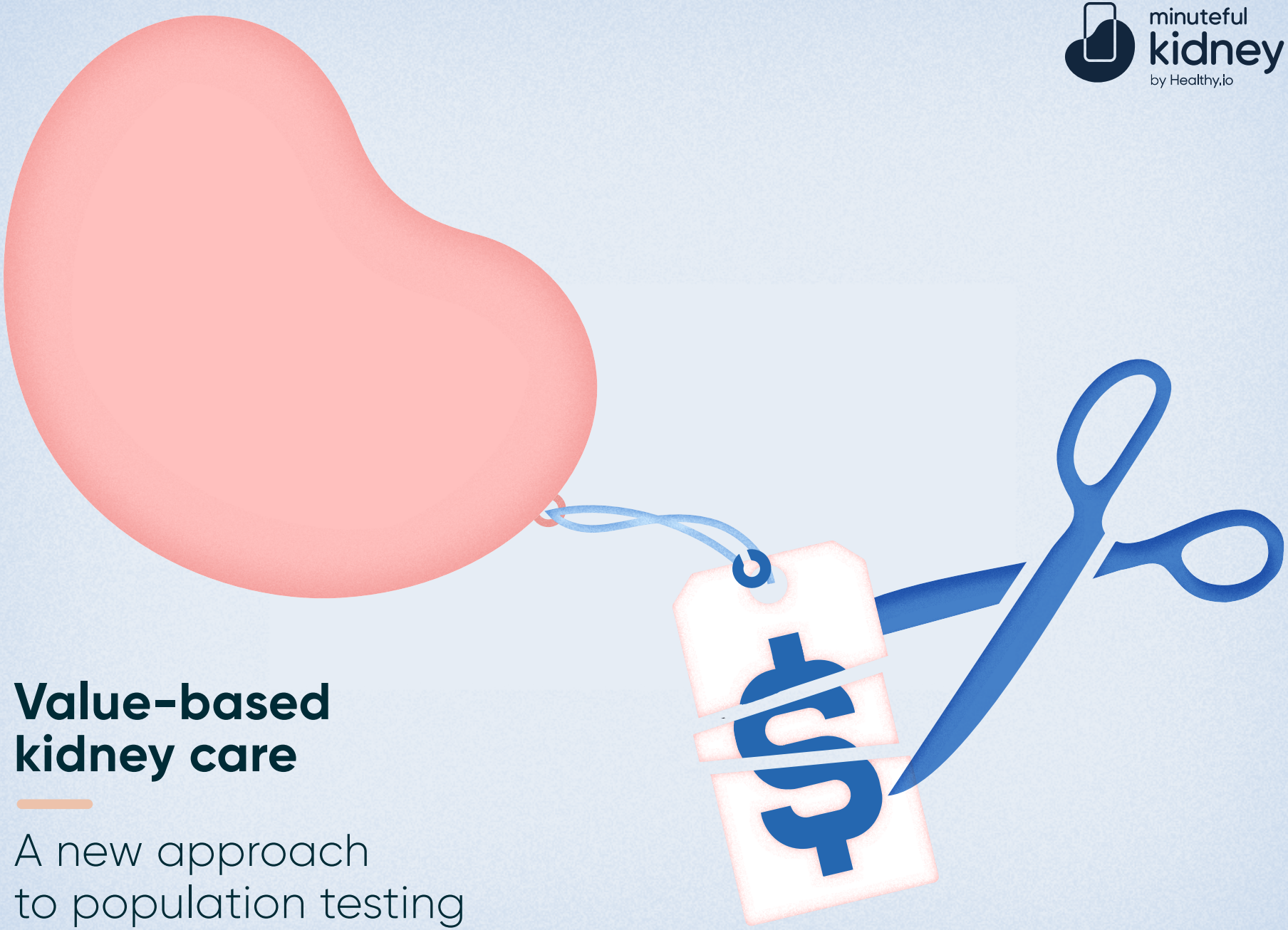
minuteful kidney
by Healthy.io



Value-based kidney care

A new approach to population testing

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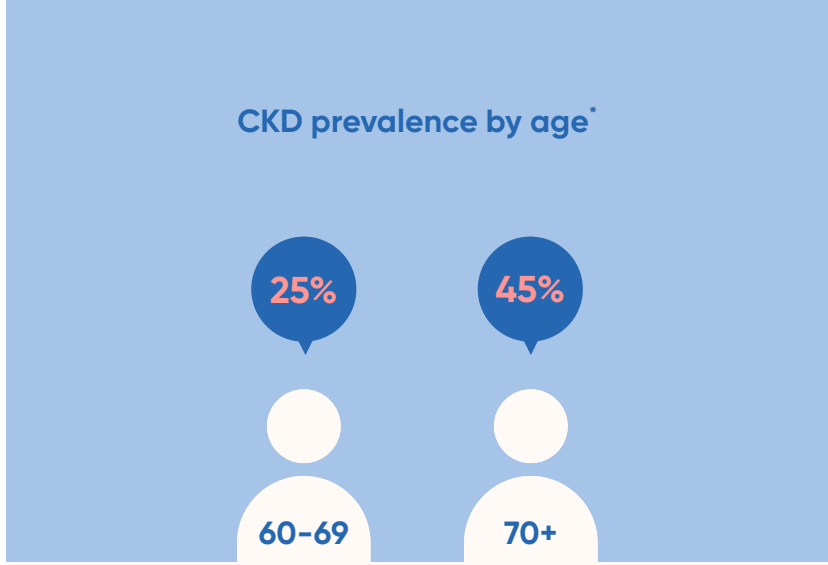
Smartphone-powered kidney testing

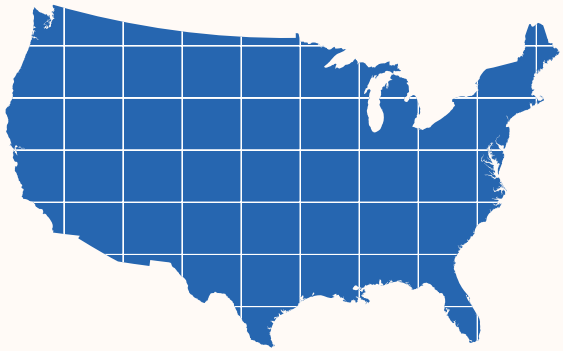
CKD prevalence and the awareness gap

A simple urine test can provide an early warning for chronic kidney disease (CKD) before it becomes symptomatic. But despite clear clinical recommendations, the albumin-to-creatinine ratio (ACR) test rates for people at-risk —primarily those with diabetes or hypertension—are as low as 20% on average.

Low adherence to testing is especially problematic because of the high prevalence of CKD. Millions of Americans with this potentially fatal disease slip through the cracks, missing the opportunity for early, life-saving interventions. The lack of early detection also contributes to the astronomical cost of care: treating CKD costs Medicare over $120 billion dollars every year—nearly a quarter of all Medicare spending.

This white paper examines why ACR is a critical data point for proper risk stratification and management of CKD, and current clinical gaps. It also discusses how smartphone-powered home testing can improve outcomes and reduce the cost of care.





120 billion
medicare spend a year.

37 million
already have it.

90%
don't know they have it.**

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

** National Kidney Foundation.

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Clinical gaps in CKD testing and management

Early Detection

Detecting chronic kidney disease in its earlier stages, using evidence-based disease markers, allows for risk stratification and targeted medical and lifestyle interventions that can slow the progression of the disease. By doing so, it can reduce the incidence of kidney failure, which potentially necessitates dialysis or transplant, and the associated risk of cardiovascular disease (CVD). Members can be given the tools to optimize their risk factors, such as diabetes or high blood pressure.

Today, the risk of CKD can be reduced and the condition can be managed. Clinicians can deploy innovative treatments to target CKD directly. In particular, recent research demonstrates that sodium-glucose cotransporter 2 (SGLT-2) inhibitors help reduce the risk of kidney disease progression and the incidence of CVD, particularly when given to members in the early stages of CKD.[1]

Early detection has additional, substantial benefits: treatment of CKD can also prevent and combat the web of complications and comorbidities associated with the disease—everything from CVD to stroke and anemia. These risks are present even at early stages of kidney damage.

[1] Perkovic, Vlado, et al. "Canagliflozin and renal outcomes in type 2 diabetes and nephropathy." New England Journal of Medicine 380.24 (2019): 2295-2306.

Clinical Guidelines

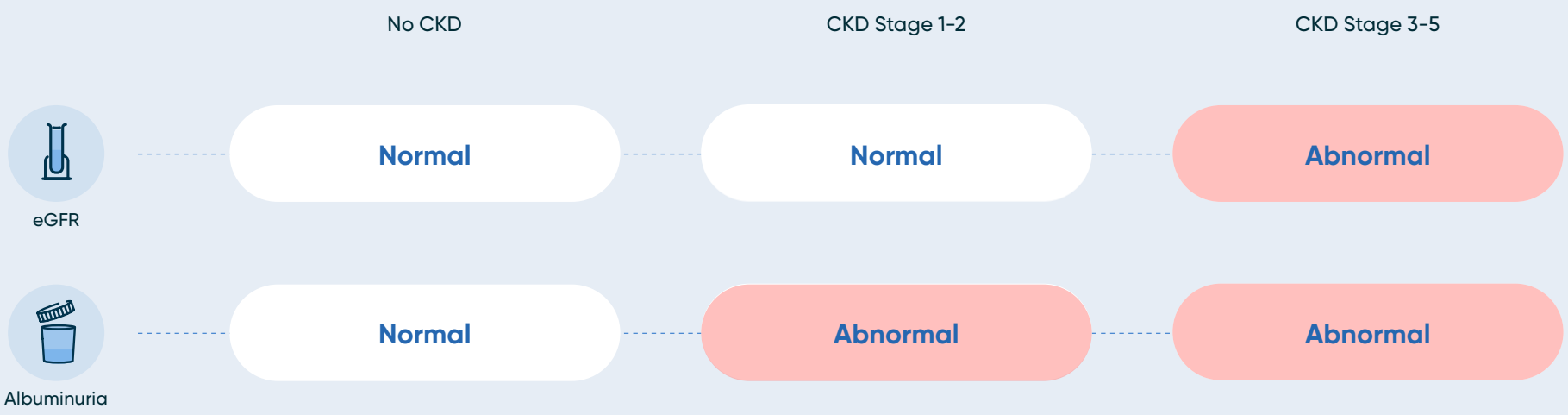
Effective management of CKD requires accurate risk stratification based on annual testing of those most at risk of developing the disease—primarily people with diabetes and hypertension—and treatment guided by the results.

According to clinical recommendations, at-risk groups should be tested using both the estimated glomerular filtration rate (eGFR) and albumin to creatinine ratio (ACR).

eGFR and ACR are complementary in that they provide indications of CKD at its different stages;

uACR allows for earlier detection of CKD, since elevated levels of Albumin are detectable from stages 1 and on. Unlike eGFR that detects signs of damage typically from stages 3 and on. the combination of the two measures can give an accurate risk level for the member based off of international standards set forth by the KDIGO working group and accepted by national guidelines bodies such as the ADA, NKF, AAFP, ACP.

ACR Identifies CKD Earlier Than eGFR



eGFR, which is obtained via a blood test, reflects kidney function. In the early stages of CKD, kidneys sustain structural damage but can compensate and function normally. Only in the later stages of the disease, when the kidneys can no longer adequately compensate for structural damage, does kidney function begin to decline in a manner reflected by eGFR.

ACR, obtained via a urine test, measures kidney damage directly and provides a strong early marker of CKD, allowing for early intervention and management. Additionally, it serves as an important early risk predictor of CVD.

Despite clinical recommendations, ACR testing rates for people at risk are as low as 20% on a weighted average.



“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, you lose glomeruli—the filtering units in the kidney—and that loss is irreversible. 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

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Barriers to Testing

Multiple factors contribute to 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 is not typically provided during a lab visit. Awareness of its importance—among clinicians and patients alike—is lower. Risks are further amplified across minority populations due to health disparities, with Black Americans almost four times as likely as their white counterparts to develop kidney failure.

A visit is difficult for any of the millions of Americans who cannot access medical care because they do not own a vehicle, lack funds for transportation, or have a mobility-limiting disability.[2] They may live in rural communities, where rates of mortality and chronic conditions are markedly higher.[3] While some services allow people to collect a urine sample at home and mail it to the lab, those raise a host of privacy concerns and don't allow for quick results.

Without bypassing those barriers, adherence to ACR testing is sure to remain low, contributing to an already heavy healthcare burden. The solution lies in enabling people to test at home.

[2] Transportation and the Role of Hospitals. American Hospital Association.

[3] Disparities between care in rural, urban areas getting worse. Rebecca Pifer. Healthcare Dive.



"Urine requires a different kind of specimen and you need a different kind of facility. And so it takes a little more time. It takes a little bit more awareness. And we know that awareness of kidney disease and awareness of albuminuria as a risk factor are lower."

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

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Smartphone-Powered Kidney Testing

Healthy.io's Minuteful Kidney is the first and only FDA-cleared smartphone-powered kidney test. It solves the problem of low adherence to ACR testing and improves access to care by allowing people to test comfortably from their homes using a test kit and smartphone app. Results are available immediately. Minuteful Kidney is compatible across all smartphone devices, ensuring accessibility for the 85% of American households with a smartphone device.



Shift testing from the lab to the home



01

ACR test kits are sent to people at risk for CKD



02

People test from home using the kit and app



03

Results available for doctor's review

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Raising Adherence, Improving Outcomes

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

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. 89% of those surveyed preferred testing at home to testing at a clinic.[4]

With Minuteful Kidney, many can now discover early signs of the disease while there is still time to stop the progression, instead of finding out that they have the disease at later and more dangerous stages. Theirs are the cases that fall through the cracks today.

[4] Survey Report: Transforming the Member Experience with At-Home Kidney Testing.

Tens of thousands of health plan members have already used Minuteful Kidney to test themselves for signs of CKD.

50% up to 50% test completion in untested populations

>40% of completed tests reveal abnormal or high abnormal results

94% members surveyed prefer testing at home

99.5% usability success among patients aged 18-81

97% of members surveyed reported a positive experience using the test[5]

Financial Outcomes for Health Plans

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,* plans deploying our at-home kidney test can yield a positive return on investment per member within two years. Net gain is calculated assuming proper management and treatment of the disease after diagnosis.

*Representing 4.9 million members managed under Medicare Advantage and 12.7 million members managed under commercial plans.

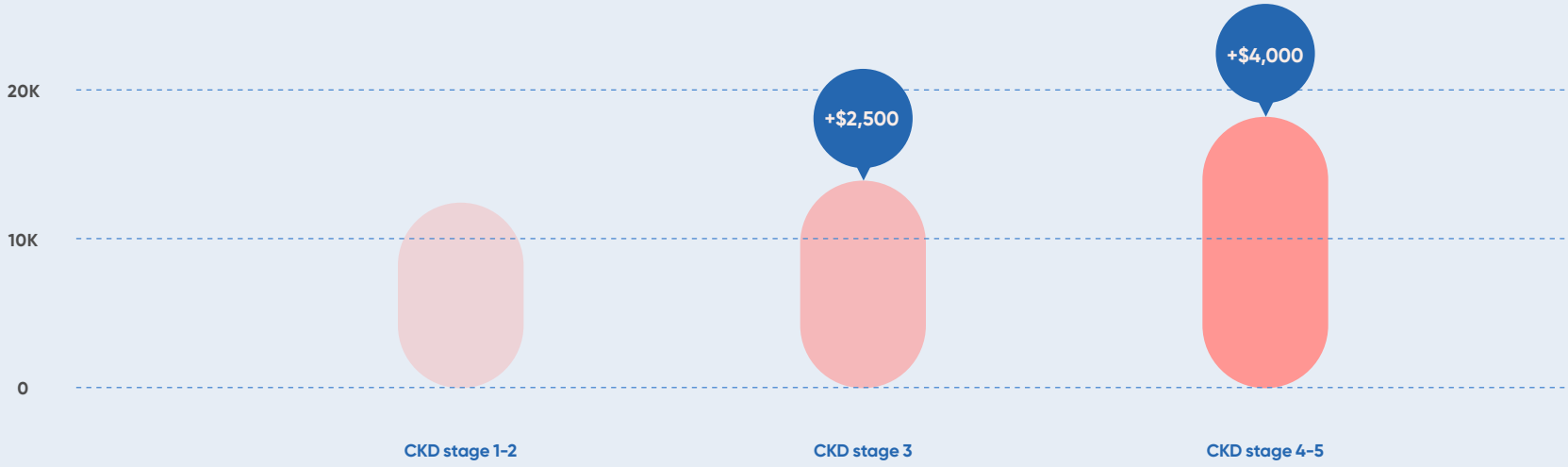
This new test has the potential to help millions of patients find out they have CKD while there is still time to prevent progression to kidney failure."

Kerry Willis, PhD,
Chief Scientific Officer
National Kidney Foundation



Total cost of care reduction

Significant reduction in TCC by avoiding progression



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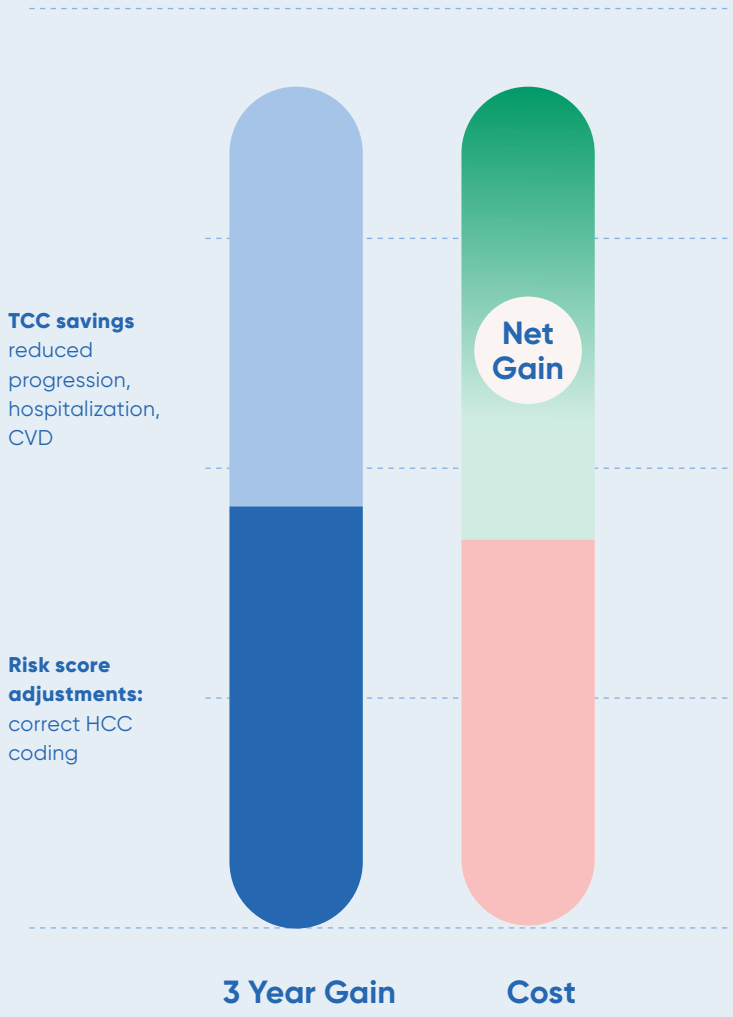
Smartphone-powered kidney testing

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 complications, leading to miscalculations of the risk and severity of their condition and associated costs. Detecting previously undiagnosed cases allows for more accurate risk scoring and better financial planning for a patient's course of care—contributing directly to the ROI.

Imminent changes to national quality metrics are another strong incentive. High levels of patient satisfaction are especially noteworthy ahead of the planned substantial increase to the weight of patient experience measures in Star Ratings, expected to account for almost a third of plans' overall Star Ratings by 2023.

Chronic kidney disease is a heavy burden on society and healthcare systems. But owing to the lifesaving possibilities afforded by early detection, Minuteful Kidney presents a valuable opportunity to dramatically improve patients' health and reduce expenditures.

Projected outcomes and savings



About
Healthy.io

Healthy.io transforms the smartphone camera into a medical device to deliver healthcare at the speed of life. The company's at-home urinalysis and digitized wound care services enable providers and healthcare systems to close gaps in access and care while increasing patient satisfaction. Healthy.io's Minuteful Kidney service is the first and only FDA-cleared smartphone-powered home kidney test.

Founded in 2013, Healthy.io is partnered with the National Kidney Foundation, NHS England, and leading national health plans, among others. The company is a global leader in digital health and is a recipient of the CNBC 2020 Disruptor 50 Award, Fast Company's World's Most Innovative Companies 2020 Award, and the Financial Times 2020 Boldness in Business Award. The company has offices in Boston, London, and Tel Aviv.

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Founded in 2013

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

Serves over 500,000 patients worldwide

Partnerships with:

- The National Kidney Foundation
- Leading national health plans
- NHS England
- Walgreens Boots Alliance