PRECISION AQ™

THERAPIES IN CARDIO-KIDNEY-METABOLIC HEALTH: Payer Perspectives and Opportunities for Manufacturers

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CONDITIONS RELATED TO CKM HEALTH HAVE RECEIVED INCREASED ATTENTION FROM PAYERS

Cardiovascular-kidney-metabolic (CKM) health is an increasingly recognized term to describe the interplay between cardiovascular, kidney, and metabolic disorders or risk factors, which can lead to poor outcomes and increased mortality.[1] While impaired CKM health can lead to complications in multiple organ systems, the most significant impact is the high incidence of serious cardiovascular events and cardiovascular mortality. In the US, there is a high prevalence of poor CKM health, a disproportionate burden of which is found among individuals with adverse social determinants of health (SDOH).[1] Therapies for CKM conditions have received increased attention from payers due to their impact on health outcomes and resulting health care costs.

Driven by advances in our understanding of the scientific underpinnings of CKM, there is now an expanding array of therapies that may improve kidney function, weight management, and glucose control while also reducing incidence of cardiovascular events.[1] These therapies have the potential to reverse the tide of poor CKM health and population-level cardiovascular mortality, but their success may be impacted by adverse SDOH and inequitable access.

In this white paper, we review the construct of CKM syndrome and present findings of a Precision AQ survey revealing how payers manage this category. We also explore strategies that manufacturers can leverage to engage payers in productive conversations that help to increase understanding of—and access to—safe, effective therapies to improve outcomes in CKM health.

BACKGROUND ON CKM SYNDROME

The high prevalence of poor CKM health in the US is a public health emergency.[1] In the period between 2015 and 2020, CKM diseases affected more than 25% of US adults and were the leading causes of mortality in 2021, contributing to >1 million deaths.[2,3]

Individuals with CKM diseases have shorter life expectancies than those without CKM diseases (Figure 1).

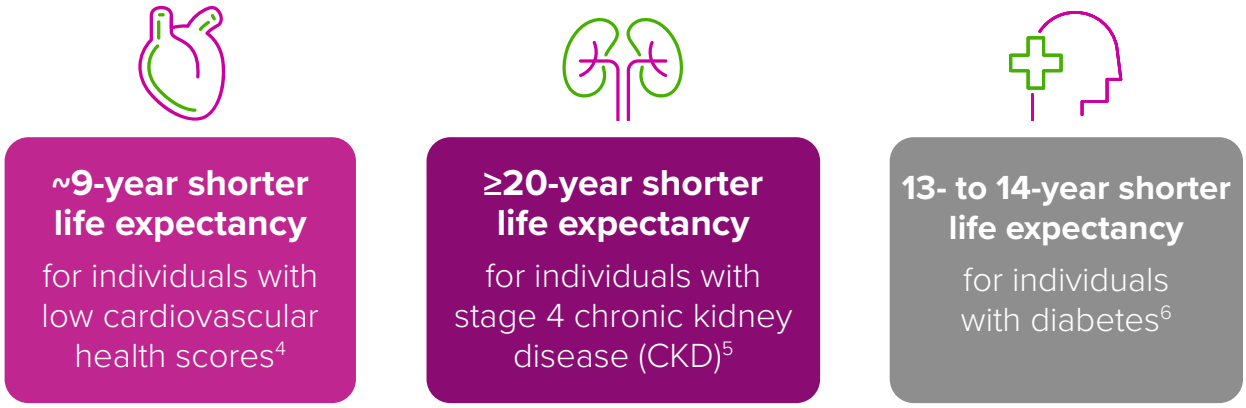

Figure 1. Life expectancy of individuals with CKM conditions.

Given that CKM diseases are inherently interconnected, many individuals have combinations of these conditions and, consequently, higher mortality rates. In a nationwide sample, the combination of CKD and diabetes was linked to a higher 10-year mortality rate than either condition alone.[7]

In 2023, the American Heart Association (AHA) introduced a new staging construct called CKM syndrome, defining it as a systemic disorder characterized by pathophysiological interactions among metabolic risk factors, CKD, and the cardiovascular system. CKM syndrome affects nearly every major organ system, leading to multiple health conditions including kidney failure, premature cognitive decline, metabolic dysfunction-associated steatotic liver disease, obstructive sleep apnea, and increased cancer risk.[1] However, the greatest clinical impact of CKM syndrome on morbidity and premature mortality is its link to a higher likelihood of cardiovascular disease (CVD).[1]

To enhance multidisciplinary approaches to prevention, risk stratification, and management of CKM syndrome, the AHA published a presidential advisory providing staging recommendations and strategies to prevent and manage CVD in relation to CKM health.[1] The advisory also emphasizes the critical importance of incorporating SDOH considerations into care models for CKM syndrome, addressing certain metabolic conditions through lifestyle modification, and reducing care fragmentation by facilitating patient-centered interdisciplinary care.[1] Given the excess burden of CKM syndrome among those with adverse SDOH and the impact of SDOH on management and outcomes, the AHA emphasizes the need for systematic screening of SDOH to incorporate these factors into risk prediction.[1]

INSIGHT INTO PAYER PERSPECTIVES AND ACTIVITIES IN CKM HEALTH

CKM diseases are linked to high health care expenditures. Each year, metabolic diseases and their downstream comorbid conditions are associated with nearly half a trillion dollars in direct health care costs and an additional $1.2 trillion in indirect costs related to lost economic productivity.

In 2024, Precision AQ conducted a survey of payers with the objectives of:

- Understanding payer perceptions of CKM therapies
- Learning which factors are likely to drive formulary decision-making for CKM therapies
- Identifying how manufacturers of therapies for CKM conditions can provide meaningful support to payers

Of the 25 survey respondents, 20 were pharmacy directors and 5 were medical directors. The organizations represented included 5 national health plans, 14 regional health plans, 5 pharmacy benefit managers (PBMs), and 1 Medicaid plan.

Key survey takeaways

Survey results showed that the CKM health pipeline is attracting a high level of attention from payers, with more than three-quarters of payers following this pipeline more closely than other categories and 40% of them following it much more closely (Figure 2).

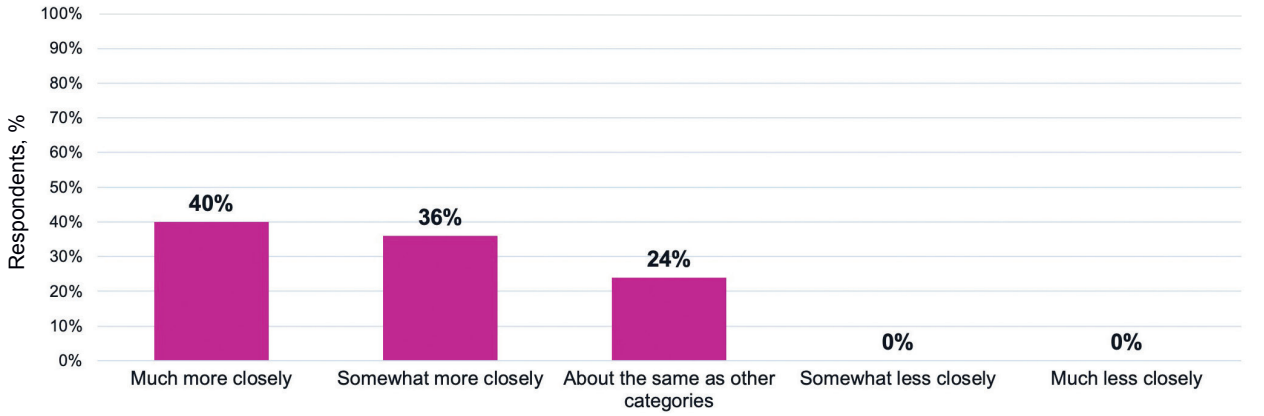

Figure 2. Payer attention to the CKM health pipeline.

CKM health is a higher current management priority for payers relative to other therapeutic areas. Nearly half of survey respondents expect that, within a year, it will be a much higher priority compared with other therapeutic areas (Figure 3).

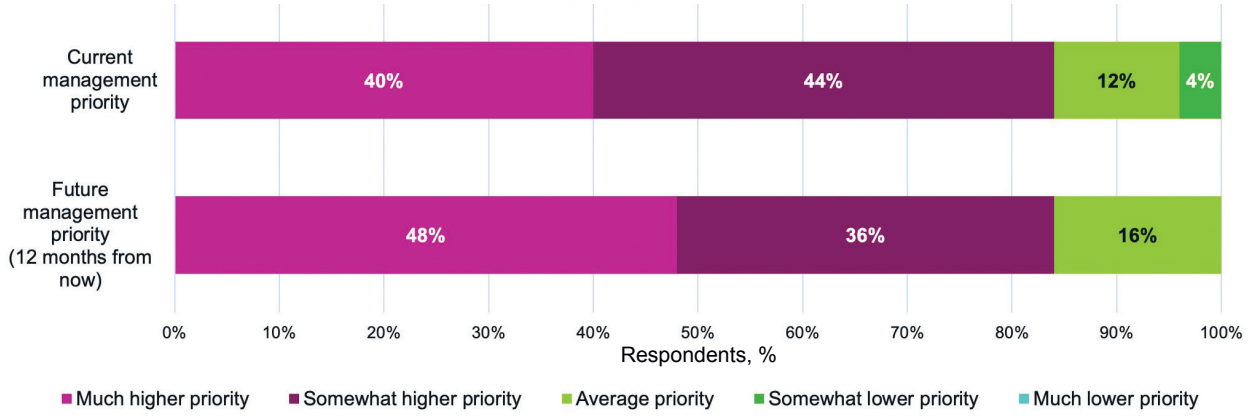

Figure 3. Management priority of CKM products.

This prioritization may be due, in part, to an increase in demand for CKM health coverage from employer groups. According to the survey, more than half of plans report that demand is increasing overall (Figure 4).

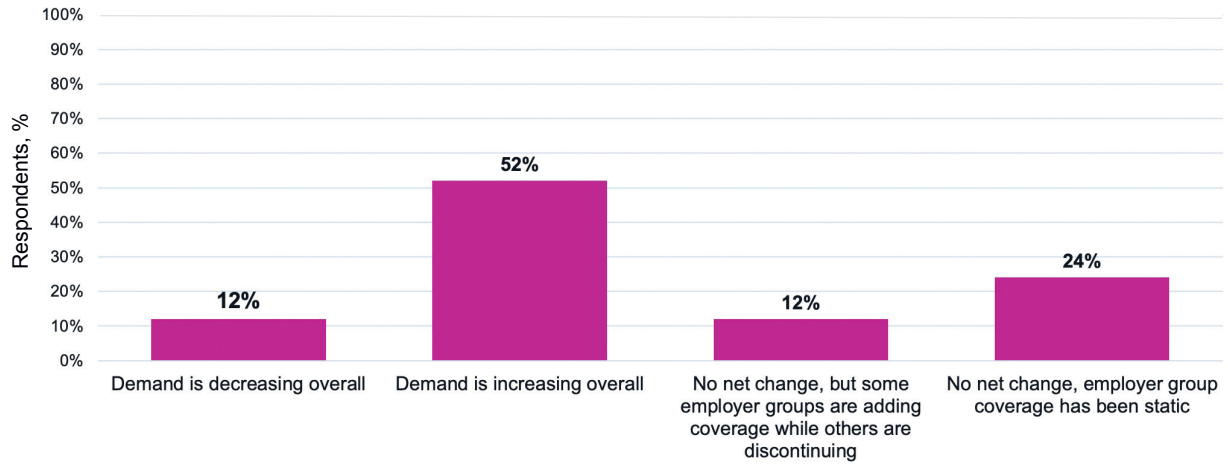

Figure 4. Employer group demand for coverage of CKM products (as reported by payer organizations).

Regarding formulary decision-making, 40% of payers are already partnering or planning to partner with vendors to provide lifestyle counseling as part of the prior authorization (PA) criteria for CKM products. More than 50% are willing to consider such partnerships (Figure 5).

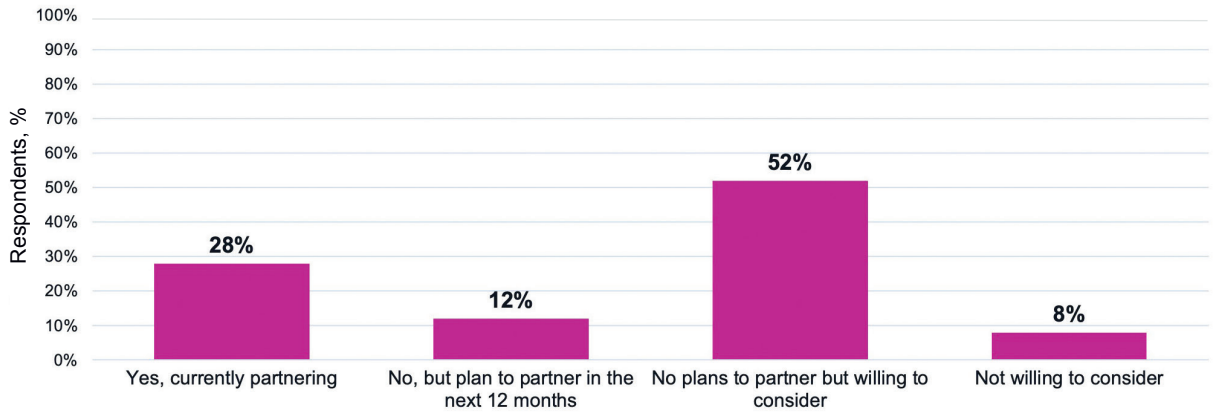

Figure 5. Payer partnerships with vendors to provide counseling as part of PA.

While few plans are actively remedying social disparities in the utilization of CKM products, nearly half are in the process of identifying or planning to address disparities (Figure 6).

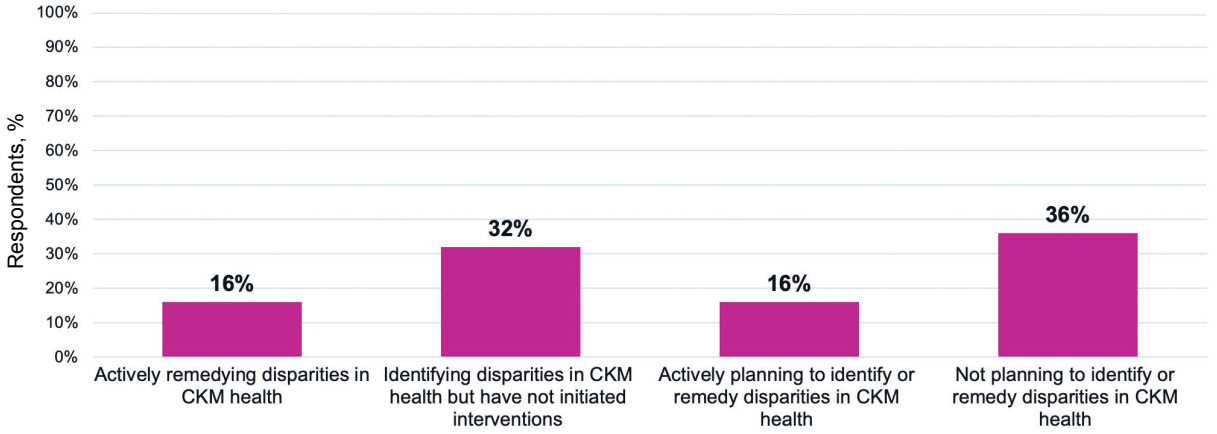

Figure 6. Status of payers' social disparities initiatives.

Strategies for manufacturers to engage payers

Appropriate utilization of CKM therapies holds promise in improving outcomes and lowering overall health care expenditures, but these therapies can be costly upfront. Payer utilization management strategies can create barriers to access and increase out-of-pocket expenses for patients, especially if there is not yet a generic equivalent.

Pharmaceutical manufacturers need to proactively engage with payers and other stakeholders to increase access to CKM therapies and to achieve commercial success. Strategies for promoting productive conversations include:

- **Getting ahead of the narrative** and providing education on the importance of diagnosing and treating CKM diseases to prevent poor outcomes and higher costs. The ability to identify individuals at early stages of CKM syndrome and to intervene in preventing progression to CVD can have meaningful downstream impacts on both outcomes and cost.

- **Reframing the use of lifestyle vendors** as an important augmentation of CKM treatment, but not a replacement. As shown in the Precision AQ survey, many payers are partnering or planning to partner with lifestyle counseling vendors as a step-through to pharmaceutical interventions in CKM health. Currently, there are key limitations in the data supporting the clinical care for CKM syndrome, including optimal strategies for supporting lifestyle modification.[3] While the AHA presidential advisory emphasizes lifestyle changes as an initial treatment strategy, it also recommends early introduction of pharmacotherapy to mitigate CVD risk.[1] Given that multifactorial risk factor control is associated with reduced CVD event rates, it is reasonable to position comprehensive lifestyle intervention as an adjunct, rather than an alternative to pharmacotherapy.

- **Highlighting the importance of SDOH** in influencing outcomes in CKM and emphasizing the need for improved access to therapies to prevent worsening of existing disparities. As with lifestyle modification, there are gaps in evidence about screening for social needs among patients with CKM syndrome.[3] For instance, studies have shown that interventions targeted at obtaining resources related to food, housing, medication, and transport were associated with reductions in blood pressure and low density lipoprotein (LDL) cholesterol, but not hemoglobin A1c. Optimal tools for SDOH screening may differ by setting, and effective interventions should be identified for geographic areas where adverse SDOH are barriers to health care and healthy behaviors. Mitigation of adverse SDOH may require implementation of care models and interdisciplinary care teams, including care navigators and social workers, who can connect patients to social need resources that protect against the effects of conditions that negatively impact access and outcomes.

- **Collecting real-world evidence (RWE)** to support deeper understanding of environmental and community-level risk factors that contribute to the development of CKM syndrome. These data can be difficult, though not impossible, to obtain in the context of a clinical trial. Collection of RWE may also pressure or inspire payers to examine their own internal data to determine where access challenges are greatest and to either loosen PA or initiate outreach efforts. Manufacturers may also find it useful to collect data on major adverse cardiovascular event (MACE) outcomes and levels of health care utilization, including urgent care, emergency room, specialty use, and hospitalizations, in the real-world population to gain insight on adherence and persistence of therapeutic effects.

To learn more about the Precision AQ survey or how to develop an effective market access strategy for novel therapy in the CKM space, contact us.

[1] Ndumele CE, et al. Cardiovascular-kidney-metabolic health: a presidential advisory from the American Heart Association. *Circulation*. 2023;148(20):1606-1635.

[2] Aggarwal R, Ostrominski JW, Vaduganathan M. Prevalence of cardiovascular-kidney-metabolic syndrome stages in US adults, 2011-2020. *JAMA*. 2024;331(21):1858-1860.

[3] April-Sanders AK. Integrating social determinants of health in the management of cardiovascular-kidney-metabolic syndrome. *J Am Heart Assoc.* 2024;13(16):e036518.

[4] Ma H, et al. Cardiovascular health and life expectancy among adults in the United States. *Circulation*. 2023;147(15):1137-1146.

[5] Turin TC, et al. Chronic kidney disease and life expectancy. *Nephrol Dial Transplant.* 2012;27:3182-3186.

[6] Salehidoost R, et al. Diabetes and all-cause mortality, a 18-year follow-up study. *Sci Rep.* 2020;10:3183.

[7] Afkarian M, et al. Kidney disease and increased mortality risk in type 2 diabetes. *J Am Soc Nephrol.* 2013;24:302-308.

[8] Waters H, Graf M. America's obesity crisis: the health and economic costs of excess weight. Milken Institute. 2018. https://milkeninstitute.org/sites/default/files/reports-pdf/Mi-Americas-Obesity-Crisis-WEB_2.pdf

[9] Heidenreich PA, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145:e895-e1032. [Published corrections appear in *Circulation.* 2022;145:e1033, *Circulation.* 2022;146:e185, and *Circulation.* 2023;147:e674].

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