December 20, 2019

American Clinical Laboratory Association

Cathy Cook, M.D.
Medical Director
Capitol Bridge LLC
2300 9th Street, South, PH3
Arlington, VA 22204

Submitted via email: ProfessionalSociety@capitolbridgellc.com

Dear Dr. Cook,

The American Clinical Laboratory Association (ACLA) is writing to express serious concerns regarding language included in Chapter X, Pathology/Laboratory Services, in both the 2020 National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services and the 2020 NCCI Policy Manual for Medicaid Services (collectively, the "Manuals"), which takes effect January 1, 2020. ACLA values 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, and we appreciate you reaching out to us to solicit comments on these edits.

We thank CMS for the changes made to the Molecular Pathology section (Section F) in the Manuals; however, we remain concerned that the broad, overarching language remains in the Introduction (Section A). We urge CMS to withdraw the 2019 edits to the Introduction, based on the information we provide herein.

As noted in our comment letter on the 2019 NCCI Policy Manual changes, the language in the Introduction section would create unnecessary administrative burdens for Medicare Administrative Contractors (MACs), State Medicaid Programs and clinical laboratories, by requiring the use of unlisted or miscellaneous codes when appropriate Current Procedural Terminology (CPT) codes already exist and should be used per coding rules. 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 American Medical Association CPT Professional Edition codebook, but also the new policies run counter to the way physicians order and laboratories perform analyses. Furthermore, moving to a miscellaneous or unlisted coding process as indicated in the NCCI edits would impact the CPT codes/volume reported for the 2014 *Protecting Access to Medicare Act (PAMA)* and skew PAMA data reporting.

A. Definition of "Procedure"

It is imperative that NCCI explain to stakeholders what is meant by the term "procedure" in the context of the new language added to the 2019 Manuals and retained in the 2020 Manuals. In common usage, a "procedure" describes a series of steps taken in a certain order, without regard to results. In the context of NCCI Procedure-to-Procedure Edits, a "procedure" is represented by

a single specific CPT or HCPCS code.[1] In the Manuals, the term is used differently in different sections. In one instance, the word appears to be used in the same way as in the Procedure-to-Procedure Edits context (referring to a "Tier 1 or Tier 2 molecular pathology procedure CPT code…").[2] In another instance, the meaning is not clear at all ("If a laboratory procedure produces multiple reportable test results…").[3] For any provider to comply with policies in the NCCI Manuals, their meaning must be clear and definitions consistent and not defined in terms of reportable test results.

The meaning is not clear in Section F.8 ("If a single procedure is performed, only one HCPCS/CPT code with one unit of service may be reported for the procedure.").[4] This language appears to contradict the changes made in Section F.8, which would indicate the use of individual CPT codes may be appropriate. We urge CMS withdraw the last sentence in Section F.8.

B. Single Code Requirement

Our concern with language inserted in the 2019 Manuals and retained in the 2020 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.

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 and creatinine) is ordered and performed, a single unlisted code would be reported (84999, unlisted chemistry procedure). This violates AMA guidance. The Pathology and Laboratory Guidelines in the 2020 CPT Professional Edition codebook states plainly: "It is appropriate to designate multiple procedures that are rendered on the same date by separate entries." Furthermore, the AMA directs providers to use the unlisted procedure codes to report a procedure that is not contained 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) 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. This broad contradictory language should be removed from the Manuals altogether.

With regard to Medicare beneficiaries, MACs would have to adjudicate a vast number of claims with miscellaneous and unlisted codes. On top of this plain administrative burden, MACs

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[1] *See* HealthData.gov NCCI Procedure-to-Procedure Edits, *available at* https://healthdata.gov/dataset/ncci-procedure-procedure-edits-ptp ("NCCI procedure-to-procedure (PTP) edits define pairs of Healthcare Common Procedure Coding System (HCPCS)/Current Procedural Terminology (CPT) codes that should not be reported together…").
[2] Ch. X, p. X-10.
[3] Ch. X, X-5.
[4] Ch. X, X-10.

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 of mistakenly denied claims. Nearly half of the MACs do not have established systems and procedures that allow laboratories to identify a test on a claim, other than 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 already identified with specific CPT codes would be inappropriately denied. 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."[5]

C. Medically Unlikely Edits

We are concerned with the changes made to the Medically Unlikely Edits (MUEs) (Section M) item number 15 (M.15). The entire first paragraph in M.15 was completely removed in the 2020 Manuals, which 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...").[6] ACLA urges CMS to add this language back to the section M.15 of the 2020 Manuals to provide clarification for reporting these laboratory services.

D. Delayed Implementation Period

When implementing sweeping changes to the NCCI Policy Manual for Medicare Services it is important for relevant stakeholders to be engaged early in the process, especially in cases where new language contradicts longstanding AMA coding guidance. ACLA recommends 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 stakeholder review, time to submit comments to CMS and implementation by Medicaid programs

E. Conclusion

ACLA respectfully requests CMS withdraw the 2019 updates to the Introduction section of the Manuals that were retained in the 2020 Manuals. The language is contrary to long-standing coding guidance. Furthermore, we urge CMS withdraw the last sentence in Section F.8 under the Molecular Pathology section and add the 2019 language back to section M.15 of the 2020 Manuals to provide clarification for reporting these laboratory services. Finally, we request CMS delay the implementation period of the annual NCCI updates for a period of six months.

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[5]Patients Over Paperwork, *available at* https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html.

[6] Ch. X, X-26

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Thank you very much for your consideration of ACLA's comments. Please contact us if you have any questions or need additional information.

Sincerely,

Joan Kegerize, J.D.
Vice President, Reimbursement and Scientific Affairs

Attachment
Correspondence from the American Clinical Laboratory Association dated December 14, 2018

cc: Carol Blackford, Director, CMS, Hospital and Ambulatory Policy Group
Ing-Jye Cheng, Deputy Director, CMS, Hospital and Ambulatory Policy Group
Edith Hambrick, M.D., J.D., MPH, CMS Medical Officer
Marsha Mason-Wonsley, CMS CPT Coding Specialist
Karen Nakano, MD, CMS, Hospital and Ambulatory Policy Group
Sarah Shirey-Losso, Director, Division of Ambulatory Services, HAPG
Corinne Axelrod, Acting Deputy Director, Division of Ambulatory Services, HAPG