COLLEGE of AMERICAN PATHOLOGISTS

June 2, 2023

To Whom It May Concern:

The College of American Pathologists (CAP) has serious concerns with Optum's new laboratory benefit management (LBM) program and the negative impact it could have on patient care. 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.

First, we understand that the Optum LBM program seeks to address "inappropriate utilization" through, for example, limits on the number of CPT 88305 units that will be reimbursed by specimen type and automatically denying payment for "inappropriate add-on tests." The CAP is committed to addressing overutilization of testing, but policies or programs that interfere with a patient's ability to receive timely and appropriate services/care risk negatively affecting patients, providers, and the entire health care system. To that point, we have serious concerns with limits on anatomic pathology that are not consistent with standard medical practices, including the published Medicare Medically Unbelievable/Unlikely Edits (MUE) policy for 88305 of 16 units of service per patient per day.[1] There are a number of common circumstances that may require more units of service on a given day, and limits should be set at a level likely to catch the rare and unlikely practices rather than restrict access to necessary services. Importantly, these kinds of restrictive policies also do not appear to account for the fact that pathologists and clinical laboratories do not control the number of specimens sent to them. It is the ordering physician that determines the number of specimens and maintain the patient information/medical records – and the outlier providers who engage in overutilization should be specifically targeted instead of generally imposing limits that could harm patient care. **To further explain our position and provide examples where it is common clinical practice to bill more 88305s, we request a meeting with Optum at your earliest convenience**.

Additionally, it is critical that utilization management policies or programs like the Optum LBM ensure transparency based upon updated and appropriate evidence. It is also critical, that as anatomical and clinical pathology are rapidly evolving specialties, this transparency allows for adoption of emerging beneficial tests for patients. **Pathologists are uniquely positioned to assist in adding value to patient care and controlling costs through application of evidence-based approaches, yet we have seen little detail on the clinical guidelines being used by the Optum LBM or other details on how laboratory claims are evaluated**. Optum asserts a lack of test management and oversight, but pathologists spend a significant amount of time and effort fulfilling their responsibility for quality laboratory services to their patients and their fellow practitioners, including approval and evaluation of appropriate test methods, pre- and postanalytical oversight, and direct involvement with technologists and clinical colleagues to ensure prioritization and proper response to test results. In fact, pathology services constitute a critical infrastructure and the foundation of appropriate care.

Further, any denials of testing should be appealable based on medical necessity to ensure proper access to quality care for patients. Administration/review of decisions,

[1] https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html

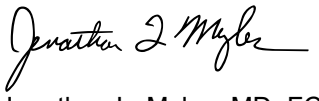
College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100

including denials/appeals, must be conducted by providers who are at least as qualified as the prescribing/ordering physician whose decision-making is otherwise subject to utilization review. **Additional details on evidence/guidelines utilized, appeals processes, and the qualification of administrators/reviewers is appreciated.**

Finally, the CAP has serious concerns with the Optum partnership with Palmetto GBA and the requirement for specific Z-code identifiers on claims in order to receive payment. **Non-standard, non-HIPAA compliant coding/reimbursement practices have serious negative consequences for pathologists and laboratories trying to implement conflicting requirements on the ground, and we ask Optum to remove this requirement**. The CAP supports the continued use of the CPT code set as it is developed with broad stakeholder input and provides a uniform language that accurately describes medical, surgical, and diagnostic services provided by physicians and other qualified health care professionals. In addition, the CPT Editorial Panel has the infrastructure and capacity to process code requests on a quarterly basis, provide transparency, and offer a public forum at regular intervals several times a year to convene interested and impacted stakeholders. This process would be the appropriate method for insurers to address any issues with information on specific tests and it would not add further requirements and reporting complexity.

Pathologists know that the right test at the right time makes all the difference for patients. The CAP is committed to improving care and addressing escalating health care costs, but excessive management of cost through overly restrictive LBM programs that inhibit patient access to required testing will jeopardize patient care. Therefore, we urge Optum to reverse its LBM program and we request an opportunity to discuss these important issues further. Elizabeth Fassbender, JD, Assistant Director, Economic and Regulatory Affairs will reach out to schedule a meeting and can be reached at efassbe@cap.org or 202-354-7125.

Sincerely,



Jonathan L. Myles, MD, FCAP
Chair, College of American and Professional Affairs

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100