October 24, 2022

VIA Electronic Mail to: CLFS_Annual_Public_Meeting@cms.hhs.gov

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CY 2023 Clinical Laboratory Fee Schedule Preliminary Determination for CPT Code 87428

Dear Administrator Brooks-LaSure:

On behalf of the Point of Care Testing Association (POCTA), joined by QuidelOrtho, and in response to CMS's posting of the CY 2023 CLFS Preliminary Payment Determinations, please see the following comments to inform the final CLFS rate determination for CPT code 87428 (*Sarscov & inf vir a&b ag ia)*.[1] CPT code 87428 describes instrumented antigen testing by immunoassay that reports separate (qualitative) results for COVID-19, influenza A, and influenza B. **For the reasons outlined below, we respectfully request that CMS "gapfill" 87428 in CY 2023.**

Background

The AMA CPT Editorial Panel created CPT code 87428 effective November 10, 2020.[2] The Medicare ratesetting history for this code is summarized below:

Year	CLFS Rate	Rationale
2021	**$63.59-$73.49**	Rates established by individual Medicare Administrative Contractors (MACs) Rates based on proprietary cost information submitted to each MAC by test developers
2022	**$30.94**	Rates established by CMS CDLT Advisory Panel overwhelmingly (10-2 vote) recommends crosswalk to 87430 (*Strep a ag ia*) x 2.0 PLUS 87400 (*Influenza a/b each ag ia*) x 2.0 • CDLT Panel-supported rate = **$61.88** Nevertheless, CMS crosswalked to 87430 x 1.0 PLUS 87400 x 1.0 • CMS-established rate = $30.94 Stakeholders request reconsideration

[1] The full descriptor for CPT code 87428 is "Infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B)."
[2] CPT Assistant, Special Edition: November Update – COVID-19 November Update (Nov. 10, 2020), https://www.ama-assn.org/system/files/2020-11/cpt-assistant-guide-coronavirus-november-2020.pdf.

At the June 23rd, 2022 CLFS Public Meeting (and in subsequent written correspondence), we requested that CMS gapfill 87428 in CY 2023. We made this request based on our understanding that CMS could not crosswalk a new or substantially revised HCPCS code to HCPCS code(s) that are going through gapfill at the same time. At the July 19th CDLT Advisory Panel meeting, Division of Ambulatory Services (DAS) Director Sarah Shirey-Losso advised that CMS may crosswalk a HCPCS code to a code that is currently being gapfilled, pending confirmation from the Office of General Counsel (OGC). The CPT code for COVID-only instrumented antigen testing – 87426 (*Sarscov coronavirus ag ia*) – is currently going through the gapfill process in CY 2022, and a CPT code with an established CLFS rate exists for instrumented antigen testing for each type of influenza (87400 (*Influenza a/b each ag ia*)). As a result, the CDLT Advisory Panel overwhelmingly (9-1 vote) recommended to crosswalk 87428 to 87426 (*Sarscov coronavirus ag ia*) with a 1.0x multiplier PLUS 87400 (*Influenza a/b each ag ia*) with a 2.0x multiplier (CDLT Panel-supported rate = $63.59).

Subsequently, we understand that CMS concluded that it does not have authority to crosswalk to a code that is currently going through gapfill. Unfortunately, this critical information was not available to inform the CDLT Advisory Panel's consideration, and was not made known to stakeholders until our October 19th, 2022 meeting. At that meeting, CMS articulated certain additional concerns with respect to that the CDLT Advisory Panel's proposed crosswalk – most notably, whether potential economies of scale were addressed, whether rates for COVID tests in general have been artificially inflated by the unique factors facing COVID test developers and providers, and whether CMS decisions on COVID tests now could serve as precedent for future ratesetting decisions. As a result, CMS proposed to crosswalk 87428 to 87430 with a 1.0x multiplier PLUS 87400 with a 2.0x multiplier (CMS-proposed rate = $45.07).

Recommendation

We respectfully request that CMS "gapfill" 87428 in CY 2023.

Rationale

When setting the payment rate for a clinical diagnostic laboratory test, section 1834A(c) of the Social Security Act requires CMS to use crosswalk if the test is "comparable" to an existing test, multiple existing test codes, or a portion of an existing test code currently paid under the CLFS.[3] CMS considers both "test methods and resources" when deciding whether a new test is "comparable" to an existing test (or tests).[4] However, if no existing CLFS test(s) are "comparable" to the new test, the Social Security Act requires CMS to use the gapfill process to set the CLFS payment rate.[5]

The test described by CPT code 87428 is comprised of three separate components – influenza A, influenza B, and COVID-19. We understand and agree with CMS that 87400 with a 2.0x multiplier represents an appropriate crosswalk for the influenza A and influenza B components of 87428. 87400 is an existing code with an established CLFS rate that is available to report instrumented antigen immunoassay testing for the influenza A and influenza B components of the assay, respectively. (The descriptor for 87400 reads "Influenza, A or B**, each", so it is appropriate to report one unit of 87400 for each subtype.) However, CMS's proposed combination of 87400 with a 2.0x multiplier PLUS 87430 with a 1.0x multiplier is not "comparable" to the test described by 87428 because 87430 with a 1.0x multiplier does not reflect the incremental resources required to run the COVID-19 component of 87428.**

[3] *See* Soc. Sec. Act § 1834A(c)(1) (referring to 42 C.F.R. § 414.508).
[4] 81 Fed. Reg. 41,036, 41,039 (June 23, 2016).
[5] *See* Soc. Sec. Act § 1834A(c)(1)(B).

We understand why CMS believes that Strep antigen testing reported with 87400 with a 1.0x multiplier would be "comparable" to COVID for purposes of building a crosswalk for 87428 – namely, that both tests utilize instrumented immunoassay methodology to detect antigens from respiratory pathogens. That being said, the assay described by 87428 requires substantial incremental resources to comply with applicable regulatory requirements and produce a COVID-specific result as compared to Strep, as evidenced by the following:

- Incremental resources required by performing laboratories. As compared to Strep, clinical laboratories performing instrumented antigen tests for COVID-19 (including the test described by 87428) incur the following additional expenses:
    - *Personal protective equipment (PPE).* Technicians require PPE because of the high transmissibility of SARS-CoV-2. Indeed, the CDC advises that "PPE, such as laboratory coats or gowns, gloves, eye protection, or a disposable mask and face shield, can help protect the skin and mucous membranes of the eyes, nose, and mouth."[6]
    - *Compliance with public health reporting obligations.* Laboratories performing COVID-19 tests are subject to substantially greater public health reporting demands than for typical microbiology tests, like Strep.
        - Laboratories must report extensive information – comprising at least twenty different pieces of information – to state public health departments for positive COVID-19 antigen tests. Reports must be submitted for each positive test, within 24 hours of results being determined, at least daily, to the appropriate state department of health based on the individual's state of residence.[7]
        - Laboratories incur additional labor costs for clinical staff to collect such data, and for the IT specialists needed to extract required data from the laboratory information system and interface with multiple public health agency reporting systems.
    - *Modifying lab procedures to assure appropriate specimen prioritization*. Local public health agencies recommend that laboratories prioritize certain types of specimens for COVID testing.[8] Laboratories incur additional costs associated with such prioritization of specimens – e.g., additional IT costs when managing this process, as well as costs associated with the disruption of normal workflow – which is not necessary for Strep testing.
    - *Higher cost structures at certain laboratory facilities.* While it may be relatively common for labs to "send out" patient specimens for Strep testing at off-site reference laboratories, ongoing pandemic response efforts require the widespread availability of SARS-CoV-2 testing at all kinds of laboratories. Small laboratories and those in rural areas tend to have higher cost structures than larger reference laboratories. Many laboratories will not be able to cover COVID testing if they cannot cover their costs, and testing will not be widely available enough for it to be a useful public health tool.

[6] Centers for Disease Control and Prevention, Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) (Dec. 13, 2021), https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.
[7] Dep't of Health & Human Services, COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 (Apr. 4, 2022), https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/HHS-Laboratory-Reporting-Guidance-508.pdf.
[8] *See, e.g.,* California Dep't of Public Health, CDPH Guidance for Prioritization of Patients for Laboratory Testing for COVID-19 (March 20, 2020), https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/GuidanceforPrioritizationofPatientsforLaboratoryTestingforCOVID19.aspx?_cldee=Y2RldmlAY2FsaG9zcGl0YWwub3Jn&recipientid=contact-fe5edad0afc9e911a842000d3a3b4cee-cad9d449a395434eba469ebba93147a7&esid=93e49b42-a76b-ea11-a811-000d3a375a4d.

- Incremental resources required by developing manufacturers. As compared to Strep, manufacturers developing instrumented antigen tests for COVID-19 (including the test described by 87428) incur the following additional expenses:
    - *Multiple premarket reviews by FDA.* Strep antigen tests can be offered by manufacturers following a single submission to FDA. In contrast, manufacturers of COVID-19 must successfully navigate two FDA review processes to remain on the market – i.e., the initial expedited Emergency Use Authorization (EUA) process (and any amendments thereto), and the subsequent *de novo* authorization or 510(k) clearance to remain on the market at the conclusion of the PHE.[9] Manufacturers will be able to rely on little, if any, of the data submitted to obtain an EUA in their "full" marketing submission, given the substantially greater regulatory hurdles required to obtain "normal" market authorization from the FDA.
        - COVID-19 test developers must also routinely monitor the performance of their tests against new variants, and make modifications to their tests to assure continued performance against common variants.[10]
    - *Less efficient development process.* Ordinarily, test manufacturers can take a measured, considered approach to the development of tests that strike a reasonable balance between resource utilization and time to market. During the PHE, however, accelerated development timelines required test developers to pursue numerous avenues of development simultaneously – including ones they would not have ordinarily pursued if access to testing were not a driving factor.
    - *Increased changeover costs*. Manufacturers incur substantial costs when moving from one project to the next. Testing resources can be redirected from one developmental product to another, and changeover costs can usually be planned so that the fewest possible changeovers are needed to achieve a steady test supply. However, under the PHE, production had to be rapidly ramped up to meet the demand, and then decreased when there is less need for testing. This continued cycle of "ramping up" and "slowing down" may occur more frequently for COVID-19 tests, given the ongoing uncertainty with respect to the need for testing (e.g., as new variants emerge outside of when increased utilization might reasonably be predicted due to seasonal trends).

- Incremental resources consistently recognized by Medicare Administrative Contractors (MACs). We previously submitted proprietary cost information to CMS and the MACs to quantify the costs associated with the above-described factors to support the differential costs of COVID-19 testing compared to other microbiology tests (like Strep) that otherwise may seem methodologically similar, but which do not involve these extraordinary costs incurred due to the PHE. After reviewing this cost data, the MACs uniformly established a rate for 87428 ($63.59-$73.49) that substantially exceeds the rate proposed by CMS ($45.07).
    - The individual MAC rate-setting for COVID-only instrumented antigen testing (87426) also reflects the incremental resources required to run COVID testing. When initially tasked with establishing rates for 87426 in late 2020/early 2021, the MACs uniformly established payment rates ranging from $35.33-$45.23[11] – i.e., rates that are 2-3 times

[9] U.S. Food and Drug Administration, Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Dec. 2021), https://www.fda.gov/media/155039/download.
[10] *See* U.S. Food and Drug Administration, Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Guidance for Test Developers and Food and Drug Administration Staff) (Feb. 2021), https://www.fda.gov/media/146171/download.
[11] Medicare Administrative Contractor (MAC) COVID-19 Test Pricing (Jan. 25, 2021), https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf.

higher than the rate for stand-alone Strep antigen testing ($14.13).[12] When the MACs were asked to revisit ratesetting for this code in 2022, each MAC affirmed its previous decision, and produced a "final" recommendation consistent with the above rates.[13]

- Incremental resources consistently recognized by CDLT Advisory Panel. On two occasions, the experts comprising the CDLT Advisory Panel have been asked for their recommendation on an approach to ratesetting for 87428. On both occasions, the CDLT Advisory Panel overwhelmingly recommended crosswalks to combinations of codes that would have resulted in payment rates that are ~50% higher than the rate proposed by CMS – i.e., $61.88 (in 2021)[14] and $63.59 (in 2022)[15].
    - The CDLT Advisory Panel's consideration of COVID-only instrumented antigen testing (87426) also reflects the incremental resources required for COVID testing. When 87426 came up for consideration in 2021, the Panel overwhelmingly (via 11-1 vote) recommended crosswalk to 87400 x 2.0, with the sole dissenter voting for crosswalk to 87400 x 2.5.[16]

Establishing the payment rate for 87428 via crosswalk would also assure consistency in rate-setting across all COVID antigen tests. In 2021, three COVID antigen tests – 87426, 87428, and 87811 (visually-read COVID antigen testing) went through the CLFS process. Two of these codes – 87426 and 87811 – were assigned to gapfill.[17] It is unclear why CMS chose to treat 87428 differently.

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During our meeting on October 19th, CMS articulated a few issues it encountered when establishing a rate for 87428. We thank CMS for its candor, and offer the following thoughts in response:

CMS Concern	POCTA Response
Economies of scale (i.e., accounting for efficiencies since 87428 describes a test that identifies multiple pathogens in a single assay)	We acknowledge that it may cost manufacturers incrementally less money to manufacture (and labs incrementally less money to perform) a multi-pathogen test run as a single assay compared to if each organism had been tested separately. However, it is unclear on what basis CMS made the determination that such efficiencies warrant a 60% reduction in the payment rate for the COVID component of the test (comparing the rates for 87426 to 87400, respectively). Selecting a Strep antigen test to estimate any incremental efficiencies is not appropriate in the absence of data supporting that degree of efficiency, particularly

[12] Clinical Laboratory Fee Schedule Files – 22CLABQ4, https://www.cms.gov/medicaremedicare-fee-service-paymentclinicallabfeeschedclinical-laboratory-fee-schedule-files/22clabq4 (last visited Oct. 20, 2022).
[13] 2022 CLFS Gapfill Final MAC Recommendations, https://www.cms.gov/files/zip/2022-clfs-gapfill-final-mac-recommendations.zip (last visited Oct. 20, 2022).
[14] CY 2022 – Clinical Laboratory Fee Schedule Test Codes Final Payment Determinations, https://www.cms.gov/files/zip/cy2022-clfs-test-codes-final-payment-determinations.zip (last visited Oct. 20, 2022).
[15] CY 2023 – Clinical Laboratory Fee Schedule Test Codes Preliminary Payment Determinations, https://www.cms.gov/files/zip/cy-2023-clinical-laboratory-fee-schedule-test-codes-preliminary-payment-determinations.zip (last visited Oct. 20, 2022).
[16] CY 2022 – Clinical Laboratory Fee Schedule Test Codes Final Payment Determinations, https://www.cms.gov/files/zip/cy2022-clfs-test-codes-final-payment-determinations.zip (last visited Oct. 20, 2022).
[17] CY 2022 – Clinical Laboratory Fee Schedule Test Codes Final Payment Determinations, https://www.cms.gov/files/zip/cy2022-clfs-test-codes-final-payment-determinations.zip (last visited Oct. 20, 2022).

CMS Concern	POCTA Response
	given the incremental resources expended when offering COVID testing as compared to Strep. Furthermore, when the individual MACs established their rates for this test in 2020/2021, they would have considered efficiencies associated with this test. Nevertheless, they still established a much higher rate that what CMS proposes here.
Unusual circumstances surrounding COVID may have led to inflated rates	We acknowledge that in some cases, the Medicare rates for COVID testing exceed the rates that may have been established for a methodologically similar test outside of the PHE. POCTA reminds CMS, however, that many of the considerations that supported incremental payment for COVID tests remain in place today – i.e., these are not costs that CMS has already accounted (and paid) for. For example: • Labs still incur additional costs for PPE; • Labs must still comply with onerous public health reporting requirements; • Test developers incur the additional costs of first obtaining (and maintaining) an EUA, and then producing a second (essentially separate) set of validation data to support "full" marketing authorization for the tests; and • Test developers also incur incremental costs when ensuring their tests continue to perform as expected as new COVID variants emerge, and modifying their tests to reflect any necessary performance changes Insofar as COVID tests may have been priced differently, such decisions are reasonable given the unusual circumstances surrounding the development and continued offering of such tests.
Precedent (i.e., that a unique rate-setting approach taken for COVID testing may influence future decision-making for tests developed outside of a PHE)	We acknowledge that the development and implementation of Medicare rates COVID testing has been the product of unusual circumstances. If CMS is concerned about the use of such codes as potential crosswalks in future CLFS ratesetting cycles, CMS could announce that it only intends to make the COVID testing codes available as crosswalks for other tests developed and performed during a PHE or other similar circumstances, given the unusual circumstances surrounding such tests.

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Sincerely,

On behalf of the Point of Care Testing Association, joined by QuidelOrtho