Congress of the United States

Washington, DC 20515

January 22, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure,

We are writing to urge the Centers for Medicare and Medicaid Services (CMS) to consider classifying the taurolidine/heparin (DefenCath) catheter lock solution, recently approved by the Food and Drug Administration (FDA), as a separately reimbursable drug rather than as a "renal dialysis drug" within the End Stage Renal Disease (ESRD) Prospective Payment System (PPS). Such a classification does not suitably reflect its role in infection prevention and could reduce patient access to this first-in-class antimicrobial drug, thereby adversely impacting patient care as well as contradicting the intentions of several federal public health initiatives.

This drug product is the first and only FDA-approved antimicrobial catheter lock solution (CLS). It is indicated to reduce the incidence of catheter-related blood stream infections (CRBSIs). The drug is for use in the limited population of adult patients with kidney failure receiving chronic hemodialysis via central venous catheter (CVC). This patient population, which is approximately 20 percent of all adult kidney failure patients receiving dialysis, is at risk of CRBSIs because they require a CVC for their treatment. Due to the critical unmet need of this patient population, this drug is one of only three products ever approved under the FDA's Limited Population Antibacterial Drug (LPAD) Pathway. CRBSIs are incredibly common for the narrow population of hemodialysis patients requiring a CVC and can lead to serious complications, long and costly hospital stays, and increased mortality risk. DefenCath has demonstrated a 71 percent risk reduction for CRBSIs compared to the standard of care and shows promise in significantly reducing one of the most prevalent healthcare acquired infections (HAIs) in kidney disease care.[1]

When considering how this drug product will meet the needs of Medicare beneficiaries requiring a CVC to treat their kidney failure, it is critical to take into account the racial inequities in kidney care and how

1 Food & Drug Administration (2023). FDA approves new drug under special pathway for patients receiving hemodialysis. Available at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-new-drug-under-special-pathway-patients-receiving-hemodialysis.

this new drug could aid in reducing the disproportionate rate of mortality among beneficiaries of color, especially Black beneficiaries. Black patients experience more than three times the rate of kidney failure than their white counterparts, and within the Medicare fee-for-service (FFS) beneficiary population, kidney disease is the highest among Black Americans (33 percent).[2] Black patients wait longer for kidney transplants on average, and they are ultimately less likely to receive a transplant.[3] The only other treatment option for kidney failure patients is chronic hemodialysis. Black patients are more likely to receive hemodialysis treatment via long-term CVC rather than a permanent, safer method of dialysis access, exposing them to a higher risk of CRBSI complications.[4] The mortality rate for Black kidney disease patients is growing at a disproportionate rate every year, with a documented 23 percent increase in 2020.[5] DefenCath was approved by FDA with clinical data indicating it is highly effective in reducing the incidence of CRBSIs (71 percent reduction in the incidence of CRBSIs) and could aid in curbing this distressing rise.

CMS's determination must also be put into the context of federal efforts to reduce antimicrobial resistance (AMR). The U.S. National Strategy for Combating Antibiotic-Resistant Bacteria (National Strategy) identifies the increase in AMR as an emergent threat to international public health and national security and prioritizes the development and strategic use of new antimicrobial products.[6] With the steep increase in antibiotic usage during the COVID-19 pandemic, the relevance of this new and highly effective antimicrobial drug product cannot be overstated. Alongside receiving expedited approval through the FDA's LPAD Pathway (21st Century Cures Act, 2016), DefenCath also received a Qualified Infectious Disease Product (QIDP) designation (FDASIA, 2012). Both programs were established by Congress for the purpose of incentivizing the development of new drugs that can address the AMR public health crisis.

Despite these pathways and market incentives, antimicrobial drug development has been limited and ultimately insufficient in overcoming the increase in antibiotic resistance of some pathogens. CMS should use its existing authority to classify DefenCath as an infectious disease drug and reimburse for its use outside of the ESRD PPS bundled payment. Doing so would ensure sustained reimbursement and broad patient access, better aligning the agency with the objectives of the National Strategy and reducing CRBSIs. As a first-in-class drug, it is not a substitute for a drug in the ESRD PPS composite rate, and it also does not fall under any of the functional categories, including that of treating infections, as it reduces the incidence of infections rather than treats them.

When determining the reimbursement methodology for DefenCath, we urge CMS to consider the potential for a significant reduction in CRBSIs for CVC-dependent dialysis patients, HHS's broader role in fulfilling the National Strategy's objectives and the gravity of the AMR public health crisis, and the

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2 Centers for Medicare and Medicaid Services (2020). Chronic kidney disease disparities in Medicare fee-for-service beneficiaries. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Snapshot-Chronic-Kidney-Disease.pdf.

3 Ng, Y., et al. (2020). Does Racial Disparity in Kidney Transplant Waitlisting Persist After Accounting for Social Determinants of Health? *Transplantation,* 104(7) 1445-1455. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7153978/.

4 Arya, S., et al. (2020). Racial and Sex Disparities in Catheter Use and Dialysis Access in the United States Medicare Population. *J Am Soc Nephrol.,* 31(3) 625-636. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7062210/.

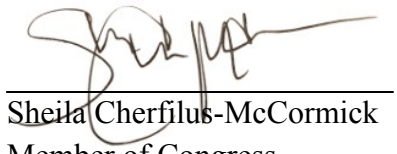
5 National Institute of Diabetes and Digestive and Kidney Diseases (2023). Kidney Disease Statistics for the United States. Available at: https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

6 National Strategy for Combating Antibiotic-Resistant Bacteria (2014). Available at: https://www.cdc.gov/drugresistance/us-activities/national-strategy.html.

vulnerable Medicare beneficiary populations that will be heavily impacted. We thank you for your attention to this important matter.

Sincerely,

Alma S. Adams, Ph.D.
Member of Congress



Sheila Cherfilus-McCormick
Member of Congress

Donald G. Davis
Member of Congress