

September 22, 2023

Re: Proposed Local Coverage Determination (LCD)
MoIDX: Molecular Testing for Solid Organ Allograft Rejection
Proposed LCD ID: DL38568

Submitted via MOLDX.POLICY@palmettogba.com

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the proposed LCD: MoIDX: Molecular Testing for Solid Organ Allograft Rejection.

AKF fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

Molecular diagnostic tests, including donor-derived cell-free DNA (dd-cfDNA) testing, plays a critical role as an accurate, non-invasive tool to monitor kidney function and detect graft injury and rejection in transplant patients. Because of this, **AKF opposes the proposed LCD that would place undue limitations on its coverage in Medicare. We urge the Medicare contractor to not finalize the LCD as currently proposed.**

To ensure the best health outcomes for a person with a kidney transplant, providers need to consistently monitor how well the new kidney is functioning. A blood draw to measure serum creatinine is a routine and inexpensive test, but creatinine is not a very sensitive marker for identifying early kidney injury. There may be significant injury to a transplanted kidney before creatinine is elevated, and treatments may not be as effective.

A kidney biopsy is considered the gold standard and most informative test to diagnose issues with a transplanted kidney, but it is an invasive procedure and comes with a small risk of bleeding after the procedure. Because of this, the biopsy is not ideal for ongoing kidney monitoring.

Donor-derived cell-free DNA tests have been a trusted test for over 15 years for heart transplant recipients and over 5 years in kidney transplant recipients. The testing of dd-cfDNA has resulted in improved early detection of graft injury and rejection, and can also reassure the provider and

the patient that there is no subtle, unrecognized damage or rejection going on with the transplant if the level of dd-cfDNA is normal. Prior to the adoption of dd-cfDNA tests, if a patient's creatinine was elevated for unclear reasons, they may have been asked to have a kidney biopsy to exclude the possibility of rejection, infection, or other acute damage to their transplant. Now with the use of dd-cfDNA testing, a patient with elevated creatinine but a normal amount of circulating dd-cfDNA typically means there is no damage to the transplant and the patient may be monitored closely, rather than undergo an invasive biopsy.

Conversely, if a creatinine level is normal but the dd-cfDNA is elevated, this may be an early warning sign that there is a need for more investigation, sometimes including a kidney biopsy, to catch problems early and allow for the best treatment before there is further kidney damage. Because dd-cfDNA testing plus serum creatinine is more accurate than just checking serum creatinine, and because it only requires a blood draw, dd-cfDNA tests have become a critical tool for monitoring a patient's kidney transplant and to help determine if they need a kidney biopsy.

AKF has heard from patients about the importance of dd-cfDNA tests to their care, and how results from the tests helped their doctors decide to adjust their immunosuppressive medications to prevent rejection. Kidney transplant is considered the best treatment option for most people with kidney failure because it increases a patient's chances of living a longer, healthier life. Donor-derived cell-free DNA tests are a significant improvement to the kidney monitoring tools that have been used before, and they can help a patient get as many years as possible out of their transplant. Given the struggles that many patients encounter in their journey to receiving a transplant, they deserve access to diagnostic and therapeutic innovations that help protect their transplant and improve their lives.

Thank you for the opportunity to provide comments on this issue. If you have any questions about our comments, please contact Holly Bode, Vice President of Government Affairs at hbode@kidneyfund.org.

Sincerely,



LaVarne A. Burton
President and CEO