GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health Care Finance

Office of the Deputy Director-Medicaid

Transmittal # 20-22

TO: All DC Medicaid Providers

FROM: Melisa Byrd
Senior Deputy Director and State Medicaid Director

DATE: May 14, 2020

SUBJECT: **Updates to the *Laboratory Billing Codes and Reimbursement Rates for COVID-19 Testing***

Purpose
This transmittal provides notice of coverage and reimbursement for additional HCPCS and CPT codes related to COVID-19 diagnostic testing. It also provides updates to the Department of Health Care Finance (DHCF) billing guidance contained in two previous transmittals: Transmittal # 20-09: Laboratory Billing Codes and Reimbursement Rates for COVID-19 Testing issued on March, 20, 2020 and Transmittal #20-13 Updates to the Laboratory Billing Codes and Reimbursement Rates for COVID-19 Testing issued on April 8, 2020. The Centers for Medicare & Medicaid Services (CMS), has issued two new HCPCS codes (U0003 and U0004) for diagnostic testing which are reimbursable by DHCF for medically necessary, clinically appropriate COVID-19 diagnostic testing effective March 18, 2020. In addition, DHCF is adding CPT code 86328 and 86769 for novel coronavirus antibody tests effective April 10, 2020.

Background
DHCF continues to make quick coverage and reimbursement decisions to meet the healthcare needs of residents during this public healthcare emergency. DHCF previously issued transmittal #20-09 allowing reimbursement for COVID-19 diagnostic tests billed as HCPCS U0001 and U0002. DHCF also previously issued transmittal #20-13 allowing reimbursement for COVID-19 diagnostic tests billed as CPT code 87635 and adopted HCPCS codes G2023 and G2024 for COVID-19 specimen collection - billable by clinical laboratories only. HCPCS code C9803 for specimen collection is covered only on claims for hospital outpatient services.

DHCF now has information about two new testing modalities that are distinct from previous testing codes; U0003 and U0004. These codes are established to report and reimburse tests that utilize high throughput technologies for the diagnosis of the virus that causes COVID–19. A high throughput technology uses a platform that employs automated processing of more than 200 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 highly sophisticated equipment requires more intensive technician training and more time intensive processes to assure quality.

It is noted that U0003 should identify tests that would otherwise be identified by CPT code 87635 but for being performed with high throughput technologies. It is further noted that U0004 should identify tests that would otherwise be identified by U0002 but for being performed with high throughput technologies. Finally, it is noted that neither U0003 nor U0004 should be used for tests that detect COVID-19 antibodies.

Addition of Coverage for COVID-19 Serology Testing

Serological tests for determining the presence of antibodies against SARS-CoV-2 are now available from commercial manufacturers. Serology tests are used to determine if antibodies against SARS-CoV-2 are present. Certain serology tests can look for the general presence of SARS-CoV-2 antibodies, while others can determine if specific types of SARS-CoV-2 antibodies, such as IgM and/or IgG, are present.

The US Food and Drug Administration (FDA) is allowing commercial manufacturers of COVID-19 serology tests to distribute these tests to laboratories once they notify the FDA that they have validated their test. Although there are manufacturers that have notified the FDA that their tests have been validated, and the FDA has approved the distribution of the tests, the data demonstrating the accuracy and reliability of the tests has not been reviewed by the FDA. In addition, these tests have not necessarily been granted approval under the FDA's Emergency Use Authorization (EUA) process. COVID-19 serological tests that have been granted EUA approval can be found at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

Two new CPT codes, 86328 and 86769, are effective April 10, 2020 for use as the industry standard for reporting of COVID-19 serology tests. Testing must be conducted by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, using supplies and equipment from manufacturers with Emergency Use Authorization (EUA) under the FDA.

Providers and laboratories conducting COVID-19 serological tests from these commercial manufacturers should be aware of the following limitations when ordering tests and reporting results:

- These tests have not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in recent contact with the virus. Follow-up testing with a molecular diagnostic test should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection, or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Billing Codes & Reimbursement
The billing and reimbursement rates for COVID-19 diagnostic test and specimen collection codes are based on the Medicare Administrative Contractor (MAC) for DC or other published guidance by CMS. If newer rates are published by CMS or the MAC, the rates may be updated with retroactive payment adjustments as necessary.

The table below provides the relevant billing and reimbursement guidance for all COVID-19 laboratory tests to date.

HCPCS/CPT	Description	Effective Date	Max Units	PA Required	Rates
U0001	CDC 2019 novel coronavirus (2019-nCoV) real-time RT-PCR diagnostic test panel	2/4/2020	1	No	$35.92
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19) using any technique, multiple types or subtypes (includes all targets)	2/4/2020	1	No	$51.33
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.	3/18/2020	1	No	$100
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.	3/18/2020	1	No	$100
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	4/1/2020	1	No	$51.33
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])	4/10/2020	2	No	$18.09

HCPCS/CPT	Description	Effective Date	Max Units	PA Required	Rates
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) (mulitple-step method)	4/10/2020	2	No	$16.85
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source	3/1/2020	1	No	$23.46
G2024	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, any specimen source	3/1/2020	1	No	$25.46
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source)	3/1/2020	N/A	N/A	Covered for hospitals only

Contact
DHCF will continue to provide updates to this information as appropriate. If you have questions, please contact Bidemi Isiaq, Associate Director, Rates & Reimbursements, at Bidemi.isiaq@dc.gov or 202-442-9202.

Cc: DC Hospital Association
DC Primary Care Association
DC Health Care Association
DC Home Heath Association
DC Behavioral Health Association
DC Coalition of Disability Service Providers
Medical Society of DC