April 23, 2021

Sent via email

Julie B. Kessel, MD
Medical Officer for Coverage Policy
Clinical Performance & Quality Organization
Cigna
kessel@cigna.com

Dear Dr. Kessel:

The College of American Pathologists (CAP) has recently become aware of a new Cigna policy "Modifier 26 – Professional Component," effective July 10, 2021, which will deny reimbursement for CPT codes "billed with modifier 26 when applied inappropriately based on the Centers for Medicare & Medicaid Services (CMS) National Physician Fee Schedule." The CAP urges Cigna to rescind this policy update and to continue payment for the professional component of clinical pathology ("PC of CP") services for all pathologists. 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. The proposed policy hinders patient access to pathology services through lack of payment for pathology and laboratory services. Now more than ever, patients and their treating physicians appreciate their reliance on the expertise of pathologists and the availability of appropriate testing.

The PC of CP services are critical to the reliable and accurate diagnosis and treatment of patients, particularly in delivery systems increasingly reliant upon care coordination, integration, and population management. The CAP's Policy on Pathologist Professional Component Billing for Clinical Pathology Services (see attached) describes the nature and type of professional services provided by the physician director of a clinical laboratory. As set forth in that policy, pathologists as directors of hospital laboratories spend a significant amount of time and effort fulfilling their responsibility for quality laboratory services to their patients and their fellow practitioners. For example, clinical pathology services include development, approval and evaluation of appropriate test methods (including instrumentation, reagents, standards, and controls), pre- and postanalytical oversight, and direct involvement with technologists and clinical colleagues to ensure prioritization and proper response to test results. During the COVID-19 public health emergency, pathologists in hospitals and independent laboratories around the country have been responsible for developing and/or selecting test methodologies, validating and approving testing for patient use, and expanding the testing capabilities of the communities they serve to meet emergent needs.

The pathologist is also professionally responsible and legally accountable for their laboratory's results. In preparation for this responsibility, pathologists complete a specific medical residency program. Moreover, federal certification standards and The Joint Commission standards require certain professional, organizational, and administrative services be provided in the clinical laboratory to assure quality laboratory services to patients. Clinical pathologists assure compliance with all laboratory regulatory and accreditation standards. In fact, pathologists are uniquely positioned to assist in adding value to patient care and controlling costs through application of evidence-based approaches. The influence of all these pathology services on clinical decision-making is pervasive and they constitute a critical infrastructure and foundation appropriate care.

The medical necessity of these services, provided by the pathologist-director, has justified their recognition by the CMS as described below. For Cigna to discontinue reimbursement for these services will thus not only prove detrimental to patients, and to the integrated delivery of care to which laboratory diagnostic services are central, but is also inconsistent with the implied rationale for this Cigna policy, which disingenuously references the CMS reimbursement criteria out of context of the CMS reimbursement mechanism.

The CMS recognizes the PC of CP services by their inclusion in the Part A payment Medicare makes to hospitals for each patient. As you know, for each patient, Medicare pays the hospital based on the patient's diagnosis related group or DRG. A payment amount is assigned to each DRG, which is for the full spectrum of services received by the patient, including PC of CP services. Hospitals are then to pay pathologists for such services at fair market value for such services. Additionally, there are several clinical pathology procedures that Medicare reimburses under Part B.

Further, actual CPT language and guidelines allow for the use of the -26 modifier as a legitimate mechanism to describe the professional component of clinical pathology services for non-Medicare patients. Certain procedures, including clinical pathology services, are a combination of a physician professional component and a technical component. For procedures with both a technical and professional component, the American Medical Association (AMA) recognizes the use of the -26 modifier when the professional component of the procedure is being reported separately. The -26 modifier is used to describe the physician professional services in those instances when the physician is only billing for the professional component and the facility is reporting the technical component. In the first article published in the CPT Assistant, Volume 9, Issue 5, May 1999, the AMA states that the use of the -26 modifier is appropriate when the physician is billing separately for the professional component of a laboratory test. More recently, in the CPT Assistant, Volume 15, Issue 8, August 2005, the AMA defined the professional component of clinical pathology by reference to the description in the CAP's Policy on Pathologist Professional Component Billing for Clinical Pathology Services.

The AMA CPT additionally discusses the use of the -26 modifier within their molecular pathology section on page 600 of the 2021 CPT Professional Edition on how to bill the

professional component of molecular pathology services. "The results of the procedure may require interpretation by a physician or other qualified health care professional. When only the interpretation and report are performed, modifier 26 may be appended to the specific molecular pathology code."

As described above, discontinuing reimbursement for PC of CP services billed with modifier 26 is inconsistent with its recognition by CMS and CPT. It is also inconsistent with results of recent litigation. Some of these recent results include:

Palmetto Pathology Services v. Health Options, Inc. -- The Florida Supreme Court's declining to review the decision of the Florida appellate court in the Palmetto case represented the judicial conclusion in favor of Palmetto Pathology Services and the 10 other groups that had been joined in the suit brought against Blue Cross Blue Shield of Florida's HMO, Health Options in 2005.

As of early 2009, Palmetto's attorneys had already collected the judgment and Health Options had paid Palmetto approximately \$1.5 million in damages for non-payment of professional component of clinical pathology claims, including interest. The case has been characterized as not only very favorable for pathologists in Florida, but also as a paradigm changer for future HMO direct payments to pathologists for the professional component of clinical pathology services under Florida law. The CAP, AMA, and the Florida Medical Association submitted amicus briefs at various stages of the litigation in support of Palmetto.

The case stemmed from the 1999 unilateral decision by Health Options to halt payment for professional component of clinical pathology services. In recognition of professional component of clinical pathology services, the Third District court in this case indicated "'Physician care,' as that term is defined by Florida law, is the 'care, provided or supervised by physicians... and shall include consultant and referral services by a physician". The court also indicated, "The record here demonstrates that the disputed services include supervisory duties, consultations, and referrals by the physician pathologists."

Neighborhood Clinics, L.L.C. v. Pathology CHP S.C., et al -- Pathologists
emerged victorious as an Illinois court upheld the validity and fairness of the
practice. In this case, the court ruled that it is fair for pathologists to bill for the
professional component of clinical pathology services. Both CAP and the AMA
submitted amicus briefs in favor of the pathologists.

A passage in the ruling gave particularly strong support for professional component billing for clinical pathology services reading "The evidence is overwhelming that patients and not just the hospitals benefit from the pathologists' quality control services billed under the PC-CP which insure the accuracy and reliability of the laboratory result needed for their diagnosis and treatment. . . It is not unfair that patients pay for pathologists' quality control

services in assuring that the pathology lab established by the hospital is run properly." Neighborhood Clinics had contracts with numerous HMOs and health plans, such as Blue Cross Blue Shield, Humana, and others.

- In the leading federal case on the topic, <u>Central States v. Pathology Laboratories of Arkansas</u>, the court rejected the insurer's argument that pathologists "do not render medical services to Hospital patients." To the contrary, the court of appeals found that "Pathology Laboratories provides supervisory services of value to all patients. . ." The court also underscored pathologists being present or on call 24 hours and intervening to ensure a test is done right, recheck a surprising result or interpret ambiguous data in support of its ruling in their favor on payment for their PC of CP services.
- Palmetto Pathology Services, P.A. v. United Healthcare of Florida, Inc. -- Most recently, on October 23, 2020, a class action settlement was reached on favorable terms to pathologists after UnitedHealthcare stopped making payments for PC-CP to its non-par providers on its Medicaid lines of business. Pathologists will now receive full PC-CP reimbursement from UnitedHealthcare on past and future Medicaid claims.

In closing, we urge Cigna to reconsider and reverse its proposed policy of discontinuing payment for PC of CP services. This policy is inconsistent with CMS practices as well as AMA/CPT guidance, and is detrimental to our patients, your beneficiaries. Elizabeth Fassbender, JD, Assistant Director, Economic and Regulatory Affairs will contact you to arrange further discussions. She can be reached at efassbe@cap.org or 202-354-7125.

Sincerely,

Jonathan L. Myles, MD, FCAP

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Chair, Council on Government and Professional Affairs