ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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Contractor Medical Director (s) Noridian Healthcare Solutions, LLC
Attention: Draft LCD Comments
4510 13th Ave. S, STE1
Fargo, ND 58103-6646

Submitted electronically via policydraft@noridian.com

Subject: DL40435 MolDX: Transcriptional Biomarkers for Therapeutic Decision-Making in Renal Carcinoma

Dear Medical Director,

On behalf of the Association for Molecular Pathology (AMP), we thank you for the opportunity to comment on the draft Local Coverage Determination (dLCD) entitled DL40435 MolDX: Transcriptional Biomarkers for Therapeutic Decision-Making in Renal Carcinoma.

AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry. AMP members are highly involved in the development, validation, and interpretation of molecular diagnostic tests.

AMP thanks Noridian for developing this draft LCD and generally considers the proposed coverage policy reasonable. However, AMP recommends clarification of the term "significant improvement" in Criterion 4. The term is currently too broad and undefined to provide clear guidance regarding how this criterion should be applied. **AMP therefore requests that the Noridian define "significant improvement" within the policy to provide greater clarity and consistency for laboratories and other stakeholders applying the coverage criteria.**

Thank you again for the opportunity to review and comment on this draft policy. We are happy to provide additional clinical or other information to assist you as you work towards finalizing the LCD. Please direct your correspondence to Samantha Pettersen Policy Manager, Public Policy and Advocacy at spettersen@amp.org.

Sincerely,

Jay Patel, MD
Chair, Economic Affairs Committee
Association for Molecular Pathology