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Laboratory Compliance manager

inside

CORONAVIRUS IMPACTS LABORATORY PROCESSES:

New Codes for Coronavirus Lab Test

The Centers for Medicare & Medicaid Services (CMS) announced on February 13, and on March 5, that it took direct action to prepare healthcare facilities and clinical laboratories to respond to the threat of the emerging 2019-Novel Coronavirus (COVID-19). CMS revealed the creation of two new HCPSC codes for providers and laboratories to use during inpatient testing for SARS-CoV-2. In addition, Clinical Laboratory Improvement Amendments (CLIA) guidelines were released to help laboratories prepare for this threat. Please notify your staff of these changes.

Specific Testing Codes

Instead of applying an unspecified code, the new codes will enable labs conducting testing to bill for a specific test. This is meant to achieve better tracking of the public health response for this specific strain of coronavirus, in order to aid in public protection against the spread of this infectious disease.

"CMS continues to leverage every tool at our disposal in responding toCOVID-19," said CMS Administrator Seema Verma in a CMS web press release. "Our new code will help encourage doctors and laboratories to use these essential tests for patients who need them. At the same time, we are providing critical information to our 130 million beneficiaries, many of whom are understandably wondering what will be covered when it comes to this virus. CMS will continue to devote every available resource to this effort, as we cooperate with other government agencies to keep the American people safe."

Healthcare providers looking to test patients for Coronavirus using the Centers for Disease Control and Prevention (CDC) 2019 Novel Coronavirus Real Time RT-PCR Diagnostic Test Panel may bill for this test using the new code: **HCPCS code (U0001)**. Starting on April 1, 2020, the Medicare claims processing system is able to accept this code for dates of service which occur on or after February 4, 2020. To recap, HCPCS is a standardized coding system that Medicare and other health insurers utilize to submit claims for services provided to patients.

The arrival of a second **HCPCS billing code (U0002)** announced on March 5 enables laboratories to bill for **non-CDC laboratory tests for SARS-CoV-2/2019-nCoV (COVID-19)**. Note that on February 29, 2020, the Food and Drug Administration (FDA) implemented a new, "streamlined policy" for particular laboratories to develop their own validated COVID-19 diagnostics.

The difference between the first and second code is that the second HCPCS code can be applied to tests developed by these additional laboratories when submitting claims to Medicare or health insurers. Ultimately, CMS anticipates that having specific codes for these tests available will cultivate more testing and improve tracking. As with U0001, the Medicare claims processing systems can accept these codes starting on April 1, 2020, for dates of service on or after February 4, 2020.

The agency notes that Local Medicare Administrative Contractors (MACs) hold the responsibility for developing the payment amount for claims they receive for these newly created HCPCS codes in their respective jurisdictions. This will occur until Medicare implements national payment rates. Laboratories are advised to seek guidance from their MAC on payment for these tests before billing them should questions arise. Understand as with other laboratory tests, CMS reminds readers that there is generally no beneficiary cost-sharing under original Medicare.

CMS Takes Charge

In a recent news release, the agency solidified its commitment to the emerging threat stating:

"CMS is authorized to ensure quality testing at laboratories under the Clinical Laboratory

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Improvement Amendments (CLIA) and provides guidance to laboratories to meet CLIA requirements to ensure that laboratories produce accurate, reliable and timely results while being responsive to the pressing needs of our health care providers."

As readers may remember from last year, on February 26, 2019, CMS, FDA, and the CDC jointly created a Tri-Agency Task Force for Emergency Diagnostics. This task force was charged to standardize the process for correct execution and facilitation of diagnostic testing needs when a crisis occurs through the FDA's Emergency Use Authorization (EUA) process. The FDA previously issued an EUA for CDC-approved laboratory tests regarding the identification of the presence of Coronavirus patients as of February 4, 2020. The goal of this Tri-Agency Task Force is to give timely recommendations to laboratories for the expedited implementation of emergency diagnostic tests during a time of crisis.

More on Assay rRT-PCR

According to CLIA, "the CDC 2019-nCoV Real-Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR) assay is a molecular in vitro diagnostic test that aids in the detection of 2019-nCoV and is based on widely used nucleic acid amplification technology." Contained in the test kits are oligonucleotide primers, dual-labeled hydrolysis probes and control material used in rRT-PCR for the in vitro presumptive qualitative detection of 2019-nCoV RNA in upper and lower respiratory specimens.

CMS and the CDC have worked together to guarantee the creation of performance verification specifications for assays developed and tested by the CDC.

As per requirements, it should be known for that subsequent assay performance verification takes place on site at each CDC qualified laboratory. According to the memo, "inclusion as a CDC qualified laboratory, as defined in the assay's Manufacturer's Instructions (MI) for use, is not automatic, and members must demonstrate certain capabilities and

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MORE ON REVISIONS TO SOM:
Basis for Action

Significant revisions to the *State Operations Manual (SOM)*, Chapter 6 "Special Procedures for Laboratories" will continue to bring consequences for laboratory entities. With the variety and scope of changes now in effect, we will continue to breakdown the changes at hand. Notify your staff of these updates.

CLIA Suspension or Revocation

Under 6268.1 – "Suspension or Revocation of Any Type of CLIA Certificate," text was added to clearly define that when the Regional Office (RO) decides to suspend or revoke a CLIA certificate of any type, the laboratory's approval to be reimbursed by Medicare for its services is cancelled concurrently.

Updates to 6268.2 – "Limitation of Any Type of CLIA Certificate," explain that when the RO makes the decision to limit any type of CLIA certificate, it simultaneously modifies the laboratory's approval to receive Medicare payment to only those specialties or subspecialties, which hold authorization by the laboratory's limited certificate.

Updates to Basis for Action

In section 6276.1.1, the RO has the right to initiate adverse action for the implementation of principal sanctions which include suspension, limitation, revocation of any CLIA certificate should CMS conclude a laboratory owner, operator or one of its employees if found guilty of any of the following:

- Was found either over the course of conclusions for the survey process, or the documents submitted to CMS, the RO or the SA, to have "potentially made a misrepresentation which was materially relevant to the laboratory having obtained or maintained a CLIA certificate"
- "Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate"
- Neglected compliance with CLIA certificate requirements and performance standards, which include failing to comply with notification of change requirements
- Neglected to oblige with "reasonable requests" made by the RO or CMS' agent regarding any information or work on materials that the RO or CMS' agent had concluded would be necessary to ascertain the laboratory's continued eligibility for its CLIA certificate "or continued compliance with performance standards set by CMS (no hearing necessary before the action)"
- Rejected a request deemed as "reasonable" by the RO or CMS' agent asking for inspection permission of the laboratory along with its operations and applicable records over the hours that the laboratory operates (no hearing necessary before the action)
- Breached or aided and abetted in the violation of any CLIA provisions and its implementing regulations
- Had compliance failure with an alternative sanction previously imposed; or
- "Within the proceeding 2-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all other laboratory's employees.)"

Should the RO decide that any of the above CLIA violations were committed, the RO will then impose a principal sanction.

The RO will notify the Office of the Inspector General (OIG) under these specific circumstances:

- "Misrepresentation in obtaining a CLIA certificate;
- Performance, or representation by the laboratory as entitled to perform, an examination or other procedure that is not authorized by its CLIA certificate;
- Violation or aiding and abetting in any provisions of CLIA and its implementing regulations
- And adverse action based on improper PT referral."

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PATHOGEN CULTURE AND DETECTION OF INFECTIOUS AGENT:
Protocol Breakdown for Best Practices

On any given day, the microbiology laboratory is responsible for a variety of specimens such as blood, urine, spinal fluids, and secretions as well as other sources such as stool, wounds and surgical incisions. The CPT code series starting with 87040 has several important options to understand when applying codes. To make things more complex, processing codes exist for concentration of specimens (87015), identification procedures and sensitivity procedures. Let's review the basic protocol to ensure an accurate understanding of the process.

Protocol Breakdown

Within the CPT series that starts with 87040, codes exist that are specific to a source (blood, stool, urine) as well as the routine culture of other sources for either aerobic (87070) or anaerobic (87075) organisms.

87070 Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates

87075 Culture, bacterial; any source, except blood, anaerobic with isolation and presumptive identification of isolates

When selecting the correct codes for each specimen submitted for culture, the initial step is to identify the specimen source, and then follow the specimen through the testing and reporting process so that capture of all appropriate CPT codes is obtained. Use the following coding and billing protocol for cultures:

1. Establish whether any diagnostic smears are performed on the primary specimen. If so, assign the proper code from the CPT range 87205–87220.
2. Identify the culture source or type.
   - Sources include blood (87040), stool (87045–87046), urine (87086) and other (87070).
   - Types include a pathogen-specific screen (e.g., Group B strep), fungal, acid-fast bacteria (AFB), mycobacterium, viral. Cultures that are specific to a type of pathogen will be located in the microbiology series starting with CPT 87081–87116.

     Note: Within this series are the associated definitive identification codes for each of the specified infectious agents.
3. Assess if the final culture report provides a presumptive or definitive identification.
   - If presumptive only, the identification is included in the CPT for the culture.
   - If definitive, the identification is billed with the appropriate CPT code or codes for anaerobic (87076), aerobic (87077), or with codes for the identification of specific infectious agent (87106, 87107, 87118).
   - If specified, additional culture typing methods (87140–87158) that are required for definitive identification are also coded.
4. Identify the type of antimicrobial sensitivity study required for each isolate.
   - Microdilution or agar dilution sensitivities (+87187) is likely the procedure that is most frequently performed for the determination of antibiotic therapy. Do not add CPT for the performance of additional sensitivity performed as validation of the MIC.
   - Other types of sensitivity studies will be represented in the code series 87181–87190.
5. Determine if additional CPT codes are required for viral culture, isolation, and identification methods.
   - Viral-specific CPT codes are found in the series 87250–87255.

Also located in the Microbiology section of CPT are individual procedures for the processing of specimens by concentration (87015) or homogenization of tissue (87176) and examination of ova and parasites (O&P), microscopic identification of arthropods, parasites and pinworms, which are listed in the code series 87168–87177.

The following scenario is given as an example for complete capture of CPT for stool specimen submitted for the

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New Text in Notice to the OIG

Under 6276.5, new text as added to the circumstances in which the RO would inform the OIG. This occurs within 30 days to take action.

- The owner, operator, or one of the laboratory's employees is considered guilty of misrepresentation when obtaining a CLIA certificate
- The owner, operator, or one of the laboratory's employees either performed or represented the laboratory as entitled to complete a laboratory examination or other testing not designated in the laboratory's CLIA certificate
- The owner, operator, or one of the laboratory's employees breached or aided and abetted in the violation of any CLIA provisions and its implementing regulations
- The laboratory made deliberate referrals of PT samples to another laboratory for analysis.

Information Source:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertification-GenInfo/Downloads/QSO-19-20-CLIA.pdf

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capacities, and meet established agent-specific performance standards."

At least one set of assay verification results is required from each laboratory, according to the CDC assay's manufacturer's instructions. Laboratories are encouraged to further evaluate assay performance while testing continues and more patient samples containing results are available.

Understand that assays which are authorized for emergency use by the FDA are still subject to CLIA regulations. All laboratories are obligated to follow any and all of the manufacturer's instructions. When the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and corresponding Manufacturer's Instructions for Use are received, CDC qualified laboratories will act to verify the assay performance specifications according to the manufacturer's instructions.

Use of Assays Without FDA Emergency Use Authorization

It is the responsibility of surveyors to determine if the laboratory is using an assay that is authorized for emergency use by the FDA. According to the memo, "Surveyors should notify their CMS Location if they discover a laboratory using an assay without an EUA that is testing for the same agent for which an emergency has been declared, or a modified EUA assay. The CMS Location will notify CMS Baltimore." The effective date is immediately according to CMS. We will continue to track and monitor potential compliance and coding changes regarding this outbreak.

Special Notice:

With the ever rapidly evolving pandemic situation, information regarding the outbreak is subject to change on a weekly, daily, and potentially even on an hourly basis, which conflicts with the timeline and scope of the normal publication process. All information is current only at the time of source publication and although the relevancy of some sources will continue to last, others will ultimately change over the days and weeks to come.

Information Sources:

https://www.cms.gov/files/document/qso-20-10-clia.pdf

https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-02-20

https://www.cms.gov/newsroom/press-releases/cms-prepares-nations-healthcare-facilities-coronavirus-threat

https://www.cms.gov/newsroom/press-releases/cms-develops-additional-code-coronavirus-lab-tests

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culture of enteric pathogens, O&P and trichrome stain:

87045 Culture Salmonella & Shigella
87046 Campylobacter
87077 Definitive identification—Salmonella
87147 Serotyping—Salmonella A
87147 Serotyping—Salmonella B
87147 Serotyping—Salmonella C
87147 Serotyping—Salmonella D
87147 Serotyping—Salmonella E/G
87147 Serotyping—Salmonella Vi
87186 Sensitivity MIC
87177 Ova and Parasite (O&P) exam
87209 O&P—Trichrome stain

Should the stool culture administered by your laboratory also include the detection of Shiga-like toxin from *E. coli (enzyme immunoassay)*, you must assign CPT 87427.

87427 Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; Shiga-like toxin

6. Judge if a modifier assignment is necessary. On any given day, a physician may order multiple cultures on a patient that must be reported with the same CPT code(s). A modifier might prove essential in order to demonstrate that the cultures are separate and distinct. Noting updated guidelines for X {ESPU} modifiers usage, make sure to know when the modifier XS is the best and most appropriate modifier for the situation instead of modifier 59.

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