
CMS Rulings

**Department of Health
and Human Services**

**Centers for Medicare &
Medicaid Services**

Ruling No.: **CMS-2020-1-R2**

Date: **January 1, 2021**

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters. They are published under the authority of the Administrator of the Centers for Medicare & Medicaid Services (CMS).

CMS Rulings are binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration (SSA) to the extent that components of the SSA adjudicate matters under the jurisdiction of CMS.

This Ruling amends CMS Ruling 2020-1-R, which articulated CMS’s policy concerning the designation and payment of certain clinical diagnostic laboratory tests (CDLTs) related to COVID-19 under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). CMS Ruling 2020-1-R defined certain highly sophisticated equipment called “high throughput technology,” and established a payment amount for molecular genomic CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and that are administered during the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (the

Act). This Ruling amends CMS Ruling 2020-1-R by modifying the payment amount established in that Ruling for such CDLTs based on a re-evaluation of the resources necessary for the timely administration of these tests.

BACKGROUND

Medicare Part B items and services that are CDLTs are paid for on the CLFS in accordance with section 1833(h) and section 1834A of the Act. CMS and the Medicare Administrative Contractors (MACs) that process Medicare claims for payment make payment based on the Act, regulations, and CMS instructions or guidance. Section 1833(h) and section 1834A of the Act contain provisions outlining the process for determining payment amounts for CDLTs. CDLTs are currently being used to detect SARS-CoV-2 or for the diagnosis of the virus that causes COVID-19 in many settings, including nursing homes and other sites where Medicare beneficiaries obtain care or reside.

On April 14, 2020, the Administrator of CMS issued CMS Ruling 2020-1-R (see the Ruling on the CMS website here: <https://www.cms.gov/files/document/cms-2020-01-r.pdf>). The Ruling established that high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day, and recognized that high throughput technologies are highly sophisticated equipment that require more intensive technician training (to ensure the role of extremely skilled personnel) and more time-intensive processes (to assure quality). The Ruling identified several examples of high throughput technology, and explained that the training and resources needed for molecular genomic CDLTs making use of high throughput technology represent an increase in resources, bringing the total resources required for these tests to \$100, which the Ruling indicated was a more accurate payment than the one that was in use at the time via MACs pricing. CMS Ruling 2020-1-R specified the following HCPCS codes to identify these tests:

- U0003: 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.
- U0004: 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.

RE-EVALUATION OF TESTING RESOURCES

CMS Ruling 2020-1-R established \$100 as the new payment amount for molecular genomic CDLTs that make use of high throughput technology for the detection of SARS-CoV-2 or diagnosis of the virus that causes COVID-19 and are administered during the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Act. The Ruling set the payment rate at \$100 based on an assessment of the resources involved in performing such tests. Since CMS Ruling 2020-1-R was issued, as the COVID-19 pandemic has continued, CMS has re-assessed the resources involved in performing such tests, particularly in light of the increasingly clear importance of the substantially greater value of clinical diagnostic laboratories completing these tests in a timely fashion.

The COVID-19 Public Health Emergency has placed increasing burdens on clinical diagnostic laboratories, which face significant pressures to perform a large number of molecular genomic CDLTs making use of high throughput technology in a timely fashion. The results of these tests are commonly used for critical treatment and public health purposes – for example, to diagnose and quarantine suspected COVID-19-infected patients – and it is critically important that they are performed within a timeframe that supports and facilitates clinical and public health benefits. When tests are completed within 2 calendar days of the specimen being collected, meaning, the results of the test are finalized and ready for release, patients and physicians can make faster and better decisions regarding the right treatment plan, including monitoring of symptoms and the need for physical isolation to avoid spreading infection to others. Timelier results enable more effective contact tracing, since less time will have passed between

the identified contact and notification to individuals of possible exposure, thereby reducing the overall number of persons that may be exposed. In these ways, timelier test results provide benefit to individual patients, their immediate communities, and the public at large. When test results are not produced within 2 calendar days of the specimen being collected, their value diminishes. For example, patients who test positive for the virus, but who remain asymptomatic, may assume they are negative before receiving their test results, and, believing they are not contagious, may unwittingly expose others to the virus.

When CMS Ruling 2020-1-R initially set the payment rate for the molecular genomic COVID-19 tests using high throughput technology at \$100, CMS assumed that clinical diagnostic laboratories running those specific types of COVID-19 tests would broadly incur additional costs to meet increased demand based on the circumstances of the pandemic, and that the payment of \$100 would account for such costs. CMS also assumed that the \$100 payment amount reflected resource costs for laboratories to ensure that these tests were completed in a time period necessary to ensure maximum clinical benefit to the patient. These initial assumptions did not account for laboratories' potential ability to lower their resource costs by allowing greater lag time between when the specimen is collected and when the CDLT is completed, thereby not returning results to the patient in a timeframe that would maximize clinical benefit. Consequently, in order to pay for the tests more accurately relative to the resources involved in furnishing them, CMS has identified a need to price those with quick turnaround times differently from those with slower turnaround times.

CMS estimates that the resources needed to complete a test within 2 calendar days of the specimen being collected continue to be accounted for with a payment rate of \$100. This payment amount accounts for costs associated with laboratories that complete CDLT results on a timely basis. CMS's estimates of the total resources needed to complete these tests within 2 calendar days are based on the costs associated with laboratories adapting to overall demand for testing due to circumstances of the pandemic, and CMS would not consider the additional costs to be incurred if entities merely prioritize Medicare patients over non-Medicare patients in order to return tests more quickly just for Medicare

patients. In other words, CMS estimates that the costs (\$100) associated with high throughput technology, hiring staff, and other resource costs, are only incurred when laboratories complete the majority of molecular genomic CDLTs that make use of high throughput technology for the detection of SARS-CoV-2 or diagnosis of the virus that causes COVID-19 within 2 calendar days of specimen collection for all patients, not just for a subset of patients.

While laboratories that complete these tests within 2 calendar days of the specimen being collected require the estimated resources identified above, tests completed in a less timely fashion require fewer resources. For example, laboratories that are able to extend the time period between when the specimen is collected and when the test is completed may be able to operate their high throughput machines with less frequency (by batching their test runs) and have fewer demands on staff. Due to these factors, CMS estimates that the total resources needed to conduct a test in a time period of greater than 2 calendar days are better reflected by a payment rate of \$75.

MODIFICATION OF PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS FOR THE DETECTION OF SARS-CoV-2 OR THE DIAGNOSIS OF THE VIRUS THAT CAUSES COVID-19 MAKING USE OF HIGH THROUGHPUT TECHNOLOGIES

This Ruling amends CMS Ruling 2020-1-R by modifying Medicare payment to clinical diagnostic laboratories for CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19. The modified payment will be for tests reported using HCPCS codes U0003 and U0004 that a laboratory completes, meaning the results of the test are finalized and ready for release, within or outside of 2 calendar days of the specimen being collected. The modification will bring Medicare payment for these tests in line with their resource costs based on CMS's best estimate of how clinical diagnostic laboratories are investing resources needed to complete tests within 2 calendar days of the specimen being collected.

This Ruling establishes that clinical diagnostic laboratories will be paid the following amounts for CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19. Beginning January 1, 2021, for such tests that are completed within 2 calendar days of the specimen being collected, the payment amount will be \$100 per test. For such tests that are not completed within 2 calendar days of the specimen being collected, the payment amount will be \$75 per test. Beginning January 1, 2021, the revised payment amounts will be effectuated as follows:

- CMS will establish a payment amount of \$75 per test for CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, as identified by HCPCS codes U0003 and U0004.
- CMS will establish a new add-on payment of \$25 as identified by HCPCS code U0005. As required by the HCPCS code U0005 descriptor, this add-on payment may be billed with either HCPCS code U0003 or HCPCS code U0004 when the applicable test is completed within 2 calendar days of the specimen being collected.
- Laboratories that do not complete the CDLT making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 within 2 calendar days may not bill HCPCS code U0005 and will not receive the \$25 add-on payment. Payment for these CDLTs will be \$75.
- As noted above, CMS estimates that the resources associated with high throughput technology, hiring staff, and other resource costs associated with quicker turnaround, are only incurred when laboratories complete tests within 2 calendar days of specimen collection for all patients, not just for a subset of patients. As required by the HCPCS code U0005 descriptor, the majority of a laboratory's CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 for all patients (including non-Medicare patients) in the previous calendar month have to be completed in 2 calendar days or less from the date the specimen was collected. More specifically, laboratories would assess the timeliness of

those tests in the month preceding the month identified by the line date of service for the corresponding CDLT (represented by HCPCS U0003 or U0004). In the circumstance that the laboratory has not completed 51% of its CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 (for all patients) in 2 calendar days from the date the specimen was collected during the applicable month, it may not bill for HCPCS code U0005 with HCPCS codes U0003 or U0004. For example, a laboratory is submitting a claim to Medicare for a CDLT performed on high throughput technology for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 using HCPCS code U0003 with a line date of service of May 15, 2021. This laboratory would assess its performance based on CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 completed during the calendar month (April 1, 2021 – April 30, 2021) that precedes the month identified by the CDLT line date of service (May 2021). If the laboratory completed a total of 1000 of those CDLTs (including all such tests for non-Medicare patients) in April, and 490 of them had been completed within 2 calendar days of the specimen being collected, the laboratory would have a 49% test timeliness completion rate and may not bill for the \$25 add-on payment as represented by HCPCS code U0005.

- In the event of an audit or medical review, laboratories will need to produce documentation of timeliness based on their performance in the month preceding the month identified by the line date of service for the corresponding CDLT represented by HCPCS U0003 or U0004. CMS has established exceptions for certain COVID-19 tests from the Medicare ordering and documentation requirements in 42 C.F.R. § 410.32(a) and (d) for the duration of the COVID-19 Public Health Emergency. For example, entities submitting claims for those tests would not, in some circumstances, be subject to Medicare requirements to maintain documentation of the order for the service billed, documentation showing accurate processing of the order and submission of the claim, or other medical information supplied to the laboratory by the ordering physician or

non-physician practitioner. However, in the event of an audit or medical review, laboratories will need to produce documentation to support the add-on payment established in this Ruling, even if such documentation would not otherwise be required under Medicare regulations.

CMS intends to promptly evaluate payment for relevant CDLTs for COVID-19 testing that make use of high throughput technologies developed after this issuance upon request for payment at an appropriate rate.

CONCLUSION

The April 14, 2020 CMS Ruling 2020-1-R established a payment rate of \$100 for CDLTs that make use of high throughput technology for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and that are administered during the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Act. Based on re-evaluation of testing resources, this Ruling amends CMS Ruling 2020-1-R by establishing new payment rates for those tests based on whether they are completed by a clinical diagnostic laboratory within or outside 2 calendar days of the specimen being collected. This payment modification will be implemented by changing the payment amount for HCPCS codes U0003 and U0004 from \$100 to \$75 and establishing a new add-on payment of \$25 for HCPCS code U0005. If a laboratory bills Medicare for the add-on payment identified by HCPCS code U0005, the laboratory must meet the requirements established in the code descriptor and this Ruling: namely that the corresponding CDLT that makes use of high throughput technology for the detection of SARS-CoV-2 or diagnosis of the virus that causes COVID-19 is completed within 2 calendar days of the specimen being collected, and the laboratory completed a majority of these CDLTs (for all patients during the prior calendar month) in 2 calendar days or less from when the specimen was collected. The MACs are hereby directed to engage in the processes that are necessary to make determinations or policies to process claims in accordance with this Ruling, including implementing any additional Agency instructions that refer to effectuating this Ruling. This includes monitoring the claims data for potential abuse, conducting medical review of claims as appropriate, and referring cases of suspected fraud or abuse for further investigation.

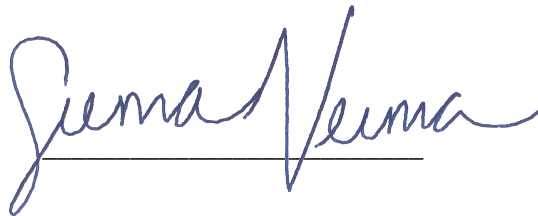
Laboratories will need to retain all records necessary to demonstrate compliance with the requirements in this Administrative Ruling for billing HCPCS code U0005. In particular, in the event of an audit or medical review, laboratories will need to retain all records that demonstrate compliance with the timeframes outlined in this Ruling, including all Medicare and non-Medicare records, and to produce these records to CMS upon request, as permitted or required by law.

This Ruling expires upon the expiration of the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Act beginning on or after March 18, 2020.

EFFECTIVE DATE

This Ruling is effective **October 15, 2020**

Dated: **October 15, 2020**

A handwritten signature in blue ink that reads "Seema Verma". The signature is written in a cursive style and is positioned above a horizontal line.

Seema Verma,
Administrator,
Centers for Medicare & Medicaid Services.