NATIONAL KIDNEY FOUNDATION®

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4208-P
Mail Stop: C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

January 27, 2025

RE: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Dear Administrator:

The National Kidney Foundation (NKF) is writing to support the Department's proposal to expand coverage of anti-obesity medications to millions of Americans covered by the Medicare and Medicaid programs thereby making measurable progress on President Trump's goal of reducing the burden of chronic disease on the American people.

In the last decade, pharmacologic treatment landscape for Chronic Kidney Disease (CKD) has been transformed. Anti-obesity medications are a pillar of this new treatment paradigm. Access to therapies that preserve kidney health and reduce progression to death or kidney failure give promise to President Trump's vision for kidney disease, articulated in his 2019 Executive Order on Advancing American Kidney Health, to reduce the number of Americans developing end-stage renal disease by 25 percent by 2030.[1]

Over 35 million people, over 1 in 7 U.S. adults, are estimated to have some form of CKD. This exacts a profound burden on the American workforce and American taxpayers through high rates of disability, premature mortality, and the costs of funding care for kidney failure. Diabetes and high blood pressure (hypertension) are the leading causes of CKD. Obesity is extremely common in CKD and contributes to the development and progression of kidney disease. In 2023, the American Heart Association (AHA) defined cardiovascular-kidney-metabolic syndrome (CKM) to describe these interactions between cardiovascular disease, kidney disease, and metabolic conditions like obesity and type 2 diabetes. An individual with CKD and obesity is at high risk for kidney failure, disability, mortality, and reduced optimal access to treatment for kidney failure, i.e., kidney transplantation.[2]

[1] https://aspe.hhs.gov/sites/default/files/private/aspe-files/262056/advancingamericankidneyhealth.pdf

[2] https://www.kidneymedicinejournal.org/article/S2590-0595(22)00201-1/fulltext

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Finalizing the Department's anti-obesity medication policy under consideration would eliminate a substantial barrier to CMS deploying every tool possible to reduce the burden of CKD on the Medicare population and the Medicare Trust Fund. Clinical trials of anti-obesity medications (also known as glucagon-like peptide-1 (GLP-1) receptor agonists (RAs)) initially showed efficacy for blood sugar control and weight loss. These studies also provided the first evidence that GLP-1 RAs could have benefits for individuals with CKD.[3] We now know that GLP-1 RAs can help slow CKD progression and lower heart disease risk for people with CKD and with and without type 2 diabetes. Clinical practice guidelines including Kidney Disease Improving Global Outcomes (KDIGO), currently recommend GLP-1 RAs in different circumstances for individuals with CKD and type 2 diabetes.[4]

Many Medicare beneficiaries with or at risk for CKD cannot benefit from the potent improvements in clinical outcomes that anti-obesity medications can provide. When an individual is covered by Part D, GLP-1 medications will only be covered for medical conditions other than overweight or obesity because of the statutory exclusion in Part D of "agents…used for weight loss." The U.S. Food and Drug Administration has approved numerous GLP-1 medications indicated for the treatment of weight management (obesity and overweight), glycemic control in type 2 diabetes, and cardiovascular conditions. Therefore, depending on the indication, some Medicare beneficiaries with CKD or at risk for CKD can access GLP-1 prescriptions. For example, a beneficiary with or at risk for kidney disease may be able to access an anti-obesity medication if he or she also has type 2 diabetes or a cardiovascular condition. According to the Congressional Research Service, as of August 2024, Medicare Part D covered Ozempic (semaglutide), Mounjaro (tirzepatide), Rybelsus (semaglutide), and Wegovy (semaglutide) for these purposes.

In figure 6.1 below, the 5.1% of traditional Medicare beneficiaries with type 2 diabetes and CKD are represented by the union in blue, which represents the population of Medicare beneficiaries with kidney disease who can benefit from anti-obesity medications under current Part D policy. Data from the U.S. Renal Data System (USRDS) show increase in GLP-1 RA prescriptions from 1.9% to 12.6% over five years among beneficiaries with CKD stage 3.[5] While Medicare Part D data show an increase in GLP-1 RA prescriptions for a proportion of beneficiaries with CKD, ***Medicare beneficiaries with CKD but without comorbid type 2 diabetes are still unable to benefit.*** This results in hundreds of thousands of missed opportunities, in the form of individual Medicare beneficiaries, to reduce

[3] https://www.ajkd.org/article/S0272-6386(24)00975-2/fulltext
[4] https://kdigo.org/wp-content/uploads/2024/03/KDIGO-2024-CKD-Guideline.pdf
[5] https://usrds-adr.niddk.nih.gov/2024/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd

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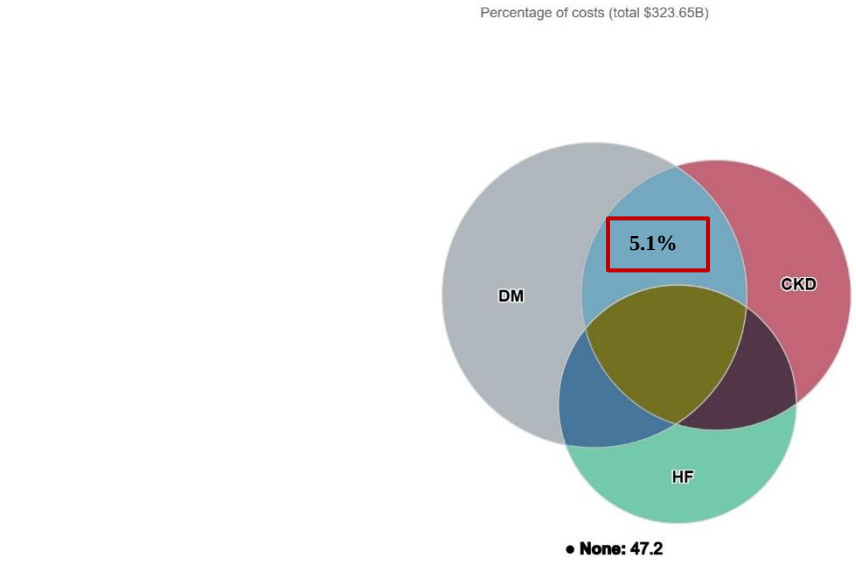
disability from chronic disease, and eliminate billions of dollars of preventable health spending associated with chronic kidney disease.

Figure 6.1 Distribution of prevalence and annual spending among older adults with CKD, diabetes, and heart failure, 2022



Data Source: 2024 United States Renal Data System Annual Data Report

Notably, CKD is underdiagnosed. CKD is highly enriched in the aged Medicare population. Approximately 33% of aged Medicare beneficiaries have a laboratory diagnosis of CKD, indicating that a significant proportion of seniors have reduced eGFR, a laboratory marker of the ability of the kidneys to filter the blood, and increased urine-to-albumin creatinine ratio, a laboratory marker of damage to the kidneys. Laboratory diagnoses do not, however, necessarily mean that a diagnosis of CKD is made by a clinician and documented in the medical record. In 2022, only 15.4% of the approximately 23.2 million Medicare FFS beneficiaries aged ≥66 years had a diagnosis of CKD.[6] Typically, a Medicare beneficiary must have documented diagnoses of CKD and type 2 to benefit optimally from anti-obesity medications. A prescribing clinician cannot make the best use of anti-obesity medications if a Medicare beneficiary has type 2 diabetes and CKD, but the CKD has not been detected. The population of Medicare beneficiaries with CKD, either diagnosed or undiagnosed, who may need an anti-obesity medication to manage weight and/or improve kidney outcomes are denied the ability to improve their health.

[6] https://usrds-adr.niddk.nih.gov/2024/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd

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Finalizing the anti-obesity medication coverage policy under consideration will not, alone, stem the tide of the chronic kidney disease public health crisis. The ability to manage CKD progression and its associated risks begins with early diagnosis and management. As we note in this letter, CKD is enriched yet underdiagnosed in the Medicare population. The NKF is working across the Department to ensure that Medicare beneficiaries at risk for CKD or who already have it receive a diagnosis as early as possible. Even when a Part D plan covers GLP-1 RAs for a beneficiary with CKD due to the presence of an associated, covered condition, beneficiaries may struggle to access the product because he or she is required to use a lower cost drug first (step therapy or a fail-first policy), the drug is on a specialty tier, or because of unaffordable out-of-pocket costs. We are eager to work with CMS to address the burden of CKD on Medicare and the Medicare trust while preventing patients unnecessarily progressing to kidney failure.

The landscape for anti-obesity medications will continue to evolve. Market intelligence estimates there are over 100 products in the anti-obesity medication pipeline, including those already marketed. Some of these products will be specifically indicated for kidney disease; for example, Novo Nordisk's label expansion in Europe for Ozempic (semaglutide) to include kidney disease through the European Medicines Agency (EMA). In a time of rapid change, NKF encourages CMS to set the standard for chronic disease prevention and management by expanding access to the full arsenal of strategies to improve America's kidney health.

We would welcome the opportunity to work the Trump Administration to ensure that seniors have access to the full continuum of obesity care, including FDA-approved obesity management medications. If you have any questions about our comments, please contact Miriam Godwin, Vice President of Health Policy, at miriam.godwin@kidney.org.

Sincerely,

Kevin Longino, MBA
NKF CEO and Kidney Patient

Kirk Campbell, MD
NKF President