

May 24, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

The American Kidney Fund (AKF) writes to voice our support for restoring Medicare Part D coverage for Auryxia (ferric citrate) to treat iron deficiency anemia for chronic kidney disease (CKD) patients not on dialysis. Part D coverage of this treatment, which is the only oral drug approved by the Food and Drug Administration (FDA) for this indication, would ensure patients have access to a safe and effective therapy to treat anemia, a frequent comorbidity of CKD that can result in serious health consequences if not appropriately treated. We urge CMS to reestablish Medicare Part D coverage for Auryxia for the treatment of anemia in non-dialysis CKD patients.

AKF is the nation's leading independent nonprofit organization working on behalf of the more than 30 million Americans with kidney disease. For the past half-century, AKF has existed to help people fight kidney disease and live healthier lives. We provide a complete spectrum of programs and services: top-rated education materials; free kidney disease screenings in numerous cities across the nation; clinical research funding; and need-based financial assistance enabling one in five U.S. dialysis patients to access lifesaving medical care, including dialysis and transplantation.

We commend the administration's efforts in improving the lives of kidney disease patients, as evidenced by the KidneyX initiative, which aims to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. We also strongly agree with Secretary Azar's recent remarks that there need to be "more efforts to prevent, detect, and slow the progression of kidney disease," and that one of the ways to do that is "better investment in effective efforts to treat early kidney disease and related conditions." Restoring Medicare Part D coverage of Auryxia's renal anemia indication would clearly align with the administration's commitment to improving kidney care and treatment options for patients.

Anemia has significant clinical consequences for CKD patients, and is associated with more rapid disease progression, greater prevalence of major cardiovascular events, increased mortality, and reduced quality of life. There are limited treatment options for CKD patients with anemia. The only other FDA-approved treatment options are intravenous (IV) iron products that are administered by a provider at an infusion center and are covered under Medicare Part B. IV options present multiple drawbacks for the patient, including higher cost-sharing and the inconvenience of having to travel to a facility to have the drug administered, which can be a significant burden for beneficiaries who face transportation barriers or live in rural areas. In addition, there are patient safety risks associated with IV options, including anaphylaxis, infection, and potential damage to veins that are needed for vascular access for hemodialysis (if the patient advances to dialysis).

Auryxia has been determined to be safe and effective by the FDA and is one of the only FDA-approved drugs in recent years that was developed for the CKD population. All other payers in the U.S. healthcare system, including state Medicaid programs, the Veterans Administration, and commercial payers, cover the therapy for its renal anemia indication. In keeping with the administration's efforts to drive innovation in kidney care, improve treatment options and outcomes for kidney disease patients, and slow the progression of CKD, CMS should also provide Medicare coverage for Auryxia, and we urge CMS to do so.

Sincerely,



LaVarne A. Burton
President and CEO