CMS Rulings

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Ruling No.: **[CMS-2020-01-R]**

Date: **April 14, 2020**

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 articulates CMS policy concerning the designation and payment of certain clinical diagnostic laboratory tests related to COVID-19 under the Medicare Part B Clinical Laboratory Fee Schedule.

MEDICARE PROGRAM

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.

CITATIONS: Section 1833(h) of the Social Security Act (42 U.S.C. 1395l(h)),

Section 1834A of the Social Security Act (42 U.S.C. 1395m-1), and 42 CFR Part 414,

Subpart G.

BACKGROUND

Medicare Part B items and services that are clinical diagnostic laboratory tests (CDLTs) are paid for on the Clinical Laboratory Fee Schedule in accordance with section 1833(h) and section 1834A of the Social Security Act (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. Sections 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.

PAYMENT FOR 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

CDLTs making use of high throughput technologies (as defined in this Ruling) and administered during the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Act 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. Examples of high throughput technology as of April 14, 2020 include but are not limited to technologies marketed on that date as the Roche cobas 6800 System, Roche cobas 8800 System, Abbott m2000 System, Hologic Panther Fusion System, GeneXpert Infinity System, and NeuMoDx 288 Molecular. 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). These tests are a type of CDLT currently paid for under

Medicare Part B. Specifically, the following codes would 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.

It is noted 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.

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

With regard to CDLTs that make use of high throughput technologies (as defined in this Ruling), are administered during the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Act beginning on or after March 18, 2020, for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19, and are a type of CDLT currently paid for under Medicare Part B using CPT code 87635 or U0002, such tests, as identified using U0003 or U0004 as appropriate, shall be paid for at the rate of $100. Payment for all other CDLTs remains at the current level.

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.

MACs are hereby directed to engage in whatever processes are necessary to make determinations or policies to process claims in accordance with this Ruling, including implementing any additional Agency instructions which refer to effectuating this Ruling. 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.

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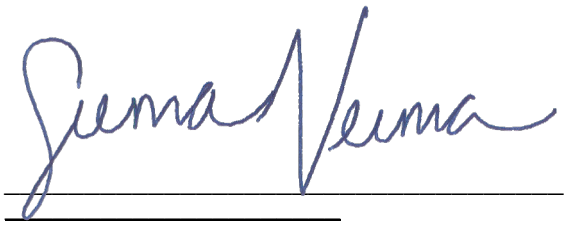
EFFECTIVE DATE

This Ruling is effective April 14, 2020.

Dated: April 14, 2020



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