

April 15, 2024

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

We are writing as transplant clinicians dedicated to the care of our patients to express our growing concern regarding Medicare coverage restrictions on post-transplant molecular diagnostic testing. These new restrictions break with longstanding policy by only covering the use of these diagnostics when we otherwise would have done an invasive tissue biopsy.

Molecular diagnostic tests have revolutionized the way we monitor transplant organ health. They allow for routine assessment of graft function, often from the comfort of the patient's home or workplace. These tests have been instrumental in detecting early signs of organ rejection, facilitating timely interventions that can preserve organ function and save lives.

Since these new restrictions were imposed just over a year ago, we have observed a concerning trend that warrants an urgent reconsideration of this policy change.

In March 2023, MoIDX issued a new billing article that restricted Medicare coverage of these tests for surveillance to clinical situations in which an invasive biopsy would otherwise be performed. Since these restrictions were imposed, many of us have observed an increase in rejection episodes among our transplant recipients. We believe this troubling trend may partly be attributable to these new coverage restrictions.

While CMS and MoIDX have repeatedly asserted that there has been no change in coverage policy, by the Centers for Medicare & Medicaid Services' (CMS) own admission, there was a 50% reduction in the number of these crucial tests being ordered following the imposition of these new restrictions. This substantial decrease in testing volume is not merely a statistic; it represents actual patient lives and tens of thousands of patients now at an increased risk of organ rejection due to these new coverage restrictions. This situation underscores the urgent need for CMS to provide unequivocal guidance that restores the more inclusive and patient-centric coverage policies that were in place before March 2023.

Our nation shares the goal of increasing the number of successful organ transplants, aligning with the OPTN Task Force's ambitious goal established in January 2024, aiming for 60,000 transplants annually by 2026, resulting in a 50% increase in transplant procedures.

Achieving this significant milestone will require the utilization of more ‘higher risk organs’ that might previously have been discarded and inevitably require heightened vigilance to prevent rejection episodes. Surveillance utilizing molecular diagnostic tests is a critical component of effective transplant organ care. Yet, the current Medicare policy, by tying the coverage of these essential non-invasive tests to the performance of a surveillance biopsy that is invasive, requires patient travel, consumes substantial hospital resources, exposes immunocompromised patients to nosocomial infections and may lead to non-diagnostic material or worse, misleading information, severely restricts our ability to utilize these effective and validated tests to their full potential.

The existing ESRD Treatment Choices (ETC) Model, encompassing 30% of ESRD facilities and their managing clinicians, is a vital element of the Department of Health and Human Services (HHS) American Kidney Health Initiative and provides payment incentives to enhance transplant waitlist referrals and to encourage living donor transplants. This model has led to an uptick in transplant referrals, a positive development for kidney patients, but places additional demands on transplant centers.

To manage this increased workload while improving continuity and quality of care, there is a pressing need to engage community nephrologists in long-term, post-transplant care, a practice that the current policy directly impedes. Community nephrologists, who are now restricted from ordering non-invasive testing methods for surveillance since they do not perform biopsies, are significantly disadvantaged by this policy. This limitation jeopardizes the survival of transplant recipients and their transplanted organs.

We urge the Centers for Medicare & Medicaid Services to address these issues now and in the pending Local Coverage Determination (LCD), which is expected to be finalized in the coming months. We are deeply concerned that the proposed LCD seeks to codify the March 2023 billing article restrictions formally.

We encourage CMS to collaborate closely with the transplant provider community to address this problem and return to a coverage policy that enables clinicians to provide care based on their independent clinical judgment and the individualized needs of their patients.

Thank you for taking this critical matter into consideration.

Sincerely,

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