



Service to those affected by chronic kidney disease

May 3, 2023

To: Gabriel A. Bien-Willner, MD, PhD
Medical Director, MolDX
Chief Medical Officer, Palmetto GBA

From: Lori Hartwell
Founder/President of Renal Support Network

RE: Molecular Testing for Solid Organ Allograft Rejection (A58019)

The Renal Support Network (RSN) serves the kidney community by empowering people who have kidney disease to become knowledgeable about their illness, proactive in their care and hopeful about their future. I founded RSN in 1993 to help my peers. I was diagnosed at age 2 in 1968 and spent 13 years on dialysis and currently living with my 4th kidney transplant. As you know, transplant is only a treatment option for kidney failure and not a cure.

RSN is very disappointed and upset to learn of Medicare's decision to limit reimbursement coverage for molecular diagnostics for transplantation such as donor derived cell free (cf) DNA and gene expression profiling.

It is important for kidney transplant patients to have access to testing that can prevent them from having rejection. Non-invasive methods to assess allograft status, modify immunosuppression regimens, and avoid unnecessary biopsies is seen by the transplant recipients as a significant breakthrough and can help the longevity of our transplant.

Rejection is far too common of a problem after kidney transplantation and to not to allow doctors to use all of the tools to prevent the "Gift of Life" from rejecting is unconscionable. The immune system sees the transplanted kidney as foreign and tries to attack it, and if rejection is not proactively detected it **will** result in failure of the transplanted organ. Regular testing and monitoring can help predict rejection and allow doctors to take timely action to treat it. This ultimately improves the patient's quality of life and will increase the longevity of the transplanted organ. With so many people waiting for life saving organs, every step should be taken to use every innovation possible to sustain this wonderful gift that someone gave to help others live the life they were meant to live. To not do so disrespects their gift.

Innovation plays a critical role in healthcare, including for organ transplant recipients and should be welcomed. Innovation in kidney transplant medicine and testing is crucial for improving patient outcomes and reducing the risk of rejection. It enables doctors to tailor treatments to individual patient's care and offers cutting-edge therapies that can help prolong the life of a transplanted organ. People who experience kidney transplant rejection can return to dialysis (which is costly to Medicare) that can serve as a bridge until another kidney is available. Wait time for an organ in Los Angeles is 10 years. But people who reject other organs don't have the luxury of dialysis and can condemn them to death.

According to the 2022 OPTN kidney transplant report "there has been no significant innovation in the last 20 years to prolong kidney allograft survival." Recent research has shown that combined biomarker tests are the most comprehensive noninvasive testing option for post-transplant care. I have lived through the evolution of transplant care and to think recipients will no longer have access to them is providing "sick care" not "health care."

An illness is too demanding when you don't have hope!

Renal Support Network

Due to the heavy workload or distance to a transplant center many patients are followed by their local Nephrologist in their area. Nephrologists should be able to perform any testing they need to help ensure their patient's transplant is not experiencing any rejection. We all know an ounce of prevention is worth a pound of cure. Also, due to the geographic locations of transplant centers many patients may have to travel quite a distance and this may not be feasible for many people. People who live out of state or are economically disadvantaged may find it challenging to make the long distance trip for testing that could be done by their own local nephrologist.

These innovations should be supported. They can reduce the risk of rejection and improve the long-term outcomes for transplant recipients. Lack of supporting innovation is comparable to stagnation and ultimately hinders progress and growth.

We understand that there have been allegations of over use of surveillance testing and hope that guardrails/guidance can be provided to help patients have access to this diagnostic innovation and work towards preventing rejection of organs all together.

We ask that you reconsider your decision to limit reimbursement coverage for molecular diagnostics and allow organ transplant recipients to have access to the next level of care to preserve the organ so they don't have to go through the pain, suffering and even loss of life from losing an organ.

Please let me know if you have any questions or need additional information.

Warmest Regards,

A handwritten signature in cursive script that reads "Lori Hartwell".

Lori Hartwell, President & Founder