COLLEGE of AMERICAN PATHOLOGISTS

May 31, 2024

Sent via email.

Lucy Langer, MD MSHS
National Medical Director/CMO, Oncology, Genomics & Laboratory
UnitedHealthcare

Dear Dr. Langer:

On behalf of the College of American Pathologists (CAP), thank you and others at UnitedHealthcare for taking the time to meet with us to discuss the upcoming Z-code requirement. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

While we appreciate the ongoing communication and implementation delays, we continue to have serious concerns with the requirement for reimbursement that molecular pathology claims contain a DEX Z-code, which is obtained from the Palmetto DEX Registry. As you know, we have concerns with the requirement itself, as we continue to support the use of the CPT code set as the appropriate method to address issues with information on specific tests. The CPT code set is transparently developed with broad stakeholder input, including CMS and other payers who are represented on the Editorial Panel. Adhering to the use of the applicable CPT codes (a recognized, HIPAA-compliant Level I HCPCS code set) for reporting of molecular pathology and genomic procedures is strongly advised, as it does not add further requirements and reporting complexity to process claims for medically necessary services and remains in alignment with the reporting requirements established by other private payers. Additionally, as the American Hospital Association emphasized in their recent letter urging UnitedHealthcare to reconsider implementation of this policy[1], revenue cycle resources are seriously strained due to the Change Healthcare cyberattack. However, we remain additionally apprehensive about the process of obtaining Z-codes and the sharing of information between UnitedHealthcare and Palmetto, as well as what this requirement means for pathologists in non-Palmetto jurisdictions. Despite UnitedHealthcare's best efforts to suggest otherwise, we feel this requirement will still prove to be highly disruptive, administratively burdensome, and extraordinarily expensive for pathologists and laboratories, and ultimately, impede patient access to medically necessary testing.

For example, especially for those pathologists in non-Palmetto jurisdictions who do not have prior experience with the MolDx program, registering with the DEX Registry and submitting tests successfully will take significant time, resources, and education. Additionally, there are likely thousands of hospital/clinic laboratories that send out molecular tests that will have to register and ask for "sharing" to link with the dozens of reference laboratories they use. Per our earlier conversations and current understanding, "both labs must register in DEX" – the performing lab

[1] https://www.aha.org/system/files/media/file/2024/03/aha-letter-to-unitedhealthcare-re-molecular-pathology-reimbursement-policy-letter-3-26-2024.pdf

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submits the test details to receive the Z-code, and the billing lab must request "sharing" in DEX to obtain access to the Z-code from the performing lab, and the 2 labs then link in DEX with a "sharing request." And once all appropriate Z-codes are obtained, requirements for plan-specific non-standard coding could have serious negative consequences for pathologists and laboratories trying to implement conflicting requirements in practice. We understand the implementation delays were intended to provide more time to address some of this complexity, but as long as the requirement remains, we believe pathologists and laboratories will unnecessarily strain under the administrative burdens and operational difficulties, which risks interfering with the ability for a patient to receive timely and appropriate services. In fact, the continued delays support our concerns around the complexity of these requirements.

Additionally, while UnitedHealthcare assures us they are using their own medical policies to determine coverage, the added requirement for laboratories to go through the Palmetto/MolDx technical assessment (TA) for certain tests is highly burdensome and financially demanding. We also find it highly inappropriate for UnitedHealthcare requirements to result in MolDx's public posting of these TA results, which are otherwise only published by Palmetto/MolDx for Medicare coverage determinations in the MolDx applicable MAC jurisdictions. The CAP is wary about how this published information could be subject to misinterpretation and urges UnitedHealthcare to ensure clarification around the different processes/usage. Relatedly, we have heard reports from members about MolDx misstating publicly that a test has a "Not Successful" technical assessment, which is being cited as a cause for denials. While some of these issues need to be addressed with Palmetto/MolDx directly, expanding these issues through the UnitedHealthcare requirements will be detrimental to patient care.

Finally, we and other stakeholders continue to be seriously concerned about the lack of protections around information sharing between Palmetto (Medicare) and UnitedHealthcare, as well as other insurers, and the potential ways in which that information could be misused. Pathologists are already under financial stress today, and increasing information sharing among insurers to collude to control payment would have serious consequences in terms of resources to provide timely access to medically necessary and high-quality testing.

Pathologists know that the right test at the right time makes all the difference for patients. The CAP is committed to improving care and increasing transparency, but we believe the UnitedHealthcare Z-code requirements are needlessly disruptive, burdensome, and financially demanding. We therefore urge UnitedHealthcare to reconsider the requirements and work with the CAP on a better solution to whatever issues these were intended to address. Elizabeth Fassbender, JD, Director, Economic and Regulatory Affairs remains the point of contact on this issue and can be reached at efassbe@cap.org or 202-354-7125.

Sincerely,

Ronald W. McLawhon, M.D., Ph.D., FCAP, FAACC
Chair, Economic Affairs Committee

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