**Elevating CVD Risk Stratification**

How health plans can address the unmet needs of Medicare Advantage members with hypertension

**The Imperative for Better CVD Risk Stratification**

Cardiovascular disease (CVD) remains the leading cause of death in the United States and around the world1. Early screening for CVD risk factors has the potential to improve clinical outcomes. Two-thirds of Americans aged 65+ live with hypertension and have a heightened CVD risk2. Yet this large hypertensive population is not uniform. Some patients are at higher CVD risk than others and without risk stratification tools, resource allocation and care remain suboptimal leading to high cost and poor health outcomes. While the traditional risk factors for CVD such as tobacco use, cholesterol, blood sugar, obesity, are relatively well covered in engaged patient populations, albuminuria testing (ACR), a critical data point for effective risk stratification and management of CVD, remains grossly under investigated. Up to 93%3 of patients with hypertension currently go untested despite guidelines from the American Heart Association (AHA) and KDIGO. This white paper explores the potential for urine albumin-creatinine ratio (uACR) testing to enhance CVD risk stratification to enable earlier detection of CVD. Healthy.io's Minuteful Kidney is an easy, at-home urine test that can enable widespread uptake of uACR testing among at-risk populations.

**Albuminuria – An Important Predictor of CVD**

Current limitations in predictors of CVD

Today, testing for CVD is challenging. Despite the presence of numerous risk factors (such as hypertension, diabetes, cholesterol, smoking, age, diet, and exercise), there is a lack of measurable predictors. Furthermore, impracticality and risk of invasive diagnostic methods like cardiac catheterization or cardiac calcium scoring via CT scans, mean primary prevention is inferred rather than empirically tested. A simple urine test to detect albuminuria provides a highly correlated indicator of CVD.

Elevated Albuminuria is associated with an increase in the risk of CVD events

Albuminuria is a strong and directly correlated predictor of CVD events, reflecting the current state of vascular health, rather than a statistical predictor of future disease like other measures.

Early detection of CVD through a non-invasive, home-based test can enable timely management of risk factors and potentially reduce future costs and morbidity.

The data is clear: early detection and management of albuminuria can significantly alter the clinical trajectory of patients at risk for CVD.

**Clinical guidelines support urine ACR screening for hypertensive members**

For effective CVD management, regular testing of high-risk members is essential.

Hypertension is a leading cause of cardiovascular disease. Yet, the risk stratification for members with hypertension, between those who are very likely to have a CVD event and those who aren’t, is currently based on adjunctive testing such as blood sugar, cholesterol, blood pressure levels, smoking status, obesity which are proxies for future risk. When combined they can give a statistical risk of future illness but do not represent the current level of cardiovascular inflammation/damage.

Accessible urine ACR testing for at-risk members offers the opportunity to close this gap by providing a real-time direct measure of kidney damage which is highly associated with wider vascular damage.Giving a current picture of the status of the blood vessels and thus stage of risk for cardiovascular events.

Clinical guidelines support the inclusion of albuminuria testing as a vital component of optimal Care.

The 2018 European Society of Cardiology/European Society of Hypertension (ESC/ESH) guidelines recommend annual urine albumin-to-creatinine ratio (ACR) testing for all hypertensive patients, The 2017 American College of Cardiology/American Heart Association guidelines and the 2020 International Society of Hypertension guidelines underscore the significance of serial ACR testing as valuable components of comprehensive care.

KDIGO 2019 recommends urine ACR testing to screen members at high risk for CKD and CVD.

The American Heart Association's Value in Healthcare Initiative echoes the importance of early prediction and prevention in cardiovascular care, aligning with the endorsement of albuminuria testing as an upstream strategy in the management of hypertension.

**Improving Care, Driving Cost Savings**

Risk stratification of members with hypertension

**Projected Benefits of ACR Testing for 1 Million Hypertensive Members Aged 65+**

* Potential Cases: With an 11%-40% prevalence rate, between 110,000 and 400,000 at-risk members could potentially have albuminuria. By identifying those in the early stages, treatments that might reverse or at least stall the progression of the disease can be introduced. Early intervention can reduce the risk of CVD events by 83% and reduce CVD mortality by three fold.
* Improving Care: Fewer events means less morbidity and cost
* Cost Savings: The future cost benefits are profound including savings from preventing extended hospital stays, specialized care, and long-term medications, benefiting both health plans and members. Urine ACR testing for members aged 65+ with hypertension not only promises significant cost savings but also holds the potential to dramatically improve health outcomes and the quality of life for members. This proactive approach could set a new standard in healthcare, emphasizing preventive care over reactive treatments.

**Simple At-home ACR Urine Test**

Healthy.io’s Minuteful Kidney is the first and only FDA-cleared smartphone-powered ACR test. It increases ACR test adherence and makes it easier for members to test at home using a kit and an app. Results are available immediately and are securely shared with the patient’s PCP.

Benefits

* Home-Based: No need for costly and timeconsuming hospital or clinic visits, making it ideal for all members with transportation limitations including the elderly and those in rural communities.
* Evidence-Based: Comprehensive data supports its efficacy, especially among at-risk populations.
* Enhanced Adherence: Along with the convenience of at-home testing, user-friendly design and simple instructions increase patient adherence to testing. Minuteful Kidney is compatible with nearly all smartphone devices, ensuring accessibility to the vast majority of American households, where approximately 85% own a smartphone.

**Proven Solution for Health Plans in Assessing Vascular Damage**

Health plans are already adopting Minuteful Kidney to test their members for signs of blood vessel damage with the kidneys as a proxy measure for the heart. This is consistent with the new cardiovascular-kidney-metabolic health syndrome.17 The solution can be easily and successfully applied on a massive scale to improve cardiovascular risk stratification for members with hypertension. This solution is already being used on the same population to detect signs of kidney Damage.

A clinical evaluation of Minuteful Kidney involving Geisinger clinics and the National Kidney Foundation, demonstrated groundbreaking results. Among hypertensive members who had never undergone urine testing, adherence was raised to up to 50% in previously untested populations. Furthermore, 94% of people surveyed would recommend using the service.

Through "nudges" and helpful reminders, coupled with accessibility, convenience, and ease of use by testing at home, Minuteful Kidney provides an easy and scalable solution for risk stratification for hypertensive members. Furthermore, as a comprehensive digital solution, members receive results quickly and do not need to mail their urine sample back to the lab, reducing operational and privacy concerns.