



COLLEGE of AMERICAN PATHOLOGISTS

March 24, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE. COVID19 Medicare Contractor Pricing

Dear Administrator Verma:

The College of American Pathologists (CAP) urges the Centers for Medicare and Medicaid Services (CMS) to delete HCPCS codes U0001 and U0002 and utilize the new CPT code 87635 to accurately price laboratory test pricing for COVID-19. The initial pricing published March 12, 2020 for HCPCS codes U00001 and U0002 is too low and lacks the transparency expected in establishing pricing for clinical laboratory fee schedule reimbursement for COVID-19 diagnostic testing.

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.

On March 12, the Centers for Medicare and Medicaid Services (CMS) announced initial payment rates of about \$36 for HCPCS code U0001 for CDC developed coronavirus tests, and approximately \$51 for HCPCS code U0002 for laboratories performing non-CDC tests. On March 13, 2020, the AMA CPT Editorial Panel published new code 87635, Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique. The CPT Editorial Panel rapidly developed and published this code to ensure CPT can accommodate accurate coding to address the current need for COVID-19 diagnostic testing.

Given that CMS will allow laboratories to bill Medicare starting in April, the payment rate was set without access to charges for the test, and the MACs have not provided any methodology used to establish their rates. Based on our review of costs from our members providing or seeking to offer the test in their laboratory, it is clear that the payment amount set for both tests by the CMS is woefully inadequate. The cost of the reagents, supplies, and labor involved to produce one test kit, as well as the incremental equipment and other fixed capital costs, far exceed the current MAC reported payment amounts. Cost estimates vary greatly between laboratories and many supplies and clinical labor are now being reported to be in erratic and short supply, resulting in even higher costs for all producers.

Initial inappropriate test pricing for COVID-19 will lead to unnecessary delays and complications to the current crisis. In this situation, independent laboratories may be providing the majority of these tests, however large and small hospital laboratories are also involved to account for the unyielding demand for these tests. It's been reported that hospitals are already estimating millions of dollars in losses due to this crisis (i.e. Columbia New York Presbyterian estimates operating losses could reach \$450 million.) Commercial payers, desperate to set appropriate pricing, typically refer to MAC



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pricing as a benchmark for their own fee schedules. The CAP urges the CMS abandon the two HCPCS codes and establish appropriate COVID-19 test pricing for CPT code 87635.

The CAP is concerned with the transparency issues and lack of full disclosure associated with the COVID-19 test prices. While the CMS published prices from each of the MACs on March 12, 2020, the singularity of pricing illustrates the transparency problems inherent in the methodology used by the MACs to determine pricing. It is unclear how each MAC determined the same exact price, and whether the majority of the MACs each independently established and submitted their own pricing information (or simply adopted another MAC's pricing). Most importantly, what data was utilized for each code? This non-transparent process and resultant pricing clearly will have many adverse and unintended consequences to providers, patients, and health care institutions that will limit access to these medically necessary services.

These and other factors leave us concerned that providing laboratories may not be able to continue to offer these services. Furthermore, because Medicaid and commercial payers often use Medicare as a benchmark when developing their own payment policies, the outcome of pricing at the MAC level could influence payment rates set by other payers as well. In some states, Medicaid state programs are set at a percentage of the Medicare rates, including those listed on the Clinical Laboratory Fee Schedule. As a result, access to these services could be further restricted.

According to the CMS, MACs-specific amounts are established using the following sources of information, if available: (1) Charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payers; (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and (5) other criteria that CMS determines appropriate. It is clear that the MACs failed to use this process when setting the price for the COVID-19 tests.

The CAP requests that the CMS withdraw HCPCS code U0001 and U0002 and establish a price for CPT code 87635 that ensures laboratories are reimbursed for the resources needed to perform the tests.

The College of American Pathologists appreciates your consideration of these comments. Please direct questions to Pam Wright at pawrigh@cap.org or Todd Klemp at tklemp@cap.org.

Sincerely,

Jonathan L Myles, MD, FCAP
College of American Pathologists
Board of Governors
Chair, Council on Government and Professional Affairs