

UPDATED INFO

See yellow highlights for updated content from previous published version.

Diagnostic Testing

Background

The American Medical Association (AMA) has expedited approval of CPT® codes for reporting laboratory testing related to the novel coronavirus. The first to be released was:

87635 – 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.

The AMA indicated that “the pathology and laboratory section of the CPT code set already contains codes for coronavirus testing. But those are for nucleic acid assays that detect multiple respiratory viruses in a multiplex reaction, while CPT 87635 is for the detection of SARS-CoV-2 (COVID-19) and any pan-coronavirus types or subtypes”, using an amplified probe technique.¹

According to the CPTA: “the appropriate code to be reported is dependent upon the payer to which the claim is being submitted... CPT and HCPCS codes should not both be reported on the same claim.”²

CPT® code 87635 was available for use as of April 1, 2020 which required providers to hold claims after February 4th before releasing them on April 1.

Reimbursement rates may be found at <https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf>.

On April 15, 2020 CMS also released a bulletin indicating payment under Medicare Supplementary Medical Insurance (Part B) 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.³

In order to identify these high throughput test methodologies two additional HCPCS codes to test for the virus were also released:

✓ **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.

In response to the release of this code CPT Assistant® (CPTA) published a Fact Sheet to help providers accurately report these testing services by creating a series of Q&A.

The Q&A addresses reporting this new code versus one of two recently released HCPCS that CMS created:

U0001 – CDC 2019 novel coronavirus (2019-ncov) real-time rt-pcr diagnostic panel, for use with CDC developed testing, and

U0002 – 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19) using any technique, multiple types or subtypes (includes all targets), for non-CDC developed testing (e.g., Hospital specific in-house developed testing).

✓ **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.

CMS has instructed providers to take note that “U0003 should identify tests that would otherwise be identified by CPT code 87635 but for being performed with these high throughput technologies. It is further noted that U0004 should identify tests that would otherwise be identified by U0002 but for being performed with these high throughput technologies. Finally, it is noted that neither U0003 nor U0004 should be used for tests that detect COVID-19 antibodies.”

	Medicare CDC Test Kit Type RC PCR Technique	Non CDC Test Type Any Other Technique	Nucleic Acid Amp Probe Technique
Standard	U0001	U0002	87635
High Throughput		U0004	U0003

Making use of high throughput technologies beginning on or after March 18, 2020, for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, are new and involve high throughput machines (which are

highly sophisticated equipment) which require more intensive technician training (to ensure the role of extremely skilled personnel) and more time intensive processes (to assure quality). A high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day.

This training and these processes represent an increase in resources, bringing the total resources required for these tests to \$100 (a more accurate payment than the one currently in use via contractor pricing).

Compared to an average payment of \$51 for the standard test the CMS press release indicated that Medicare will pay the higher payment of \$100 for COVID-19 clinical diagnostic lab tests making use of high-throughput technologies.⁴

As indicated these new codes are not meant to be reported for antibody testing. However, in response to the need for CPT® codes specific for antibodies the AMA also expedited the release of two additional codes on April 14, 2020:

- ✓ **86328** – Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, **single step method** (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]).
- ✓ **86769** – Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]). (A parenthetical note has been added to the CPT Manual indicating this is a multi-step method test).⁵

Additionally, code 86318 was revised as the parent code for code 86328. The description updates the word “antibody” to “antibodies.” Code 86318 is described as: “Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip);”

Additionally, CMS updated its *COVID-19 Frequently Asked Questions (FAQ) on Medicare Fee-for-Service (FFS) Billing* on 4/17/2020:

<https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>

Guidance

- ✓ Determine test methodologies used by the Lab.
- ✓ Ensure all applicable codes are added to the CDM for testing reported by the hospital.
- ✓ Link CDM charge codes to Laboratory testing orders.
- ✓ Appropriately code and release claims held since February 4, 2020.



Sources

1. <https://www.ama-assn.org/delivering-care/public-health/new-cpt-code-covid-19-testing-what-you-should-know>
2. CPT Assistant, Special Edition: April Update, Volume 30, 2020.
3. <https://www.cms.gov/files/document/cms-2020-01-r.pdf>
4. CMS Increases Medicare Payment for High-Production Coronavirus Lab Tests, [cms.gov/newsroom](https://www.cms.gov/newsroom), April 15, 2020.
5. CPT® Assistant Special Edition, April Update, Volume 30. ■