



New Survey Shows that 95% of Patients are Concerned that a New Medicare Billing Article Limits Coverage of Non-Invasive Post-Transplant Tests

Findings show majority of patients believe that reduced coverage of non-invasive blood tests would negatively impact their post-transplant care and that they should be consulted as part of the process for Medicare policy changes.

May 3, 2023—According to a recent survey conducted by leading transplant patient organizations to people impacted by kidney, heart, lung and liver transplants, a majority of patients (98%) believe that it is important to have Medicare coverage for non-invasive tests to routinely monitor transplant rejection. The survey, which was fielded after the release of a Medicare [Billing Article related to MoLDX molecular testing for allograft rejection](#), also found that a majority of patients (95%) are concerned that the billing article limits coverage for non-invasive post-transplant tests and agree (95%) that reduced coverage for non-invasive tests would negatively impact their post-transplant care.

The Medicare billing article restricts coverage of non-invasive post-transplant diagnostic tests like donor-derived cell free-DNA (dd-cfDNA) and gene expression profiling (GEP), which are routinely used instead of tissue biopsies to monitor a patient’s transplanted organ health and immune status, respectively. The billing article does not pose restrictions or changes to coverage of more invasive, costly biopsies. The billing article went into effect just 30 days after its release and without following appropriate procedures for changing coverage policy, including incorporating patient input and a public comment process—leading to a substantial care gap for patients and disproportionately impacting transplant recipients in underserved communities.

“We had immediate concerns about Medicare making coverage changes to post-transplant care without understanding the serious impact to patient lives,” said Bill Ryan, President and CEO of the Transplant Life Foundation. “The results of this survey allow us to voice transplant patient concerns in the absence of having an official forum with MoLDx to do so.”

“Patients are confused and scared about what this billing article means for coverage of their tests and wish they had been afforded the opportunity to voice their concerns,” said Lorrinda Gray-Davis, President of Transplants Recipients International Organization (TRIO). “In fact, the results show that 84% of patients strongly believe that they should be consulted as part of the process for making changes in Medicare coverage policies. We hope that Medicare considers these serious concerns.”

The survey, which was fielded by the [Transplant Life Foundation](#), [TRIO](#), [Transplant Families](#), and the [HeartBrothers Foundation™](#) resulted in nearly 1,200 responses from patients, as well as some caregivers and family members. The study showed the following additional data:

- 57% frequently worry about transplanted organ rejection. It is estimated that 1 in 3 lung transplant recipients will experience graft failure within the first year post-transplant¹, and 1 in 3 heart², and 1 in 5 kidney³ transplant recipients will experience graft failure within 5-years post-transplant, respectively.
- Overwhelmingly, nearly 95% prefer a simple non-invasive blood test to monitor the health of their transplant, rather than a traditional biopsy. This may be due to the adverse events, pain, anxiety, and inconvenience associated with biopsies, since 57% reported that biopsies had negatively impacted their quality of life.
- 95% are concerned that the new Medicare billing article limits coverage of non-invasive testing, and with it, physicians' ability to provide the best care for transplant patients.
- Having to pay out of pocket for a non-invasive test would be a financial burden for 91%, with over 75% strongly agreeing with this sentiment.
- 97% believe that patients should be consulted as part of the process for determining new or making changes to existing Medicare coverage policies.

"These changes are a real setback for the transplant community," said Patrick Sullivan, Co-Founder of the HeartBrothers Foundation. "Without access to these noninvasive blood tests, transplant survivors, who have already endured so much, will need to undergo much riskier heart biopsies. We've already heard from several transplant patients who are very concerned and upset about this."

"Caregivers of transplant recipients are frustrated and want to know why their voices weren't considered. The alternatives are invasive and traumatic for young children and teens and have lifelong impacts," said Melissa McQueen, Founder of Transplant Families and mother to a heart transplant recipient. "Medicare's coverage will lessen or take away entirely options that both clinician and patient have in non-invasive testing. We implore you to consider hearing the voices of those that these tests affect the most in your decision making."

The Protect Access to Non-Invasive Testing for Transplant Patients Survey was deployed on April 10, 2023, to post-transplant patients affiliated with Transplant Life Foundation, TRIO, Transplant Families, and the HeartBrothers Foundation™. The sample size upon closure of the survey on April 20, 2023, was 1,173. Detailed survey findings available [here](#).

About Transplant Life Foundation

The Transplant Life Foundation is the nation's leading advocacy nonprofit for those in the donation and transplantation world—transplant recipients, living donors, donor families, individuals on the waiting list, caregivers, transplant professionals and supporters.

About Transplant Recipients International Organization (TRIO)

TRIO is an independent, not-for-profit, international organization committed to improving the quality of life of transplant candidates, recipients, their families and the families of organ and tissue donors.

About Transplant Families

Transplant Families unites families who have children with solid organ or bone marrow transplants by providing inspiration, support, and education. Its aim is to help patients and families find the most of life before, during, and after transplant.

HeartBrothers Foundation™

The HeartBrothers Foundation™ is a non-profit organization dedicated to helping heart failure patients and their families navigate the complex journey of Heart Failure, mechanical circulatory support, and heart transplantation. Its sole mission is to bring resources together to help heart failure patients and their loved ones survive life with heart failure and all its challenges.

References:

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2. Wilhelm, Markus J. "Long-term outcome following heart transplantation: current perspective." *Journal of thoracic disease* vol. 7,3 (2015): 549-51. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4387387/>.
3. Sussell, Jesse et al. "The economic burden of kidney graft failure in the United States." *American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons* vol. 20,5 (2020): 1323-1333. [doi:10.1111/ajt.15750](https://doi.org/10.1111/ajt.15750).

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