ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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August 28, 2025

Noridian Healthcare Solutions, LLC JE Part B Contractor Medical Director(s)
Attention: Draft LCD Comments
4510 13th Ave. S, STE1
Fargo, ND 58103-6646
policydraft@noridian.com

Re: DL40140 MolDX: Molecular Testing for Solid Organ Allograft Rejection

Comments submitted electronically via policydraft@noridian.com

Dear Medical Directors:

Thank you for the opportunity to submit these comments in response to the draft Local Coverage Determination (dLCD) entitled DL40060 and DL40062 MolDX: *Molecular Testing for Solid Organ Allograft Rejection*. The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical technologists involved with laboratory testing based on knowledge derived from molecular biology, microbiology, genetics, and genomics. Our membership includes experts in molecular testing from the academic medicine, private and hospital-based clinical laboratories, the government, and the in vitro diagnostics industry that work to ensure coverage policies meet the highest standard of care and allow patients access to needed molecular testing.

AMP thanks Noridian for the inclusion of coverage for molecular tests for solid organ allograft rejection. We believe providing a noninvasive method for assessing organ rejection is a critical component of transplant care and are pleased that this dLCD provides coverage for this essential service. To improve compliance with the dLCD, we encourage Noridian to provide clarification on two aspects in the final LCD to ensure that the document provides a clear, comprehensive, and accurate representation of the coverage limitations.

Coverage Indications, Limitations and/or Medical Necessity

The acronym for Donor-Derived Cell-Free DNA within the definitions provided in this policy is inconsistent with scientific and clinical terminology. The acronym cfDNA is widely recognized as the abbreviation for cell-free DNA in general and is not specific to the donor-derived version of cell-free DNA. Using cfDNA to represent Donor-Derived Cell-Free DNA introduces ambiguity and may cause confusion regarding the scope of coverage for relevant testing. **Instead, AMP recommends that Noridian use the widely accepted abbreviation dd-cfDNA for Donor-Derived Cell-Free DNA, as used by**

organizations such as the American Society of Transplant Surgeons and the National Institutes of Health[1].

While AMP has interpreted the dLCD to have positive coverage of molecular testing for Solid Organ Allograft Rejection, ambiguity in the coverage or non-coverage of dd-cfDNA and Gene Expression Profiling (GEP) testing for transplant rejection remains. For instance, the Summary of Evidence includes the following contrasting statements:

> *"In heart transplantation, molecular biomarker testing has been used for over a decade and, unlike the outdated Banff guidelines for kidney transplantation (at the time of this work), the ISHLT guidelines do recommend the use of molecular biomarker testing in the evaluation of heart transplant recipients."*

> *"Though GEP will continue to be covered in heart transplantation only as it has become a standard of practice, providers should be aware that they may be performing an inferior service."*

AMP is concerned that this ambiguity could inadvertently restrict patient access to these potentially life-saving diagnostics in situations where coverage might be applicable. To prevent such confusion, **AMP requests that the document be revised to specify the coverage scenarios for dd-cfDNA and GEP testing in the Coverage Indications, Limitations, and/or Medical Necessity section**. This would help ensure that both patients and providers have a clear understanding of when these tests are covered, thereby improving access and supporting better clinical decision-making.

The Association for Molecular Pathology thanks Noridian for the opportunity to comment on DL40060 and DL40062 MolDX: Molecular Testing for Solid Organ Allograft Rejection. If AMP may be of further assistance, please contact Annie Scrimenti, AMP Director of Public Policy and Advocacy at ascrimenti@amp.org.

Sincerely,
Jane S. Gibson, PhD
President, Association for Molecular Pathology

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1 https://pmc.ncbi.nlm.nih.gov/articles/PMC9634115/#:~:text=Rationale%20for%20using%20donor%2Dderived,filtered%20through%20the%20glomerular%20barrier.