

October 21, 2020

**VIA Electronic mail to: CLFS Annual Public Meeting@cms.hhs.gov**

Ms. Carol Blackford  
Director  
Hospital and Ambulatory Policy Group  
Centers for Medicare & Medicaid Services (CMS)  
7500 Security Boulevard  
Baltimore, MD 21244

**RE: CLFS Crosswalk Recommendation for SARS-CoV-2 Testing under codes U0002, U0003, U0004, 87635, 86328, and 86769**

Dear Ms. Blackford:

On behalf of the organizations listed below, which represent the major clinical laboratory stakeholders involved with testing for COVID-19, we are writing in response to the Preliminary Determinations for the above-referenced HCPCS codes for the CY 2021 Clinical Laboratory Fee Schedule (CLFS). In the Preliminary Determinations,<sup>a</sup> the Centers for Medicare & Medicaid Services (CMS) has proposed to set the CLFS rates for these six COVID-19 in CY2021 using the gapfill process. For the reasons specified below, **we strongly urge CMS to assign rates for these codes using crosswalk rather than gapfill for CY2021, and we offer specific crosswalks that we believe best reflect the resources required to develop and furnish these tests.**

Below is a list of the codes, the descriptors, the CMS Preliminary Determination, and the stakeholder consensus recommendations:

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<sup>a</sup> [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory\\_Public\\_Meetings](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings)

Code	New Code Descriptor	CMS Prelim Rec	Stakeholder Crosswalk Recommendation		
			Code	Crosswalk Code Descriptor	Rate
<b>U0002</b>	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	Gapfill	<b>87502</b>	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or subtypes	\$95.80
<b>U0003</b>	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, making use of high throughput technologies as described by CMS-2020-01-R	Gapfill	<b>87502</b>	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or subtypes	\$95.80
<b>U0004</b>	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	Gapfill	<b>87502</b>	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or subtypes	\$95.80
<b>87635</b>	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	Gapfill	<b>87502</b>	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or subtypes	\$95.80
<b>86328</b>	Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	Gapfill	<b>2.5*86318</b>	Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent strip)	\$45.23
<b>86769</b>	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	Gapfill	<b>2.5*86318</b>	Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent strip)	\$45.23

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The laboratory stakeholders strongly urge CMS to adopt rates for the COVID-19 tests through crosswalk rather than gapfill because there are appropriate crosswalks to substantially similar tests that will establish rates appropriate to cover the resources required for COVID-19 detection tests and will incentivize appropriate testing. Establishing rates through crosswalk rather than gapfill will facilitate medically necessary testing. By contrast, gapfill leads to uncertainty about payment for a substantial part of the gapfill year. Preliminary rates not announced till nearly half-way through the year; final rates not announced till nearly the end of the year. Moreover, gapfill leads to different rates across the country, which risks differential access to testing if rates are inadequate in some regions. Therefore, the stakeholders strongly urge CMS to adopt CY2021 CLFS rates for the six codes using the crosswalk—rather than gapfill—process.

The specific crosswalks recommended by the stakeholders reflect the significant resources required to develop and furnish COVID-19 tests. Clinical laboratories and manufacturers rose to meet the needs of the healthcare community by investing substantial resources rapidly to develop tests for SARS-CoV-2. The development of these tests involved substantial costs, including:

- Development and ramping up production capabilities under the EUA program requires many test developers to stall other projects which is associated with a significant opportunity cost.
- Changeover costs in test development are significant. While some testing resources can be redirected from one product to another, there are significant changeover costs. Usually changeover costs can be planned so that the fewest possible changeovers are needed to achieve a steady test supply. However, under the public health emergency (PHE), production had to be rapidly ramped up to meet the demand. We anticipate that when the public health emergency is over, the demand for tests may drop significantly, and test developers will experience changeover costs again.
- The FDA has not announced any pathways to permit COVID-19 tests on the market under an EUA to continue to be marketed following the end of the PHE. As such, it appears that manufacturers will have to take current COVID-19 tests through FDA premarket review processes following the conclusion of the PHE.
- Accelerated development timelines require test developers to pursue numerous avenues of development that they would not normally pursue if they had more time.

Several of the stakeholders listed below previously submitted proprietary cost information to CMS and the MACs to quantify some of the costs associated with the factors above in order to support the differential costs of COVID-19 testing compared to other microbiology and immunology tests that otherwise may seem methodologically similar but which do not involve these extraordinary costs incurred due to the PHE.

In addition to the substantial development costs, ongoing operational costs for COVID-19 testing include the following:

- Technicians need additional PPE because of the high transmissibility of SARS-CoV-2.
- Reagent costs are several times what they were prior to the pandemic.
- Patient service centers need additional shifts/expanded hours, resulting in higher labor costs.
  - Demand for testing continues to be high.
  - Waiting rooms cannot be crowded with individuals who may be infectious.
  - Appointments must be spread further apart to allow for social distancing and collection station sterilization.
- The entire cost of the specimen collection – already higher than normal – will be attributed to the COVID-19 test alone.

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- Oftentimes the cost of specimen collection is spread among several tests for which specimens are collected at once (e.g., CBC, cholesterol, HbA<sub>1C</sub>).
- In most cases a specimen will be collected only for the COVID-19 test.
- Laboratories need to repurpose equipment that otherwise would be used for different testing in order to accommodate higher demand for COVID-19 testing, in some cases even developing multiple kinds of tests to meet test demand in the presence of supply chain shortages.<sup>b</sup>
- Laboratories have far greater public health reporting demands now than with typical microbiology and immunology tests.
  - Laboratories are reporting different information to multiple public health agencies in different states and different levels of government.
  - There are additional labor costs for IT specialists to extract data from the laboratory information system and interface with multiple public health agency reporting systems, including to provide real time reporting.
- Laboratories incur additional costs associated with prioritization of specimens to ensure only the proper patients are tested in the right order, in accordance with public health guidance, including IT costs and costs associated with disruption of the normal workflow.
- Widespread availability of COVID-19 testing requires the involvement of all kinds of laboratories.
  - Small laboratories and those in rural areas tend to have higher cost structures.
  - Many laboratories will not do this testing if they cannot cover their costs, and testing will not be widely available enough for it to be a useful public health tool.

In conclusion, test developers invested significant resources and set aside important projects to assist to develop COVID-19 testing in response to the COVID-19 pandemic. Clinical laboratories performing these tests continue to incur extraordinary costs in furnishing these tests—costs that are substantially in excess of costs incurred when performing amplified probe testing for a single type or subtype of influenza. These test developers have been acting under the hope that CMS would establish appropriate and fair reimbursement for this testing. **Therefore, we strongly urge CMS to establish rates for the six COVID-19 tests listed above by crosswalk to the codes shown above consistent with the recommendations made by the stakeholders at the Public Meeting and the extraordinary resources required to develop these tests and required to continue to offer these tests to Medicare beneficiaries.** We also ask that CMS consider the precedent of its decision for future public health emergencies when test developers must act with uncertainty regarding future payment.

Sincerely,

AdvaMedDx  
American Association for Clinical Chemistry  
American Clinical Laboratory Association  
American Society for Clinical Pathology  
American Society for Microbiology  
Association for Molecular Pathology  
College of American Pathologists  
Point of Care Testing Association

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<sup>b</sup> See Association of Molecular Pathology Survey: <https://www.amp.org/advocacy/sars-cov-2-survey/>