September 13, 2020

Ms. Carol Blackford
Director
Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

RE: National Correct Coding Initiative and COVID-19 Clinical Diagnostic Laboratory Testing

Dear Ms. Blackford:

On behalf of the undersigned organizations, representing the major clinical laboratory stakeholders involved with testing for COVID-19, we are writing to express concern regarding the National Correct Coding Initiative ("NCCI") Policy Manual and medically unlikely edits (MUEs) effective July 1, 2020, which negatively impact clinically appropriate COVID-19 clinical diagnostic laboratory testing.

We appreciate the extraordinary efforts shown by CMS to address the COVID-19 pandemic. Although the duration of the public health emergency is uncertain, data suggest that COVID-19 will continue to spread. Moreover, the CDC has indicated that it is likely that influenza viruses and the virus that causes COVID-19 will both be circulating this fall and winter suggesting that access to clinically appropriate diagnostic testing will continue to be imperative. As such, CMS should continue to work to ensure that Medicare policies facilitate access to medically necessary clinical diagnostic laboratory testing for COVID-19 and related services.

With respect to the NCCI, we strongly encourage CMS to:

1. *Suspend enforcement of the NCCI Policy Manual Section K.5 through calendar year 2021or the end of the public health emergency (PHE), whichever is later; and*

2. *Refrain from applying future procedure to procedure (PTP) edits for CPT® and HCPCS® codes 86328, 86769, 87426, 87635, U0002, U0003, and U0004 as well as other and future codes describing testing for COVID-19.*

Background

The Medicare National Correct Coding Initiative (NCCI) promotes correct coding to control inappropriate payment of Part B claims. To achieve this objective, NCCI utilizes a Policy Manual that outlines general correct coding policies, MUEs and PTP edits. We are concerned that current coding guidelines as outlined in the NCCI Policy Manual and recently implement MUEs are restricting clinically appropriate COVID-19 clinical diagnostic laboratory testing. We are also concerned that NCCI may implement PTP edits, which would further limit such testing.

Congress and CMS have recognized the importance of facilitating access to COVID-19 testing. In the Families First Coronavirus Response Act (FFCRA), sections 6003 and 6004 respectively waive patient cost sharing for coronavirus testing for Medicare Advantage and Medicaid patients. For Medicare, there already was no cost sharing for laboratory tests prior to the FFCRA but Congress encouraged treatment of potential COVID-19 by waiving cost sharing for visits that result in an order for or administration of a COVID-19 clinical diagnostic laboratory test.

In an interim final rule with comment published on May 8, 2020, CMS recognized the critical importance of COVID-19 testing by amending several Medicare policies on an interim basis to cover Food and Drug Administration (FDA)-authorized COVID-19 serology tests, to allow any healthcare professional authorized under state law to order COVID-19 diagnostic laboratory tests (including serological and antibody tests), and to provide for new specimen collection fees for COVID-19 testing under the Physician Fee Schedule and Outpatient Prospective Payment System, during the public health emergency (PHE) for the COVID-19 pandemic.

We are grateful to CMS and supportive of these flexibilities to ensure patients receive needed laboratory tests to help contain the spread of COVID-19. Similar flexibility is needed with respect to NCCI to ensure that critical COVID-19 testing continues to occur.

Below, we describe the current COVID-19 clinical diagnostic laboratory testing types and outline in detail our concerns with the NCCI Policy Manual, MUEs and potential PTP edits.

COVID-19 Clinical Diagnostic Laboratory Testing

Clinical Diagnostic Laboratory Testing (CDLT) for COVID-19 is comprised of three distinctly different types of tests: (1) diagnostic molecular RT-PCR tests that detect the virus' genetic material, (2) diagnostic antigen tests that detect specific proteins associated with the virus, and (3) serology tests that detect the presence of the antibodies demonstrating previous COVID-19 infection.[1] A healthcare professional during a patient encounter may order, when medically necessary, a combination of these tests to diagnose active or previous COVID-19 infection.

Performing COVID-19 CDLTs in combination is used, when medically necessary, to improve the accuracy of results to better manage patients:

- For example, with antigen tests, positive results are usually highly accurate but negative results may need to be confirmed with a molecular test.
- While many molecular tests may not need to be repeated, antibody and/or antigen test(s) may be ordered concurrently with the molecular test and other types of molecular tests may be ordered at the same patient encounter, depending on the strengths and limitations of each test (positive or negative predictive value).
- For persons who present late (9-14 days after illness onset) for COVID-19 diagnostic testing, CDC *Interim Guidelines for COVID-19 Antibody Testing* support antibody testing used in conjunction with viral detection tests as a method to support diagnosis.[2]

As described above, multiple immunoassay tests and molecular diagnostic tests may be medically necessary for accurate diagnosis.

1. Section K.5 of the Policy Manual

Section K.5 of the NCCI Policy Manual indicates that "CMS policy prohibits separate payment for testing for a single microorganism from an anatomic site by more than one methodology."[3] This Policy Manual

[1] Coronavirus Testing Basics. U.S. Food & Drug Administration, Accessed 6/12/20 https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics

[2] Interim Guidelines for COVID-19 Antibody Testing Interim Guidelines for COVID-19 Antibody Testing in Clinical and Public Health Settings. Centers for Disease Control and Prevention. National Center for Immunization and Respiratory Disease (NCIRD), Division of Viral Disease, page last reviewed May 23, 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

[3] National Correct Coding Initiative NCCI Policy Manual for Medicare Services (effective January 1, 2019), X-18.

language limits payment to a single type of COVID-19 diagnostic test, even if testing using multiple types of COVID-19 diagnostic tests is clinically appropriate. There are multiple clinical situations where such testing is warranted. For example, as noted above, when initial testing with an antigen test is negative, FDA labeling for certain tests specifically encourages follow up molecular testing when clinical conditions warrant. We are concerned that the language contained in Section K.5 is inconsistent with these labeling recommendations and current testing practices. We strongly urge CMS to not enforce section K.5 of the Policy Manual or other restrictive policies that would disallow the use of multiple types of COVID-19 diagnostic tests when clinically appropriate.

We further note that question six of CMS-developed frequently asked questions (FAQS) about the FFCRA and Coronavirus Aid, Relief and Economic Security Act (CARES)[4] addresses coverage for the use of multiple diagnostic tests for COVID-19 and indicates that multiple tests are covered.

> *"The coverage required under section 6001 of the FFCRA for items and services described in section 6001(a) of the FFCRA is not limited with respect to the number of diagnostic tests for an individual, provided that the tests are diagnostic and medically appropriate for the individual, as determined by an attending health care provider in accordance with current accepted standards of medical practice.[14] Although plans and issuers may not impose prior authorization or other medical management requirements to deny coverage for individuals who are tested multiple times, providers are urged to consult guidance issued by the CDC, as well as state, tribal, territorial, and local health departments or professional societies, when determining whether diagnostic testing is appropriate for a particular individual.[15]"*

Finally, section 6003 of the FFCRA amended section 1852(a)(1)(B) of the Social Security Act to state that "an MA plan may not impose any prior authorization or other utilization management requirements with respect to coverage of [clinical diagnostic laboratory tests for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and the administration of such test]." While this provision specifically applies to MA plans, it is clear that Congress was concerned about utilization control mechanisms that discourage testing for SARS-CoV-2. Diagnostic testing for this novel coronavirus is critically important for controlling this pandemic, and we urge CMS to consider this evidence in its evaluation of our request regarding Section K.5 of the NCCI policy manual.[5]

2. PTP Edits

The most recent hospital and practitioner PTP edits show no edits for the CPT® codes that describe the range of available COVID-19 diagnostic tests - 86328, 86769, 87426, 87635, U0002, U0003, and U0004. We strongly urge CMS to continue not to adopt PTPs edits for these services or other codes that may be issued describing COVID-19 testing. As previously described, COVID-19 diagnostic tests are ordered in combination or may be repeated during the same visit or subsequently. Additionally, COVID-19 diagnostic testing may be performed with related respiratory virus testing to aid in optimal triaging and patient care management. PTP edits that do not permit multiple types of COVID-19 CDLTs to be billed together or that limit the reporting of COVID-19 related respiratory virus testing that may occur in conjunction with COVID-19 testing should not be implemented. Doing so will negatively impact

[4] https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf

[5] In the interim final rule released on August 25, CMS also recognized that multiple tests may be required to diagnose COVID-19, when indicating that Medicare will only cover one COVID diagnostic test without an order and that coverage of additional COVID diagnostic testing will require an order from a treating physician or other practitioner.

clinically appropriate testing and may limit current public health strategies to respond to the COVID-19 pandemic.

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Again, we applaud CMS for its responsiveness, innovation and foresight in addressing critical policy issues during the COVID-19 PHE. Thank you for your consideration of our comments. We welcome the opportunity to meet with you and your colleagues to discuss these recommendations in greater detail at your convenience.

Sincerely,

AdvaMedDx
American Association for Clinical Chemistry
American Clinical Laboratory Association
American Society for Clinical Pathology
Association for Molecular Pathology
College of American Pathologists
Point of Care Testing Association