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UPDATE – Follow-up to 2021 Pricing Change for High Throughput COVID-19 Testing

In our recent white paper, *New in 2021: Complete High Throughput COVID-19 Diagnostic Tests Within 2 Calendar Days or Medicare Payment Drops*, we described how, effective January 1, 2021, CMS decreases its base rate for payment for COVID-19 tests run on high-throughput technology from $100 to $75. At the same time, new add-on code U0005, becomes effective that allows labs to bill Medicare for an additional $25 for tests run on high throughput technology if certain requirements are met.

This update further discusses those requirements and the operational considerations they represent.

CMS Ruling CMS-2020-1-R2 provides CMS' rationale for incentivizing fast turnaround time of high throughput test results, establishes the upcoming change in payment structure and states the criteria labs must meet in order to be eligible for billing U0005. In short, CMS will make an add-on payment of $25 per test to labs:

1. who complete high throughput COVID-19 diagnostic tests within 2 calendars days of specimen collection **AND**
2. where the majority of their high throughput COVID-19 diagnostic tests in the previous calendar month were completed in 2 calendar days or less for all of their patients – not just Medicare patients

Let's break some of this down.

What is U0005 and how does it work?

U0005: *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, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date and time of specimen collection. (List separately in addition to either HCPCS code U0003 or U0004).*

U0005 is an 'add-on' code and, as described above, would be billed with U0003 (high throughput tests via amplified probe technique) or U0004 (high throughput tests - other methodologies than amplified probe technique) to indicate the test was completed within 2 calendar days. (Note: see our previous white paper, Guidance for Reporting Coronavirus Lab Tests for additional information regarding U0003 and U0004.)

How does CMS define a test as 'complete?'

CMS considers the test to be complete when the results are finalized and ready for release.

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How do I approach the requirement that the majority of my lab's high throughput COVID-19 diagnostic tests were completed in 2 calendar days or less for all patients 'in the previous month?'

This requires laboratories to assess overall completion timeliness of the high throughput COVID-19 diagnostic tests (U0003 and U0004) performed in the calendar month preceding the date of service being billed. If, in the preceding month, the lab hasn't completed 51% of those tests within 2 calendar days from the date the specimen was collected during the applicable month, it may not bill U0005 in addition to U0003 or U0004.

For example, a lab is going to submit a claim to Medicare for U0003 or U0004 with a service date in May 2021 and needs to determine if it qualifies to additionally bill the U0005 code:

- The lab would need to assess the completion timeliness of all U0003 or U0004 tests for the entire preceding calendar month (April 2021)
- If at least 51% were not completed in 2 calendar days from the date of specimen collection during the applicable month, the lab may only bill for U0003 or U0004 as it doesn't meet the requirement for the additional charge represented by U0005

This could be a little tricky for labs that might not know right away whether the majority of their U0003 or U0004 tests for all patients are completed in the required 2 calendar day turn-around time to be eligible for billing the additional code, U0005. For this situation, careful consideration should be given to developing appropriate billing processes and, indeed, at the time of this article there doesn't appear to be a one-size-fits-all optimal solution. For example, where some industry recommendations direct billing Medicare for the tests (U0003 or U0004) as performed then later submitting adjustment claims for the add-on code (U0005), others suggest billing the prior month's tests all at once, after verification that the requirements were met to support U0005.

Take note that the CMS Ruling concludes with this statement: "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."

APS will continue to monitor this topic and provide relevant updates as they become available. In the meantime, please reach out to your Practice Manager with any questions.