

April 5, 2023

Gabriel A. Bien-Willner, MD, PhD  
Medical Director, MoIDX  
Chief Medical Officer, Palmetto GBA

Via email at: [MOLDX.POLICY@palmettogba.com](mailto:MOLDX.POLICY@palmettogba.com)

RE: Billing and Coding: MoIDX: Molecular Testing for Solid Organ Allograft Rejection (A58019)

Dear Dr. Bien-Willner:

On behalf of the American Society of Transplantation (AST), an organization of more than 4,200 transplant professionals dedicated to advancing the field of transplantation and improving patient care, I am writing to outline our concerns and seek clarification regarding the recent MoIDX decision to limit reimbursement coverage for molecular diagnostics for transplantation such as donor derived cell free (cf)DNA and gene expression profiling.

Transplant professionals have been using molecular diagnostic testing, most commonly to monitor heart and kidney recipients, as a non-invasive method to assess for allograft injury or rejection. We were surprised to see the rapidity with which the recent change was announced with limited notice and without any call for public comment or request for data. Changes in reimbursement directly impact the way these tests can be used for patient care. We believe that these changes have the potential to significantly restrict physician's judgment in considering the best testing option for their patients and their individual circumstances.

We recognize that the MoIDX Program was developed in 2011 to identify and establish coverage and reimbursement for molecular diagnostic tests. However, the process to develop this billing article was not well-defined without acknowledgement of the ensuing consequences to testing algorithms at transplant centers and to patients. The AST respectfully requests additional information regarding the process used to come to the decision outlined in A58019. As outlined in our [December 19, 2022 letter to HHS and CMS](#), we wholeheartedly support development and research into the clinical utility of biomarkers in transplantation. However, we firmly believe a reimbursement change of such magnitude must take into account comprehensive stakeholder input, with a public comment period, all in a fair and transparent process that places the needs of the patients first.

We thank you in advance for your consideration of this request and look forward to future dialogue. Please do not hesitate to contact me directly if you have questions or require any additional information. Additionally, the AST Senior Policy Advisor, Chris Rorick, may be

---

#### **AST NATIONAL OFFICE**

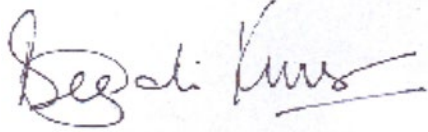
1000 Atrium Way, Ste 400 • Mt. Laurel, NJ 08054  
856.439.9986 • Fax: 856.581.9604  
[info@myAST.org](mailto:info@myAST.org) • [myAST.org](http://myAST.org)

#### **GOVERNMENT RELATIONS**

William Applegate, Director of Government Relations  
Polsinelli  
1401 Eye Street NW, Ste: 800 • Washington, DC 20004  
202.258.4989 • [bapplegate@polsinelli.com](mailto:bapplegate@polsinelli.com)

reached at (202) 626-8369 or [crorick@polsinelli.com](mailto:crorick@polsinelli.com).

Sincerely,

A handwritten signature in black ink that reads "Deepali Kumar". The signature is written in a cursive style with a horizontal line underneath the name.

---

Deepali Kumar, MD, MSc, FRCPC, FAST  
President