July 1, 2024

Gabriel Alejandro Bien-Willner, MD, PhD
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**Re: New LCD Request – Proteomics Testing for Nonalcoholic Steatohepatitis/Metabolic Dysfunction Associated Steatohepatitis**

Dear Dr. Bien-Willner,

Following up on the conversations held with Siemens Healthineers throughout June 2024, we are writing to request a new Local Coverage Determination (LCD) for proteomics testing for metabolic dysfunction-associated steatohepatitis (MASH), also referred to as nonalcoholic steatohepatitis (NASH). As you are aware, Siemens Healthineers is the developer of the ADVIA Centaur® Enhanced Liver Fibrosis (ELF™) test, which received De Novo marketing authorization from the U.S. Food and Drug Administration (FDA) in August 2021. The ADVIA Centaur® Enhanced Liver Fibrosis (ELF™) test is indicated for in vitro prognostic use in the determination of an ELF™ score based on the combined quantitative measurements of hyaluronic acid, amino-terminal propeptide of type III procollagen, and tissue inhibitor of matrix metalloproteinase 1 in human serum. The ELF™ test is indicated as a prognostic marker in conjunction with other laboratory findings and clinical assessments in patients with advanced fibrosis (F3 or F4) due to non-alcoholic steatohepatitis (NASH), to assess the likelihood of progression to cirrhosis and liver-related clinical events.

As detailed in the request below, the ELF™ test has become the standard of care and is widely recommended by clinical guidelines. The test is described by a Category I Current Procedural Terminology (CPT®)[1] code—81517 (Liver Disease, Analysis of 3 Biomarkers (Hyaluronic Acid [HA] Procollagen III Amino Terminal Peptide [PIINP], Tissue Inhibitor of Metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years). According to the January 2024 Billing and Coding Article on Proteomics testing, the ELF™ test was required to obtain a DEX Z-code. Although the test had received consistent payment from Medicare since its launch in January 2022, the establishment of the Z-code caused a sudden stop in payment for our customers. After discussions with MolDx regarding this issue and our concern on its impact and disruption on the standard of care for patients, a subsequent article was published stating a continuation in payment until January 2025. However, we were notified that a Local Coverage Determination would be required to establish coverage with payment after the January 2025 deadline. Due to this sudden change in requirements, we are concerned about negative impacts to Medicare beneficiary access to the test given that it has been paid for several years, and clinicians rely

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on it for managing patient care. While we appreciate that MolDX has delayed enforcement[2] for changes to reimbursement under the Billing and Coding Article we are concerned that further delay to develop and finalize an LCD and then perform a technical assessment will inappropriately delay Medicare beneficiary access to care.

For this reason, we request that MolDX consider the below LCD request and issue an LCD covering the ELF test urgently to avoid access interruptions for Medicare beneficiaries to a test that is widely recommended in clinical guidelines and that has been paid for several years. If you have any questions about the below request please do not hesitate to contact me.

Thank you for your consideration of this LCD request.

Sincerely,

Hilary Imai
Senior Director, Reimbursement

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[2] *Enforcement Delay for Reimbursement – Billing and Coding: MolDX: Proteomics Testing A59636*, MolDX, https://www.palmettogba.com/palmetto/moldxv2.nsf/DID/D7TP8WFSCU (published May 17, 2024).