ASTS
American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

March 21, 2023

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

RE: *Article - Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection (A58019)*

Dear Dr. Biel-Willner,

As President of the American Society of Transplant Surgeons (ASTS), I am writing to express ASTS' deep concerns about the document entitled, *Article - Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection (A58019)* (the "Billing Article") (Appendix A). ASTS is a medical specialty society representing approximately 2,000 professionals dedicated to excellence in transplant surgery and to the patients that we serve. Our mission is the advancement of the art and science of transplant surgery through patient care, research, education, and advocacy.

We appreciate that data for the rapidly emerging field of molecular diagnostic testing is still maturing and that the global costs associated with such testing are significant. However, we feel strongly that molecular diagnostic testing may provide massive clinical and economic benefits in the early detection and management of solid organ allograft rejection. Utilizing molecular testing for detection of allograft injury is an emerging standard of care that can directly aid in clinical decision making and may improve patient and allograft survival. We support the access of transplant patients to these diagnostic technologies and believe that continued Medicare coverage of these tools is critical to further refine their utility and cost effectiveness**.** We have recently issued an ASTS White Paper on molecular diagnostic testing (**Appendix B**), which provides additional background that was not made public in time to be taken into consideration by MolDX when it formulated the Billing Article.

We have scientific, ethical, and process-related concerns about the Billing Article, which are enumerated below. We are puzzled that the coverage limitations set forth in the Billing Article have been put forward at a time when CMS has clearly acknowledged that transplantation is the best, and most cost-effective, treatment option for those with ESRD, and without consideration of the potential chilling impact on innovation in the field or continuity of care for patients. **We request that MolDX delay the implementation of the Billing Article; subject the Billing Article's modifications of limitations on coverage for these tests to public comment prior to adoption; and provide sufficient notice before any new coverage limitations are implemented.**

I. <u>The Billing Article Inappropriately Circumvents the Public Comment Process and is Inconsistent with the Input Recently Provided by the Palmetto/Noridian Contract Advisory Committee (Joint CAC).</u>

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The Medicare Administrative Contractors only recently completed the process of adopting comprehensive Local Coverage Determinations (LCDs) for molecular diagnostic testing in solid organ transplant recipients; in fact, the applicable Noridian LCD was only finalized on January 14, 2022 (Current LCD) (**Appendix C**[1]). The process of developing and refining the LCD involved required public comment periods as well as input from a MAC-initiated Contract Advisory Committee (CAC).

It is our understanding that MolDX, acting in response to a request from Noridian and in conjunction with Noridian, convened a Joint CAC in the latter part of 2022, to solicit guidance on the subject. The 2022 CAC was strongly supportive of the utility of molecular diagnostic testing in allograft monitoring and supportive of the expansion, not the curtailment, of patient access to these testing modalities.

It is concerning to us that a Billing Article, historically utilized to facilitate implementation of an LCD and not to implement significant policy changes, would be utilized to introduce sweeping limitations on coverage of these critical tests (discussed below). The use of a Billing Article that circumvents public comment is particularly troublesome in the face of significant evidence of the clinical validity of these tests, widespread acceptance of molecular testing by transplant professionals for use in clinical decision making, and the Joint CAC advice supporting expansion—not limitation—of Medicare coverage for these tests. Further, the process used here is completely at odds with today's emphasis on transparency and shared decision making: Curtailing Medicare beneficiary access to validated testing methods in a manner that appears to be designed to circumvent public comment undermines the public trust.

II. The Billing Article Is Inconsistent with the Coverage Policy Reflected in the Current LCD.

The Current LCD states:

> [G]iven the invasive nature and risks associated with a biopsy, tests that can potentially mitigate the need for a biopsy while still providing clinicians with actionable information that can be used to help optimize immunosuppressive therapy are reasonable and necessary. Additionally, ongoing studies have supported that *cfDNA and GEP can accurately determine allograft status in several organ types*, and that molecular characterization can both precede and enhance histologic findings. As such, *these approaches, as a service type, are reasonable and necessary for graft assessment*." (**Appendix C (Emphasis Added**)).

The Current LCD also states that:

> *While these technologies are new, large and multicenter studies have supported their use in renal and heart transplantation as minimally and non-invasive methods to assess allograft status, modify immunosuppression regimens, and avoid unnecessary biopsies*. Evidence continues to develop for other transplant allograft organs and other analytes. Additionally, there is evidence that while some cfDNA and GEP tests may have different intended uses, *combining both may further improve graft rejection determination*. (**Appendix C (Emphasis added**)).

The Billing Article would dramatically and substantively change the LCD by limiting access to these critical tests to those transplant centers that utilize a surveillance biopsy protocol approach (which is an approach used by at most 20% of transplant centers); by dramatically increasing the documentation requirements for ordering tests; by excluding physicians not directly affiliated with transplant centers from utilizing these tests; and by eliminating dual (combined cell-free DNA and gene expression profiling)

tests. These limitations on coverage are adopted without clinical or other support and without explanation.

[1] This letter focuses on the Noridian LCD because Noridian is the primary MAC with jurisdiction over the laboratories that provide molecular testing for solid organ allograft rejection.

It is particularly troublesome that the Billing Article appears to exclude community nephrologists from ordering molecular testing for transplant recipients, instead limiting the ability to order tests to transplant center staff. This change is inconsistent with the many efforts made over multiple Administrations to foster multidisciplinary care, to improve the transition of stable transplant recipients from specialized care at transplant centers back to their communities, and to improve the continuity of care of these complex and vulnerable patients. The recent extension of Medicare immunosuppression drug coverage past the three-year mark was a banner, bipartisan victory, and one that will both save money and improve patient lives. That signature victory was driven by the alignment of stakeholders on the importance of improving long-term transplant survival and increasing access to life-extending and life-saving therapy. As transplant surgeons, we are the primary drivers of allograft monitoring for the first year after transplant, however community nephrologists are also key providers for transplant recipients, especially after expiration of the initial post-transplant period. The promise of molecular testing of transplant recipients is that this important advance in transplant monitoring may dramatically improve long-term allograft survival, and it is thus counterintuitive to deprive access to these tools for the community nephrologists who co-manage these patients over the long term.

III. The Billing Article Implementation Timeline Ignores the Needs of Patients and Makes Continuity of Care Impossible.

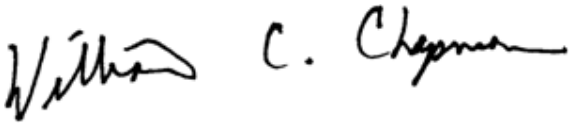
Billing Articles historically have been utilized to provide the detailed billing and coding information necessary to implement coverage policy that is set forth in an LCD. The Billing Article in question, however, would dramatically impede the access of Medicare beneficiaries to vitally important testing and is slated to go into effect only 30 days after the Billing Article was first published.

This timeline does not allow time for transplant hospitals and other providers to establish the clinical care protocols required of them, time to develop adequate documentation, time to implement the necessary hospital electronic health record (EHR) updates, time to revise, review, and implement order sets, or time to train for and implement revised workflow processes. Uncertainty regarding the new coverage limitations likely will result in substantial rescheduling of appointments and potentially lead to delay in the diagnosis of acute rejection events that put patient grafts and lives at risk. The clinical utility of molecular testing in pediatric and adult heart transplant recipients has been revolutionized by the ability of molecular testing to spare transplant patients unnecessary biopsies. If the Billing Article is implemented as scheduled, highly vulnerable patients will need to be informed and new care protocols implemented. In summary, imminent implementation of the substantial changes mandated by the Billing Article imposes an unreasonable burden on patients and on the transplant hospitals and providers that serve them.

For these reasons, we strongly urge MolDX to reconsider the limits on access to critical molecular testing that would be implemented under the new policies reflected in the Billing Article. We also request that any substantive changes impacting coverage of molecular testing for solid organ rejection be adopted through the LCD process and subject to public comment as required by applicable regulations. At a minimum, we request that MolDX delay the effective date of the Billing Article to ensure continuity of care for the vulnerable Medicare patient population we serve. We stand ready to work with you to ensure that any changes to transplantation do not have a deleterious impact on patient care and access to and quality of this life-saving procedure.

We are grateful for the opportunity to share our concerns and welcome a dialogue on this matter.

Sincerely,



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