

VIA ELECTRONIC MAIL

September 15, 2021

Carol Blackford, Director
Hospital & Ambulatory Policy Group
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CY2021 National Correct Coding Initiative Policy Manual for Medicare and Medicaid Services

Dear Ms. Blackford:

On behalf of the undersigned organizations, which represents the broad range of stakeholders involved with developing and providing clinical laboratory services, we are writing to express our concerns regarding language included in Chapter X, Pathology/Laboratory Services, in both the 2021 National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services and the 2021 NCCI Policy Manual for Medicaid Services (collectively, the “Manuals”), which took effect January 1, 2021. Our organizations all value the collaborative relationship we have held with NCCI and the Centers for Medicare & Medicaid Services (CMS) to ensure the integrity and accuracy of this process. We appreciate NCCI and CMS consideration of our previous input to revisions to the NCCI Policy Manual.

Below we discuss our concerns with the 2021 Manuals.

A. Introduction, Section A

Our concern with language inserted in the 2019 Manuals and retained in the 2020 and 2021 Manuals is with the following in the Introduction section:

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.¹

¹ 2021 NCCI Policy Manual for Medicare Services, Ch. X, Pathology/Laboratory Services X-5.

The Pathology and Laboratory Guidelines in the 2021 CPT Professional Edition codebook states plainly: “In the CPT code set, the term “procedure” is used to describe services, including diagnostic tests.”² The AMA codebook describes laboratory services or procedures that appear within the different pathology and laboratory subsections of the codebook. A laboratory procedure may use different methods and have different components. The AMA CPT code set describes different method codes and analyte specific codes. To eliminate confusion, we urge CMS to remove this broad contradictory language from the Manuals altogether.

The clinical laboratory members and customers of the organizations below use Healthcare Common Procedure Coding System (HCPCS) Level I Current Procedural Terminology codes and Level II codes to report laboratory procedures for Medicare beneficiaries. Our laboratories follow the industry-standard CPT codes, descriptions, and guidelines as defined in the AMA’s “CPT codebook” and the Medicare NCCI Procedure-to-Procedure (PTP) code pair edits and Medically Unlikely Edits (MUEs). When reporting codes for a procedure, laboratories utilize CPT guidelines, parenthetical instructions, and coding resources, including *CPT Assistant* to assure the accuracy of coding. It is imperative that the NCCI manual does not circumvent the coding structure established by the AMA, MUE and PTP edits.

The NCCI introductory language provides guidance to report a procedure with a single miscellaneous or unlisted CPT code that provides no information on what was actually tested. This coding guidance is overbroad and unclear. Read literally, the language in the Manuals suggests, for example, that if analysis of two or more chemistry analytes (*e.g.*, urine protein, albumin, and creatinine) is ordered and performed, and there is no applicable panel code describing the group of analytes, a single unlisted code would be reported (84999, unlisted chemistry procedure). This violates AMA CPT guidance. The Pathology and Laboratory Guidelines in the 2021 CPT Professional Edition codebook state plainly: “It is appropriate to designate multiple procedures that are rendered on the same date by separate entries.”³ Furthermore, the AMA directs providers to use the unlisted procedure codes only to report a procedure not otherwise described in the CPT codebook. In this example, CPT guidelines call for a laboratory to submit a claim with the existing CPT codes that describe the analytes separately measured: 82570 (creatinine), 82043 (albumin) and 84156 (protein). A laboratory cannot comply simultaneously with guidance in the CPT codebook and with the policy in the NCCI Manuals given the contradictory nature.

The lack of clarity makes the introductory statement difficult to interpret. An example of this is amplified probe testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Testing is performed utilizing two separate amplified probes reported as 87491 (*Chlamydia trachomatis* amplified probe technique) and 87591 (*Neisseria gonorrhoea* amplified probe technique). This is an example of a laboratory procedure which produces multiple reportable test results, so using the NCCI introductory language as guidance conflicts with the AMA guidance to code laboratory procedures at the highest level of specificity. Billing a single HCPCS/CPT method code such as 87801 (Infectious agent detection by nucleic acid, multiple organisms, amplified probe technique) when analyte-specific coding exists (87471-87660) for the procedure(s) performed is not aligned with AMA guidance.

² See American Medical Association, 2021 CPT, Introduction at xiii.

³ See American Medical Association, 2021 CPT, at 583.

The language in the introduction section also is not consistent with the NCCI PTP code pair edits and MUEs. This creates confusion for laboratories and is subject to misinterpretation. Through the years laboratory coding has become more complex. To meet the needs of rapidly evolving laboratory services, the AMA implements changes to the CPT code set to streamline the reporting of novel laboratory services. The NCCI introductory language guides laboratories to report procedures with a miscellaneous or unlisted procedure code when a specific CPT code exists to report the service. This guidance contradicts CMS developed NCCI PTP and MUE coding policies and also the AMA guidance to use the code with the highest level of specificity.

With regard to Medicare beneficiaries, if laboratories were to follow the instruction in the Manuals, Medicare Administrative Contractors (MACs) would have to adjudicate a vast number of claims with miscellaneous and unlisted codes. On top of this plain administrative burden, MACs will have to request and process a tremendous amount of additional documentation to determine which tests were performed, and contend with a far greater number of appeals for mistakenly denied claims. Nearly half of the MACs do not have established systems and procedures that allow laboratories to identify a specific test on a claim form other than by using CPT and HCPCS codes. Moreover, with regard to Medicaid beneficiaries, unlisted codes such as 84999 do not appear on the State Fee Schedule for the majority of States. In these cases, otherwise medically necessary covered services that could be readily identified with specific CPT codes likely would be denied when billed using an unlisted service code. In many ways, this policy would run contrary to CMS's "Patients Over Paperwork" initiative to "reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience."⁴

The approach set forth in the Manuals is a step backwards and would result in far less transparency about testing that is ordered by physicians, performed by laboratories and paid for by the Medicare and Medicaid programs. Not only would the changes put laboratories in a position of violating long-standing coding guidance set forth plainly in the AMA CPT Professional Edition codebook, but also these policies run counter to the way physicians order and laboratories perform analyses. Furthermore, moving to a miscellaneous or unlisted coding process as instructed by the Manuals would impact the CPT codes and volume reported for ratesetting under Section 216 of the *Protecting Access to Medicare Act (PAMA)* and skew PAMA data reporting.

B. Molecular Pathology, Section F.8

The AMA CPT codebook provides clear guidance when reporting individual molecular pathology services. The Manuals in section F.8 are ambiguous and we recommend that the Manuals follow CPT correct coding instructions which stipulate the most specific code should be used rather than a non-specific miscellaneous code. For example, a laboratory that performs assays for several genes that have individual Tier 1 and/or Tier 2 codes should bill the respective Tier 1 and/or Tier 2 codes (e.g., or) , when there is no PLA code, MAAA, or specific GSP code that applies. Two specific examples are: (1) coding for MLH1 (81292), MSH2 (81295), MSH6 (81298), and PMS2 (81317) for Lynch Syndrome because code 81435 for hereditary colon

⁴ Patients Over Paperwork, *available at* <https://www.cms.gov/About-CMS/Story-Page/patients-over-paperwork>

cancer disorders applies only when a test involves a genomic sequence analysis panel including at least 10 genes and must include a minimum specified list of genes, and (2) coding for CFTR (81220), SMN (81329), and HBB (81361) for severe inherited genetic disorders because code 81443 applies only when a test involves a genomic sequence analysis panel including at least 15 genes. Language in the Manuals is ambiguous, and we recommend the Manuals allow for billing each component tested when performed, consistent with CPT instructions, rather than the unlisted 81479 molecular pathology code. Reporting the individual component Tier 1 and/or Tier 2 CPT codes provides transparency for the genes interrogated in each assay. We recommend CMS revise the language in section F.8 as suggested in our redline version of the manual.

C. Microbiology, Section K.2

The codes added to Section K.2 of the 2021 Manuals 87910, 87901, 87906, 87912, 87903, and 87904 are used to report for infectious agent genotype analysis or infectious agent phenotype analysis. These codes are not a part of the AMA CPT code range 87471 – 87801 (Infectious agent detection by nucleic acid (DNA or RNA) assays using nucleic acid probes). Instead, these procedures represent testing that may determine viral phenotype and genotype resistance to commonly prescribed antiretroviral drugs: nucleoside reverse transcriptase inhibitors (NRTI), nonnucleoside reverse transcriptase inhibitors (NNRTI), protease inhibitors (PI), and integrase inhibitors (INI). We recommend CMS remove codes 87910, 87901, 87906, 87912, 87903, and 87904 from section K.2 as suggested in our redline version of the Manual.

D. Medically Unlikely Edits, Section M.15

The language in section M.15 is contrary to long standing coding guidance set forth plainly in the American Medical Association CPT Professional Edition codebook. The CPT manual clearly states in the Microbiology Section of Pathology/Laboratory:

“The most specific code possible should be reported. If there is no specific agent code, the general methodology code (eg, 87299, 87449, 87450, 87797, 87798, 87799, 87899) should be used. . . . When separate results are reported for different species or strain of organisms, each result should be coded separately. Use modifier 59 when separate results are reported for different species or strains that are described by the same code.”⁵

The manual also states under CPT 87801:

“For detection of multiple infectious agents not otherwise specified which report a single result, see 87800, 87801.”⁶

⁵ See American Medical Association, 2021 CPT, at 660.

⁶ See American Medical Association, 2021 CPT, at 665 (emphasis added).

The AMA has also clarified the use of 87801 below in a *CPT Assistant* Frequently Asked Questions document published in 2013.⁷

Question:

When performing an amplified DNA probe test for both GC and Chlamydia on the same specimen at the same time, is code 87801 the correct code to report? Or should codes 87491 and 87591 both be reported?

Answer:

The reporting of codes 87491, 87591, and 87801 will depend on how the results of the combination analysis are reported. If the test results differentiate between Chlamydia trachomatis and Neisseria gonorrhoeae, then it would be appropriate to report codes 87491, Chlamydia trachomatis, amplified probe technique, for the hybrid capture Chlamydia trachomatis test and 87591, Neisseria gonorrhoeae, amplified probe technique, for the hybrid capture Neisseria gonorrhoeae test. If the results do not differentiate, then it would be appropriate to report code 87801, Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique.

The language in section M.15 is contrary to long standing coding guidance set forth plainly in the AMA CPT codebook and further supported by the FAQ in the attached *CPT Assistant* article. This guidance supports our position that it may be appropriate to use multiple CPT codes to report infectious agent testing when the results differentiate between different organisms.

Furthermore, the language in the MUE section M.15 is not consistent with NCCI MUEs.⁸ This creates confusion for laboratories and is subject to misinterpretation. For example, when multiple procedures are performed as distinct services for which specific CPT codes do not exist, not otherwise specified (NOS) codes such as 87798, 87800, 87801 may be reported with multiple units of service. The established MUE limit for CPT code 87798 is currently set at (13) units of service recognized as medically appropriate when separately performed and billed according to MUE guidance. An example would be testing for bacterial vaginosis by semi quantitative PCR analysis of three predictive marker organisms (Atopobium vaginae, BVAB-2, and Megasphaera-1) billable as 87798 x3 units of service. The organizations below recommend removing the contradictory language as suggested in our redline version of the Manual.

E. Delayed Implementation Period

When implementing sweeping changes to the Manuals it is important for relevant stakeholders to be engaged early in the process, especially in cases where new language contradicts longstanding AMA CPT coding guidance. The organizations below recommend a delayed implementation period following the release of the annual manual updates before it would be effective. We propose a six month delayed implementation period, which would allow time for adequate

⁷ See *CPT Assistant*, June 2013: Frequently Asked Questions, Amplified DNA probe test for both GC and Chlamydia, at 14

⁸ CMS NCCI MUE files. See <https://www.cms.gov/files/zip/practitioner-services-mue-table-effective-04-01-2021-posted-march-1-2021.zip>.

stakeholder review, time to submit comments to CMS and implementation by Medicaid programs.

F. Conclusion

The organizations below respectfully request CMS withdraw the 2019 updates to the Introduction section of the Manuals that were retained in the 2020 and 2021 versions of the Manuals. The language is contrary to long-standing coding guidance. Furthermore, we urge CMS to review our recommendations for manual language and make changes to Section F.8, Section K.2, and Section M.15 to the 2021 Manuals to provide clarification for reporting these laboratory services. Finally, we request CMS delay the implementation period of the annual Manuals updates for a period of six months to allow for interested stakeholder input before implementation.

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Thank you very much for your consideration of our comments. Please contact Paul Radensky, MD, JD at pradensky@mcdermottplus.com or 202.756.8794 with any questions.

Sincerely,

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

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