CORONAVIRUS DISEASE 2019
(COVID-19)

High Throughput COVID-19 Testing Payment Update
CMS 2020-1-R2 Revision FAQ 508 Update 10/16/20

Trinity Health

Audience: PBS, HIM, Revenue Integrity, CFO, MGPS, TIS, Laboratory, ICO
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Version : 3
COVID-19 Response Team Owner: Finance
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What's Changed: Adding updates and clarification to implementation guidance for the Health Ministries.

Background

On October 15, 2020, CMS released CMS 2020-1-R2 which provides updated guidance and instructions to providers billing for high throughput COVID-19 tests. On October 16, 2020 CMS updated their CMS COVID-19 FAQ document to include details around this requirement.

In April, CMS created the following two HCPCS codes to report COVID-19 molecular testing using high throughput technology. High throughput is defined as instrumentation that has the ability to run more than 200 COVID tests per day.

- 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

In 2020, both of these codes are reimbursed at $100.

Changes to Payment and Add-on Codes

CMS notes that it is critically important that COVID-19 tests are performed within a timeframe that supports and facilitates clinical and public health benefits. COVID-19 test results are commonly used for critical treatment and public health purposes (e.g., to diagnose and quarantine suspected COVID-19-infected patients). In an effort to increase rapid turn-around time for results, CMS is making the changes below.

In CMS-2020-1-R2, CMS is making changes to payment for U0003 and U0004. **Effective January 1, 2021, these codes will reimburse at $75.00 (instead of $100).**

CMS is instituting an add-on payment of $25.00 which will be paid if the high throughput COVID testing is resulted within 2 calendar days of collection. CMS has created a new HCPCS code that will be billed **if both of the parameters discussed below are met**. This code will trigger the add-on payment.

- 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)

Qualifying Parameters Required to Bill U0005

CMS has established two criteria that must both be met in order to bill U0005 and receive the add-on payment:

1. Complete that specific COVID-19 test in 2 calendar days or less from the date of specimen collection (qualified as when results are finalized and ready for release to the provider or patient); and
2. The majority (at least 51%) of COVID-19 tests performed using high throughput technology in the previous calendar month were completed in 2 calendar days or less for all patients (not just Medicare).
    a. CMS expects that each month an analysis of this threshold is performed, documented and retained in case of audit.

Currently this requirement and payment schema is effective for Medicare beneficiary's only. System Office PSPD will monitor commercial payers to determine if they will implement new code U0005.

Additional Considerations

- The code description of U0005 refers to 2 calendar days from the date and time of specimen collection. During the November 4, 2020 CMS Office Hours call, CMS indicated the specimen collection date is day 0 allowing for two calendar days after the collection date to complete the test. CMS has not yet published this guidance in writing.
- CMS updated the COVID-19 FAQ document on December 16th to add FAQ 13 in the High Throughput Testing section which provided clarification that specimen collection date is day 0. CMS provided the following example: "if the specimen is collected anytime Wednesday then the COVID-19 CDLT would need to be completed, that is, results are finalized and ready for release, by 11:59PM Friday. In other words, the specimen collection day (Wednesday) is day 0, Thursday is day 1, and Friday is day 2. "
- During the November 4, 2020 CMS Office Hours call, CMS was also asked if this requirement applies only to in-house testing. The caller explained the supply issues and the extended length of time for reference labs to perform these tests. CMS said they would consider this information. As of December 15, 2020, CMS has not addressed this question.
- On December 8, 2020, Trinity Health Advocacy sent questions to CMS on these two topics. On December 15, 2020, CMS acknowledged our request and forwarded it to the Baltimore Office for review. No additional information was provided.
- Until or unless further CMS guidance is published regarding reference lab testing versus in-house testing, all Ministries are directed to track and report test results reporting separately for in-house testing versus reference laboratory testing. If in-house testing meets the monthly TAT minimums, but the reference laboratory testing does not, CPT U0005 can be billed for the in-house testing only. See further discussion below regarding billing CPT code U0005 for reference lab tests.

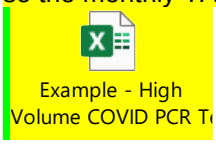
Implementation

HM Laboratory Directors, Revenue Integrity Directors, Finance, and Integrity & Compliance Officers should work together to make sure the following processes are in place. Once confirmed, the site can request the auto-generation of U0005 when U0003 is charged, where appropriate, based on the EHR's capability.

For HM's with multiple hospitals, the reporting would be by each hospital provider number.

HM Responsibility: There will be multiple responsibilities for each site in this process.

1. Create a Laboratory Information System (LIS) report which shows the turn-around time (TAT) for in-house testing and each reference laboratory for all services billed with HCPCS code U0003.
2. Beginning on January 1, 2021, run the Laboratory Information System (LIS) report daily to identify those tests with TATs of <3 calendar days. The optimal reporting would be to use calendar days rather than hours if that can be accomplished through LIS reporting. If the LIS cannot report by calendar days, then the criteria of <72 hours could be used (but is not preferable).
    a. Refer to the embedded template for the minimum data needed. System Office will send a monthly survey so the monthly TAT data can be collected in System Office.



3. Create a monthly summary Laboratory Information System report of the COVID high throughput testing TAT to identify the average TAT for in-house testing, for each reference laboratory, and an average for all reference laboratory testing combined.
    a. Refer to the embedded template for how the summary data should be reported.
    b. A December 2020 report must be generated as the baseline to verify U0005 can be charged for January services.
4. Create a process to save these reports for 7 years in case of audit. If the monthly report includes all the daily report patient detail, only the monthly report needs to be retained. Otherwise, the daily reports need to be retained as well.

In-House Testing

Trinity Health Ministries that can perform COVID-19 testing on high-throughput equipment (>200 tests/day) in-house. These HMs will track their in-house TAT performance separately and if TAT of <3 calendar days is achieved the U0005 can be charged.

Equipment that can report >200 tests/day includes:

1) **Single analyzers such as:**
    - Abbott Alinity M
    - Abbott M2000
    - Hologic Panther
    - BD Max
    - NeuMoDx

2) **Analyzer platforms with testing module expansion capabilities, or multiple units of the same kind such as:**
    - Cepheid GeneXpert
    - Biofire Torch

Site Responsibility: There will be multiple responsibilities for each site in this process.

1. Beginning on January 1, 2021, run the Laboratory Information System (LIS) report daily to verify that each test met the TAT
2. Daily crediting of the U0005 charge if the TAT time is not met for a specific patient (if it is auto-generated). If U0005 is not auto generated (or until it is) the charge for U0005 needs to be added.
    a. Each HM is to determine the resources needed to perform this work.
3. Monthly Laboratory Information System reporting of the in-house COVID high throughput testing TAT to verify that at least 51% of this testing met the TAT requirements.
    a. If the monthly TAT requirement is not met, Laboratory Leadership needs to coordinate with their Revenue Integrity Leadership to have the U0005 charge automation turned off for the next month (where automated). (For example, if the 51% TAT is not met for January, the site cannot charge/bill U0005 for the testing performed in February.)
    b. A December 2020 report must be generated as the baseline to verify U0005 can be charged for January services.

Reference Laboratory Testing (including Warde Lab)

Most HMs send COVID-19 PCR testing to outside reference laboratories, which use high throughput testing platforms. System Office Supply Chain will be monitoring the performance of these reference laboratories to address poor TAT performance and the potential for a reduction in current fee schedules for underperforming laboratories.

Site Responsibility: If sites would like to capture the extra charge and $25.00 payment for U0005, Laboratory Leaders need to pull the reference lab TAT (by reference laboratory) from their LIS for the daily and monthly reports as discussed above.

Whether the charge for U0005 can be auto-generated for reference lab testing would depend on the monthly performance. We do not recommend auto-generating the U0005 charge for reference lab testing at this time until historical data shows the reference lab consistently meets the TAT threshold. The sites should create a process to manually add the charge based on the daily and monthly reports.

Purveyor Law and Anti-Markup States: If TAT allows U0005 to be charged with U0003, the Purveyor Law and other anti-markup States require additional consideration. Assuming criteria for billing U0005 are met, use the following guidance:

- If the charge for U0003 is more than $75.00, the total charge can be split between U0003 and U0005.
    - For example, if the reference lab charges $100 for U0003, split that charge to $75.00 for U0003 and $25.00 for U0005.
- If the charge for U0003 is less than $75.00, it is not worth splitting the charges or adding U0005 as the total reimbursement would not change. These lab services reimburse on the CLFS and will pay on the lesser of the charge or the fee schedule amount.

References

- CMS COVID FAQs High Throughput section beginning on page 12: Frequently Asked Questions to Assist Medicare Providers (PDF)
- CMS-2020-1-R2

CMS Ruling
2020-1-R2 High Throu

We appreciate your support as we work Together to ensure the safety of our patients, and community at large

Trinity Health