June 25, 2020

Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Street, S.W.
Washington, D.C. 20201

RE: National Correct Coding Initiative Policy Manual for Medicare Services 2020 Updates for Pathology/Laboratory Services

Dear Administrator Verma:

The undersigned organizations, representing a broad range of stakeholders involved with offering clinical laboratory and pathology services critical to improving the health of Medicare and Medicaid beneficiaries are writing in follow-up to earlier discussions regarding concerns with the Pathology/Laboratory Services section of the National Correct Coding Initiative ("NCCI") Policy Manual for Medicare Services, as well as corresponding updates to the Policy Manual for Medicaid Services. For 2020, the Centers for Medicare & Medicaid Services (CMS) has made revisions to the NCCI Policy Manual which we believe were intended to be responsive to our concerns. We appreciate the agency's responsiveness, but we continue to have some important concerns as outlined below.

We also appreciate the extraordinary efforts shown by CMS to address the COVID-19 pandemic. The current public health emergency has highlighted the need for balanced regulation and that removing unnecessary barriers to medically necessary diagnostic testing is important both to the health of individual Medicare/Medicaid beneficiaries as well as to the broader public health.

In addition to the specific issues raised with respect to the manual text, we would like to remind CMS of the concerns we raised last year about the process by which manual updates are provided. Despite the significant impact that the NCCI Policy Manual updates are likely to have, the broad range of clinical laboratory and pathology stakeholders are not provided a chance for input. Moreover, manual updates are effective nearly immediately and without adequate time for laboratories to implement the necessary changes. It is important for CMS to consider stakeholder input to revisions to the NCCI Policy Manual, so that changes will occur that not only successfully reflect CMS concerns but also modern laboratory test ordering practices and laboratory work flow. Providing laboratories sufficient notice of changes is equally important.

Below we outline in detail our ongoing concerns with the NCCI Policy Manual and current process. In the attached copy of Chapter 10 of the NCCI Policy Manual, we provide a redline of the changes and clarifications we are seeking.

NCCI Policy Manual

In Chapter X, Section A of the NCCI Policy Manual, CMS includes language stating a general rule that *"if a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that*

describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service."

This instruction is overbroad and unclear. However, we continue to seek clarity on what constitutes "a laboratory procedure." Many laboratory procedures are performed today in batches or using multiplex procedures that produce multiple different clinically significant reportable test results. Is each batch or multiplex process a single procedure? If so, tests ordered across different patients could constitute a single procedure. If each test performed using a multiplex process is considered a single procedure, many procedures that today do not have a single test-specific CPT® code would need to be reported under miscellaneous or unlisted procedure codes. There is concern that such a policy would increase use of miscellaneous or unlisted procedure codes, complexity of CPT coding, and ambiguity of tests performed as well as pricing. Moreover, such a policy would: (1) be inconsistent with AMA guidance to use CPT® codes to the greatest level of specificity; (2) cause Medicare claims processors to lose visibility as to the exact test(s) performed; (3) create a heavy claims processing burden for Medicare Administrative Contractors (MACs); (4) create substantial delays in payment for laboratory providers; and (5) result in much more limited data being "applicable information" for rate setting purposes under the new Clinical Laboratory Fee Schedule under Section 216 of the Protecting Access to Medicare Act.[1] Use of miscellaneous and unlisted procedure codes also defeats the purpose of PAMA for rational price-collection and price-setting.

For example, a multiplex amplified probe test for evaluating *Chlamydia trachomatis* and *Neisseria gonorrhea* (CTNG) is currently reported using 87491 and 87591; the modifier -59 is used if the physician suspects infection in multiple body sites. It appears that, under the new policy, laboratories may be required to report code 87801 for a CTNG test in order to reflect the multiplex nature of the testing procedure despite the fact that the two distinct organisms are reported out separately and the clinical information from each is unique. Code 87801 was created to report multiplex tests of two or more microbiology analytes that are not reported out separately. Not only are most CTNG tests reported out separately for CT and NG, they represent two clinically different – albeit sometimes co-existing – infections that require different treatments, which is to say that reporting a single result would not be clinically meaningful. However, there is no specific CPT® code for the combination test reporting out both results independently. Enforcement of such a coding policy will require clinical laboratories to have different CPT® reporting practices for CMS versus commercial payers.

Additionally, some would interpret the current policy as requiring laboratories to bill an unlisted procedure code for individual components of an organ or disease oriented panel when all components of the panel are not performed. For example, a lipid panel described by CPT® code 80061 includes total cholesterol, high density lipoprotein (HDL) cholesterol and triglycerides. If a physician orders only total cholesterol and HDL cholesterol, but not triglycerides and these tests are run multiplex the current policy suggests that the laboratory would have to bill under an

[1] The concerns raised in this letter are unrelated to the issue of reporting multi-channel chemistry tests under panel codes when there are panel codes under the CPT® codebook. The changes to Chapter X of the coding Policy Manual for 2019 to make such reporting mandatory are not being challenged here.

unlisted procedure code rather than reporting 82465 (*"cholesterol, serum or whole blood, total*") and 83718 (*"Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)* as there is no specific CPT® code that describes this combination of tests. Like in the example above, enforcement of such a coding policy will require clinical laboratories to have different CPT® reporting practices for CMS versus commercial payers.

The NCCI Policy Manual includes other guidelines that continue to contradict longstanding coding instruction, will substantially increase administrative burden and confusion, and will not ultimately lead to more efficient physician practices or better patient outcomes, including:

1. Section F.5 and current procedure-to-procedure (PTP) edits still prohibit reporting code 81445 for a Genomic Sequencing Procedure (GSP) of 5 to 50 genes for a solid organ neoplasm together with code 81450 for a GSP of 5 to 50 genes for a hematolymphoid neoplasm. The edit does not permit these to be reported together under any circumstance even with a modifier indicating that these are distinct procedural services. This suggests that a patient could not simultaneously have a hematologic malignancy and a solid tumor for which both tests may be medically necessary.

2. Section F.8 continue to prohibit the use of multiple component codes when billing for a Next Generation Sequencing (NGS) procedure and would require the billing of an unlisted molecular pathology procedure code if there is no code for the specific combination of markers comprising the procedure. We acknowledge that CMS has implemented revisions to Section F.8, however, we are concerned that language contained within the last sentence of this section indicating that a single procedure must be reported using one HCPCS/CPT® code with one unit of service remains. This guidance is inconsistent with instruction provided earlier in Section F.8. Moreover, this policy contradicts existing CPT coding guidance that states when all of the components of a descriptor are not performed, Tier 1 and Tier 2 codes may be used to describe genes using next generation sequencing. It also does not consider that laboratories may run larger panels for operational efficiencies, but actually report only those specific tests actually ordered for a particular patient. Laboratories should be permitted to bill for testing as ordered and consistent with coverage policies even if it is operationally more efficient for the laboratory to perform such testing as a broader panel.

3. In Section K.6, we recommend that CMS further clarify that physicians may report separate CPT® codes for nucleic acid testing. For example, CPT® codes 87631-87633 describe multiplex testing for respiratory pathogens. If testing is performed for bacterial pathogens within the same multiplex reaction that service should be reported separately. These are distinct procedures and should be reported separately even when performed on the same patient on the same date of service.

4. In Section M.15, the entire first paragraph was removed. This creates confusion for reporting infectious agent antigen detection. In the second paragraph of M.15, the agency removed a portion of the first and second sentence that provided context for billing a

single infectious agent antigen detection test or agent antibody test that provides results for more than one species or strain of organism (" (1) code with (1) unit of service (UOS) for the procedure. Based on the methodology utilized..."). We recommend CMS add the 2019 language back to section M.15 of the 2020 NCCI Policy Manual to provide clarification for reporting these laboratory services.

These guidelines require laboratories to report for Medicare and Medicaid purposes following coding policies that contradict long-standing coding guidance set forth in the AMA's CPT® codebook. The new policies also run counter to the way physicians order and laboratories perform analyses.

To address the concerns outlined above, in the attached copy of Chapter 10 of the NCCI Policy Manual we provide a redline of the changes and clarifications we are seeking.

Process Concerns

In addition to the outstanding issues in the NCCI Policy Manual, we remain concerned about the process by which annual updates to the NCCI Policy Manual are established. Stakeholders are notified of changes, without any chance for input, only a few weeks before their effective date. We urge CMS to implement a process that engages AMA CPT® early to identify and address any concerns with CPT® coding instruction before the NCCI Policy Manual is updated. Once AMA CPT® and NCCI are aligned we request the opportunity for a broad array of stakeholders to review and comment on draft changes and a timeline that provides laboratories with **at least six months** to prepare for changes that impact laboratory coding and billing. Given the diversity of clinical laboratory and pathology testing services considering analyte, specimen type, and platform, it is particularly important for CMS to consider broad stakeholder input prior to finalizing revisions to the NCCI Policy Manual. A timely process that engages a broad array of stakeholders will allow CMS to address billing concerns the agency may have while allowing modern laboratory test ordering practices and work flow to be reflected in the NCCI Policy Manual.

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Unless these concerns are addressed, inconsistencies between CPT® coding instruction and the 2019/2020 NCCI Policy Manual updates will continue and will be disruptive to laboratory billing and claims processing by MACs and could require significant revisions to the CPT® code set. To avoid these outcomes, we respectfully request that CMS further revise the NCCI Policy Manual and work proactively with stakeholders, including AMA CPT®, to address reasonable concerns the Agency may have about clinical laboratory and pathology billing processes while avoiding problematic unintended consequences. Additionally, we request CMS begin a process that ensures timely stakeholder notification to provide comments and make adjustments to coding and billing practices. In the setting of the COVID-19 pandemic, it has been clear that removing unnecessary barriers to medically necessary diagnostic testing is important both to the health of individual Medicare/Medicaid beneficiaries as well as to the broader public health.

Sincerely,

AdvaMedDx
American Association for Clinical Chemistry
American Clinical Laboratory Association
American Society for Clinical Pathology
American Society for Microbiology
Association for Molecular Pathology
Coalition for 21st Century Medicine
College of American Pathologists
Physician Fee Schedule Pathology Payment Coalition
Point of Care Testing Association