will enable innovative healthcare providers to insert themselves upstream of nephrologists and capture patients before they are referred to established dialysis organizations. Prominent players like CVS and startups like Cricket Health, Strive Health, and Monogram Health, are disrupting the status quo by leveraging patient data and predictive analytics to preemptively identify patients at risk of developing ESRD. As the adoption of value-based kidney care grows, population health, care coordination, and patient engagement platforms will play an increasingly important role for payers, risk-bearing entities, and home dialysis companies.

Preemptively identifying these patients solves two significant obstacles to home dialysis: a lack of CKD awareness and a lack of time and education.

LACK OF CKD AWARENESS

Of all US patients with stage 3 CKD or higher, only ~21% are aware of their condition. These patients often don't get medical help until they present symptoms, by which point they have already begun the progression to ESRD. Some patients remain undiagnosed until they develop ESRD. Estimates vary, but most nephrologists report that this population represents about 40% of dialysis patients. These patients invariably require in-center treatment to start, after which point it is highly unlikely that they will convert to home therapy.

LACK OF PATIENTS' TIME AND EDUCATION

Many patients don't have the time they need to learn about dialysis options before they progress to ESRD. Patients who have more time to learn about modality options before beginning dialysis are more likely to choose home care. As a result, identifying patients earlier will be critical to increasing home dialysis adoption.

Starting the identification process earlier, raising awareness of CKD and ESRD would grow the patient pool, enable faster home dialysis adoption, and ultimately save lives.



Key Considerations for Device Manufacturers

Provider disruption due to home dialysis opens the door to enter a previously cornered market. Although the ETC Model reduces barriers to home dialysis, meaningful market changes in the dialysis space won't happen overnight. A transition to home therapy will require advancements in predictive diagnostics, improved telehealth technologies, and updated regulatory guidelines, all of which will take several years. Existing dependence on in-center treatment and traditional diagnostic pathways will likely persist until then.

Device manufacturers developing innovative home dialysis technologies must develop a strategic roadmap that allows them to capture a share of the near-term opportunity while also adapting to long-term trends. There are several factors device manufacturers must consider as they create these strategies, including potential challenges and differentiation opportunities.

Creating a Strategy for the Future

NEAR-TERM STRATEGIES



Device manufacturers interested in entering the market should tailor their strategy to fit existing market structures, which will require them to sell their devices to and partner with dialysis organizations.

- Dialysis organizations, which are under pressure to increase adoption, will be eager to adopt new technologies that attract a new demographic of patients
- The projected concentration of opportunity (within DaVita and medium dialysis organizations (MDOs)) will likely result in intense competitive pressure among device manufacturers to capture share within these large accounts or possibly develop exclusive partnerships with them

LONG-TERM STRATEGIES



Over the long-term, adoption of home dialysis and upstream patient care are expected to disrupt existing consolidation.

- Reduced entry costs in the home dialysis market will correspond to reduced potential for defensibility, decreasing the likelihood that the market becomes dominated by a concentrated number of prominent players
- Increased fragmentation and competition will benefit manufacturers trying to enter the space, allowing them to recapture pricing power

Key Home Dialysis Market Entry Challenges

INFRASTRUCTURE REQUIREMENTS



There is a need for investment into infrastructure for both near-term and long-term market entry strategies.

- Those entering the market must invest in partnerships with existing infrastructure in the short term
- Long-term plans must include the change in distribution requirements due to the transition to home therapies
- Machines and consumables delivered to each patient's home will increase operational complexity and costs. This is particularly challenging for peritoneal dialysis (PD) device manufacturers, who need to regularly ship high volumes of dialysate bags to patients due to the higher amount of dialysate fluid needed for a typical PD patient

INCREASED NEED FOR DEVICE SUPPORT SERVICES



With equipment distributed across the country to patients' homes, more elaborate networks of customer support services are required.

- Support service strategies must include remote device support
- If support services can't resolve issues remotely, they must repair or replace malfunctioning machines quickly to ensure treatment continuity
- The size and portability of machines are critical in determining the resource requirements of a manufacturer's repair fleet
- Organizations need a dense network of technicians who can quickly respond to interruptions from larger devices that a delivery driver cannot easily replace
- Smaller devices can be easily replaced with repairs at a centralized repair site. This shift produces operational cost efficiencies while creating a better customer experience and care continuity

Key Differentiators in the Home Dialysis Market

TECHNOLOGY INNOVATIONS



As dialysis and dialysis-related technology continue to evolve, companies must stay on the cutting-edge to differentiate themselves.

- The top priority is increased portability, making it easier for patients to receive dialysis with minimal interruption
- One step in achieving this near-term is prioritizing sorbent filters, which dramatically reduce total dialysis fluid volume and make portability possible
- Eventually, artificial kidneys will be the next step for those with CKD, but these technologies are still early-stage prototypes
- Once artificial kidneys enter the market, regular dialysis treatments will be rendered obsolete
- Partnering with remote monitoring software solutions, like Baxter Renal Care's Sharesource, empowers providers to closely monitor a patient's care and ensures the quality of care doesn't decline compared to in-treatment center care

ENHANCED PATIENT EXPERIENCE



Home dialysis provides patients with a high standard of care, and expanding on the improved patient experience is the most significant opportunity to differentiate.

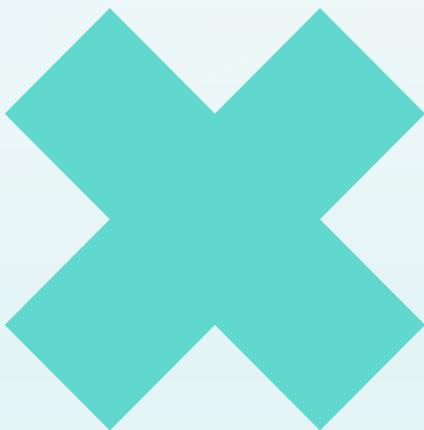
- Device companies prioritizing the following will see huge returns:
 - Lower storage requirements
 - Easier-to-use and intuitive machines
 - Better patient support
 - Remote management and service offerings
 - Streamlined ordering
- One step in achieving this near-term is prioritizing sorbent filters, which dramatically reduce total dialysis fluid volume and make portability possible
- Patients often doubt their ability to manage their care and perceive home therapies as unpleasant care experiences
- Care providers can overcome this barrier and increase both adoption and adherence with innovative, patient-friendly technologies
- Manufacturers can develop more holistic care models to boost adoption and mitigate patient burnout

Moving Forward

The US dialysis market is evolving. The combination of policies incentivizing home dialysis and new technological innovations creates opportunities for device manufacturers to enter the dialysis market. Despite the challenges of the evolving landscape, device manufacturers who act swiftly and differentiate themselves with user-friendly technology and a focus on patient care can gain share in this previously impenetrable market.

How Kx Can Help

With our expertise in [corporate strategy](#), [medical device](#), and [digital health](#) experience, Kx Advisors can guide your strategy team through entering the home dialysis market. Our experts will evaluate the competitive landscape, identify key market trends, create a market entry strategy to grow market share, and position your organization for long-term success.



About Kx

For more than 40 years, Kx Advisors (operating as Kaiser Associates' healthcare practice) has provided strategy consulting services to help healthcare executives achieve critical business growth goals. With a highly collaborative approach they have developed pragmatic solutions for leading pharmaceutical, biotechnology, medical device, health IT, and digital health clients, with data-driven insights to give those clients the tools to compete and win across the healthcare industry.

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