



A New Approach to Kidney Health:

How Payers Can Improve Outcomes with Smartphone-Powered Kidney Testing

Table of Contents

Executive Summary	3
The Prevalence of CKD in the United States	5
Early Detection and Clinical Guidelines for Testing	9
Low Adherence and Widening Care Gaps	12
The Smartphone as a Medical Device	15
Improving Outcomes, Reducing Cost of Care	18
Sources	21
About Healthy.io	22





Executive Summary

Executive Summary

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

Sources

A simple urine test can provide an early warning for chronic kidney disease during the stages where the disease is otherwise asymptomatic. But despite clear clinical recommendations, the albumin-to-creatinine ratio (ACR) test rates for at-risk people are as low as 20% on average. As a result, millions of Americans with a costly and potentially fatal disease slip through the cracks, missing the opportunity for early, life-saving interventions.

The reasons for low ACR testing adherence range from a lack of awareness of its importance to patient discomfort with urine samples. To solve those problems and improve access to care, Healthy.io introduced the CKD Early Detection Service,* allowing people to test comfortably from their homes using a test kit and smartphone app.

In a clinical evaluation done in partnership with Geisinger primary care clinics in Pennsylvania and the National Kidney Foundation, the service raised compliance from 0% to 71% among people with hypertension who had never undergone urine testing for CKD and consented to participate in the evaluation.

The service's potential impact for health plans is substantial, due to the significant reduction in total cost of care and more accurate risk scoring. According to an external actuarial evaluation based on medical and pharmacy claims data by Optum, representing 4.9 million members managed under Medicare Advantage and 12.7 million members managed under commercial plans, payers deploying the CKD Early Detection Service can yield a net gain of \$708 per identified Medicare Advantage member over three years and a positive return on investment per member within two years.

Imminent changes to national quality metrics also provide a strong incentive for early ACR testing. The high level of patient satisfaction with the service is especially noteworthy ahead of the planned substantial increase to the weight of patient experience measures in Star Ratings, with patient experience expected to account for almost a third of plans' overall Star Ratings by 2023.

* FDA-cleared for professional use. Home-testing device is currently limited to investigational use in the United States.



**The Prevalence of CKD
in the United States**

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

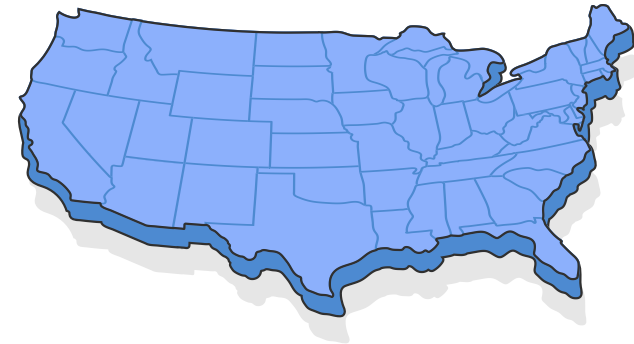
Improving Outcomes, Reducing Cost of Care

Sources

The Prevalence of CKD in the United States

In the face of the endless stream of healthcare news, it is easy to lose sight of an astonishing fact: the majority of American adults suffer from at least one chronic disease. Four out of 10 American adults have two or more chronic conditions.¹ These conditions stem from the realities and risks of contemporary life, such as poor nutrition, sedentary habits, alcohol and tobacco use. Thus, even among the members of the healthy minority, virtually all are at risk for such “lifestyle diseases.”

That chronic kidney disease is one of the lesser known chronic conditions stands in stark contrast with its prevalence. Many people are undoubtedly familiar with kidney failure, which requires dialysis or transplant, but relatively few know that it is often the culmination of years of largely asymptomatic—yet progressively worsening—kidney disease. Over the course of those years, early interventions can be made to stave off the progression of the disease—or even prevent it entirely. Untreated cases that progress to kidney failure face the prospects of a five-year mortality rate that is 50% worse than that of most cancers.²



80 million

American adults are at risk for CKD.

37 million

already have it.

90%

don't know they have it.*

CKD Prevalence by Age



25%
ages 60-69

45%
70 and older**

* National Kidney Foundation.

** Coresh J, Selvin E, Stevens LA, et al. Prevalence of chronic kidney disease in the United States. JAMA 2007; 298:2038.

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

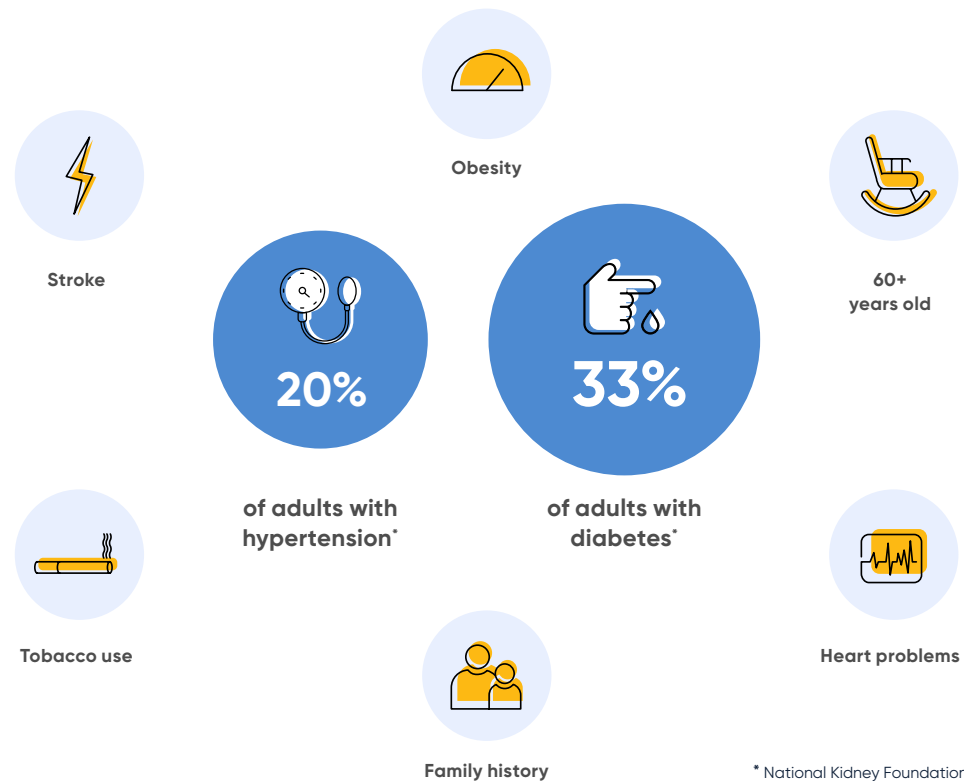
Sources

The Prevalence of CKD in the United States

A landmark study in 2007 found that the prevalence of CKD in the United States had increased substantially between 1988 and 2004.³ Even though prevalence has stabilized somewhat in the intervening years, the aging of the population translates directly into a greater burden of disease,

because the two main risk factors associated with CKD—diabetes and hypertension—get worse with age. Additionally, minorities and socially and economically disadvantaged people have higher rates of disease, which are exacerbated by the barriers to care facing them.

CKD Risk Factors



Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

Sources

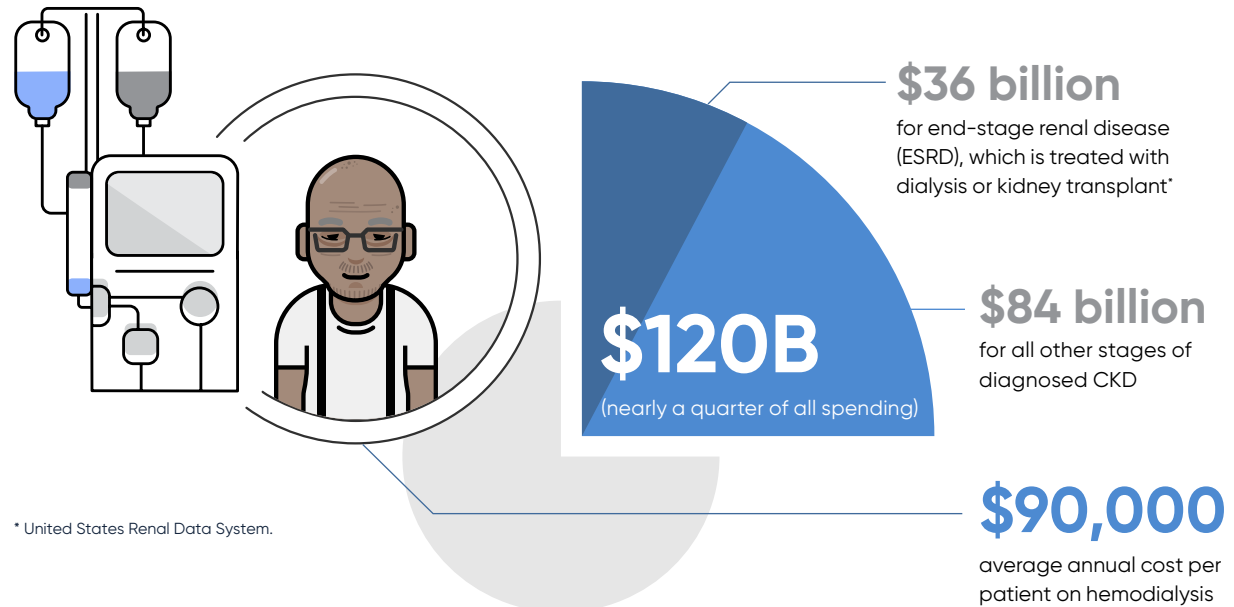
The Prevalence of CKD in the United States

The Financial Burden

The treatment of chronic kidney disease costs Medicare over \$120 billion dollars every year—nearly a quarter of Medicare spending. End stage renal disease (ESRD) alone costs \$36 billion, despite the fact that less than 1% of Medicare beneficiaries have ESRD—the final stage of CKD. Managing all other stages of CKD costs another \$84 billion annually (including comorbidities such as cardiovascular disease).

Because the cost of treating CKD rises as the disease progresses, preventing such progression is vital to cutting costs. As the United States Renal Data System noted in a recent report:

*"The analysis of expenses for beneficiaries with CKD indicates the effect of cost-containment efforts in this population, and avenues for potential savings. Reduction in expenditures could be achieved through the prevention of disease progression to later stages of CKD, and prevention of the development of concurrent chronic conditions such as diabetes and heart failure."*⁴



A photograph of an elderly woman with short, white hair, smiling broadly. She is wearing a light gray t-shirt and holding a glass of milk. The background is a soft-focus indoor setting with a blue couch and a light-colored wall. A large blue circular graphic is overlaid on the left side of the image.

Early Detection and Clinical Guidelines for Testing

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

Sources

Early Detection and Clinical Guidelines for Testing

Detecting chronic kidney disease in its earlier stages allows for medical and lifestyle interventions that can slow the progress of the disease, thus reducing the incidence of kidney failure and the associated cardiovascular disease. Patients can be given the tools to optimize their diabetes or high blood pressure, as applicable, with positive outcomes for their kidney disease and cardiovascular system. Innovative new treatments can be deployed to target CKD directly. In particular, recent research suggests that sodium-glucose cotransporter 2 inhibitors (SGLT-2) play a role in reducing the risk of kidney disease progression and the incidence of cardiovascular disease, particularly when administered to patients in the early stages of CKD.⁵

But other benefits of early detection are also substantial and often overlooked. Treatment of CKD can also be individually optimized to prevent and combat the web of complications and comorbidities associated with the disease, which in turn are associated with other corollaries—everything from cardiovascular disease to stroke and anemia. These risks are multiplied by kidney dysfunction even for those who never progress to kidney failure.

eGFR and ACR Testing

Effective detection of CKD takes a risk stratification approach, entailing the annual screening of those most at risk of developing the disease—chiefly people with diabetes and hypertension—and deciding on further treatment based on the results. Expert organizations such as the National Kidney Foundation and KDIGO recommend that at-risk groups be screened using both the estimated glomerular filtration rate (eGFR) and albuminuria, by measuring their albumin to creatinine ratio (ACR).



“I think there are huge benefits for early detection. You can do some good at every stage. But the earlier stages where kidney function is intact, especially if you have damage due to albuminuria detected with protein in the urine, that is the reversible part of the disease. Later on in the disease, you lose glomeruli—the filtering units in the kidney—and that loss is irreversible. At that point, you can slow down further loss, slow down further damage. That’s why the staging is by both criteria, albuminuria and GFR.”

Dr. Josef Coresh, G.W. Comstock Professor of Epidemiology, Biostatistics & Medicine at Johns Hopkins University

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

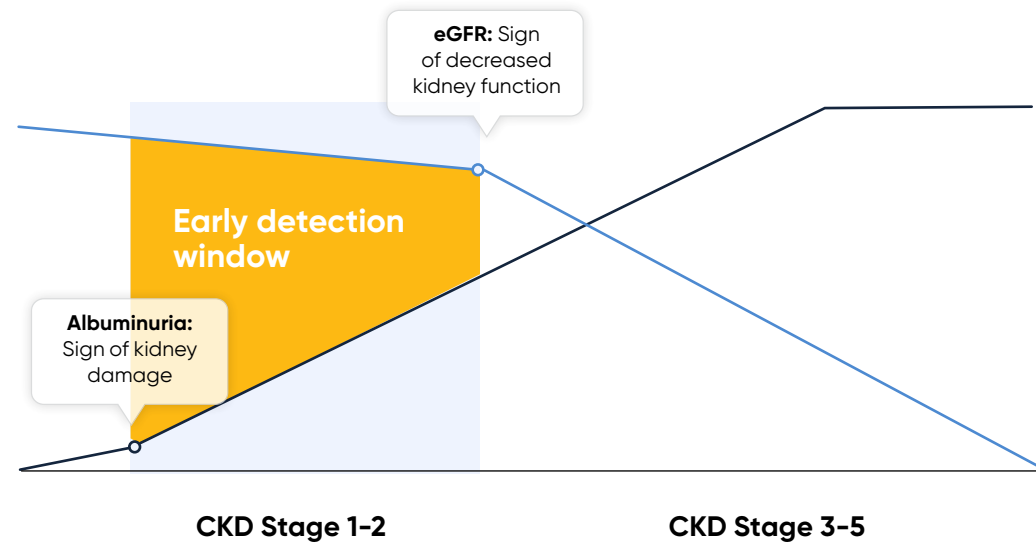
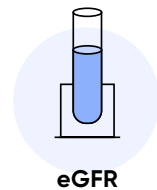
Sources

Early Detection and Clinical Guidelines for Testing

eGFR and ACR are complementary in that they provide indications of CKD at its different stages; the combination of the two measures can give an accurate risk score for the patient. eGFR, which is obtained via a blood test, reflects kidney function, which starts to decline after the kidneys can no longer adequately

compensate for structural damage and thus does not detect kidney damage in its earlier stages. ACR, obtained via a urine test, measures kidney damage directly and provides a strong early marker of CKD, allowing for early intervention and management.

Albuminuria: Key Indicator for CKD Early Detection





The Adherence Problem

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps



The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

Sources

The Adherence Problem

Despite the clear clinical recommendations, ACR testing rates for at-risk people are as low as 20% on a weighted average. In 2017, only 42.2% of Medicare patients with diabetes, and just 6.8% of those with hypertension, had their urine tested for ACR.⁶

The sharp divide between clinical guidelines and actual testing is accentuated by a new HEDIS quality metric that stipulates that people with diabetes should have both their eGFR and ACR measurements checked annually. Because of the low rate of ACR testing, current average performance could drop from 85% to 49% under the new metric.

The very low rate of ACR testing for people with hypertension is particularly noteworthy because high blood pressure is an independent risk factor for CKD and CVD, with similar adverse outcomes to diabetes once the end organ damage begins.⁷ The relative lack of screening may stem from past recommendations not being as clear about the benefits of testing hypertensive populations—especially compared to people with diabetes—but contemporary clinical evidence and multiple society guidelines make a compelling case for parity in screening.

Barriers to Testing

There are multiple reasons for the low rates of ACR testing. Unlike eGFR, which can be measured as part of a routine blood test, ACR requires a urine sample that isn't as comfortable or convenient to provide during a visit to the lab. And the general awareness of its importance—among clinicians and patients alike—is lower.

“Urine requires a different kind of specimen and facilities. And so it takes a little more time and awareness. We know that awareness of kidney disease and awareness of albuminuria as a risk factor are lower.”

Dr. Josef Coresh



Executive Summary

The Prevalence of CKD
in the United States

Early Detection and
Clinical Guidelines
for Testing

**Low Adherence and
Widening Care Gaps**



The Smartphone as a
Medical Device

Improving Outcomes,
Reducing Cost of Care

Sources

The Adherence Problem

Additional widespread factors amount to barriers to care that oftentimes make a visit to the lab difficult if not near impossible. Patients may belong to the 3.6 million Americans that do not receive medical care because they do not own a vehicle, lack the funds for transportation, or have a disability that limits their mobility.⁸ Or they may live in rural communities, where quality care is often hard to access—and rates of mortality and chronic conditions are markedly higher.⁹

Other factors are behavioral. The same unhealthy habits so conducive to chronic conditions can also keep people from seeking medical care. Some opt to stay home for fear of hearing unpleasant news.¹⁰ In the face of the global pandemic, many of the people most vulnerable to chronic conditions now also face a well-founded fear of contracting COVID-19, in many cases delaying or canceling medical appointments.¹¹

Without bypassing those barriers, adherence to ACR testing is sure to remain low, further contributing to an already heavy healthcare burden. But the barriers to testing also suggest the contours of a solution: one that avoids the problems of distance and transportation, allowing people to test safely and comfortably at home.





The Smartphone as a Medical Device

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

Sources

The Smartphone as a Medical Device

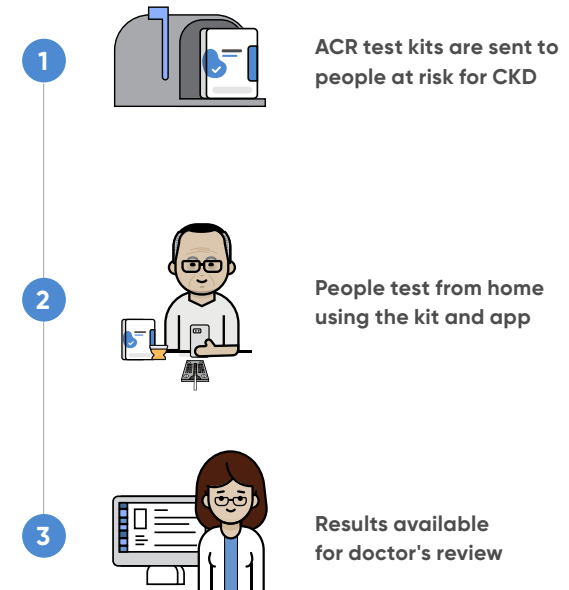
Technology has long had an important role in making healthcare more accessible, and patients have slowly warmed to new digital methods. But by erecting new barriers to care across virtually all swaths of the population, the coronavirus pandemic paved the way for rapid widespread acceptance of digital innovation. In particular, appointments that would otherwise have been held in person quickly shifted to remote online platforms. Yet the potential of remote care goes far beyond videoconferencing.

The vast majority of patients have easy access to a cutting-edge tool that can also serve as a clinical-grade medical device. The ubiquity of the smartphone—and especially its camera—makes it by far the leading candidate to improve access to care, just as it has transformed the ways that people travel, shop, eat, and listen to music.

“Using technology effectively, in partnership with physicians—it’s quite exciting. Tools like Healthy.io’s bring the technology of cameras that are very sophisticated and can do a lot more than just take a selfie.”

Dr. Josef Coresh

Healthy.io’s Kidney Check* obviates the need to administer ACR tests at the clinic to everyone at risk for the disease—the central barrier to testing today. Instead, people receive a simple test kit in their mailbox. They perform the test from the convenience of their homes, and scan it with a smartphone app, making the results available immediately. Those who still haven’t done the test receive a helpful reminder or two.



* FDA-cleared for professional use. Home-testing device is currently limited to investigational use in the United States.

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

Sources

The Smartphone as a Medical Device

In a clinical evaluation in partnership with Geisinger primary care clinics in Pennsylvania, and with funding by the National Kidney Foundation, the service raised compliance from 0% to 71% among people with hypertension who had never undergone urine testing for CKD and consented to participate in the evaluation. 89% of those surveyed preferred testing at home to testing at a clinic.¹² A similar increase in testing compliance was achieved in a clinical evaluation in cooperation with Modality Partnership clinics in the United Kingdom.¹³

Many of the men and women who discover early signs of CKD thanks to the Early Detection Service would most likely otherwise find out that they have the disease at later and more dangerous stages. There are

the cases—sometimes even the majority of cases—that fall through the cracks today.

The impact of this new approach begins on the individual level. Patient activation through "nudges" and reminders, coupled with accessibility, convenience, and ease of use, can significantly raise testing rates among groups where testing is historically low.





**Improving Outcomes,
Reducing Cost of Care**

Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

Sources

Improving Outcomes, Reducing Cost of Care

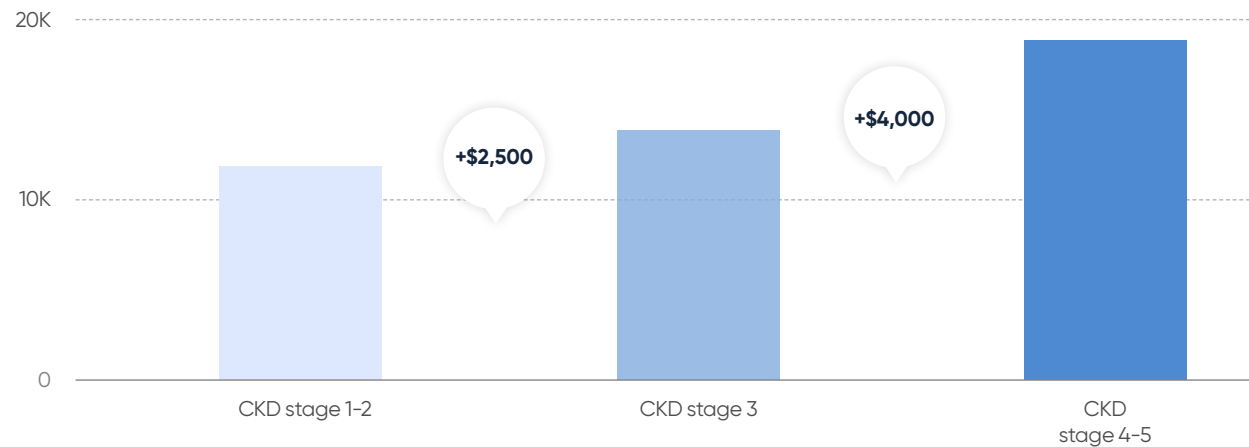
On a systemic level, the financial outcomes are no less impactful, according to an external actuarial evaluation based on medical and pharmacy claims data by Optum. The evaluation, representing 4.9 million members managed under Medicare Advantage and 12.7 million members managed under commercial plans, demonstrates that payers deploying the CKD Early Detection Service can yield a net gain of \$708 per identified Medicare Advantage member over three

years and a positive return on investment per member within two years. Net gain is calculated assuming proper management and treatment of the disease after diagnosis.

Such gains owe to the early interventions enabled by early detection, which significantly impact the total cost of care as progression is avoided.



Total cost of care reduction Significant reduction in TCC by avoiding progression



Executive Summary

The Prevalence of CKD
in the United States

Early Detection and
Clinical Guidelines
for Testing

Low Adherence and
Widening Care Gaps

The Smartphone as a
Medical Device

**Improving Outcomes,
Reducing Cost of Care**



Sources

Improving Outcomes, Reducing Cost of Care

Improved risk scoring also contributes to savings. Low ACR testing rates lead to a significant number of members with diabetes receiving inaccurate HCC codes—the codes that estimate each member’s risk and anticipated future healthcare costs. Such patients are classified as having no complication, leading to miscalculations of the risk and severity of their condition and the associated cost. The proper detection of previously undiagnosed cases allows for more accurate risk scoring and better financial planning for patients’ future course of care—contributing directly to the return on investment.

Imminent changes to quality metrics also provide a strong incentive for early ACR testing. The high level of patient satisfaction with the CKD Early Detection Service is especially noteworthy ahead of the

planned substantial increase to the weight of patient experience measures in Star Ratings, with patient experience expected to account for almost a third of plans’ overall Star Ratings by 2023.¹⁴

To be sure, chronic kidney disease is a heavy burden on society and healthcare systems. But owing to the lifesaving possibilities afforded by early detection, CKD presents a valuable opportunity to dramatically improve patients’ health and reduce expenditures.



Executive Summary

The Prevalence of CKD in the United States

Early Detection and Clinical Guidelines for Testing

Low Adherence and Widening Care Gaps

The Smartphone as a Medical Device

Improving Outcomes, Reducing Cost of Care

Sources



Sources

1. Chronic Diseases in America, Centers for Disease Control and Prevention.
2. Vassalotti, Joseph A., and Sumeska Thavarajah. "Combined Albuminuria and Estimated GFR Laboratory Reporting Affects Primary Care Management of CKD." *Kidney Medicine* 2.3 (2020): 235.
3. Coresh J, Selvin E, Stevens LA, Manzi J, Kusek JW, Eggers P, Van Lente F, Levey AS. Prevalence of chronic kidney disease in the United States. *JAMA*. 2007 Nov 7;298(17): 2038-47.
4. US Renal Data System 2019 Annual Data Report: Epidemiology of Kidney Disease in the United States.
5. Perkovic, Vlado, et al. "Canagliflozin and renal outcomes in type 2 diabetes and nephropathy." *New England Journal of Medicine* 380.24 (2019): 2295-2306.
6. US Renal Data System 2019 Annual Data Report: Epidemiology of Kidney Disease in the United States
7. Matsushita, K., Coresh, J., Sang, Y., Chalmers, J., Fox, C., Guallar, E., ... & Roderick, P. (2015). Estimated glomerular filtration rate and albuminuria for prediction of cardiovascular outcomes: a collaborative meta-analysis of individual participant data. *The Lancet Diabetes & Endocrinology*, 3(7), 514-525.
8. Transportation and the Role of Hospitals. American Hospital Association.
9. Disparities between care in rural, urban areas getting worse. Rebecca Pifer. Healthcare Dive.
10. The Fear of Finding Out. 2020health.
11. More than Half of Older Adults Already Experiencing Disruptions in Care as a Result of Coronavirus. NORC at the University of Chicago.
12. Leddy J, Green JA, Yule C, Molecavage J, Coresh J, Chang AR. Improving proteinuria screening with mailed smartphone urinalysis testing in previously unscreened patients with hypertension: a randomized controlled trial. *BMC Nephrol*. 2019 Apr 18;20(1):132. doi: 10.1186/s12882-019-1324-z. PMID: 30999886; PMCID: PMC6471866.
13. Shore, Judith, et al. "The compliance and cost-effectiveness of smartphone urinalysis albumin screening for people with diabetes in England." *Expert review of pharmacoeconomics & outcomes research* 20.4 (2020): 387-395.
14. Star Ratings Take Aim at Member Experience in 'Huge' Shift, Gorman Health Group Blog.

About Healthy.io

Healthy.io delivers healthcare at the speed of life. Using image and color recognition technology, we transform the smartphone camera into a medical device to provide clinical results at moments when it matters most. Our at-home urinalysis and digital wound management services create new clinical pathways and streamline existing ones to benefit patients and providers alike. Healthy.io was selected as one of Fast Company's Top 50 Most Innovative Companies for 2020 and won the Financial Times Boldness in Business Award.

Founded in **2013**

150 employees

Offices in **Boston (US), London (UK) and Tel Aviv (Israel)**

Serves over **500,000 patients worldwide**

Partnerships with the **NKF, NHS England, leading Israeli HMOs, and Walgreens Boots Alliance**, among others

NKF Partners

"This new test has the potential to help millions of patients find out they have CKD while there is still time to prevent progression to kidney failure."

Kerry Willis, PhD, Chief Scientific Officer,
National Kidney Foundation



Receive a free ROI report for your health plan, including a breakdown of your at-risk population and cost-effectiveness analysis

[Request your free ROI report](#)