

Association for Molecular Pathology Education. Innovation & Improved Patient Care. Advocacy. 6120 Executive Blvd., Suite 700, Rockville, MD 20852 Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

February 28, 2019

Niles R. Rosen, M.D. Medical Director National Correct Coding Initiative Correct Coding Solutions LLC P.O. Box 907 Carmel, IN 46082-0907

Dear Dr. Rosen:

The Association for Molecular Pathology (AMP) welcomes the opportunity to comment on the revisions to the National Correct Coding Initiative (NCCI) policy manual that took effect on January 1. AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists and medical technologists who perform or are involved with clinical laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories and the in vitro diagnostics industry.

We are concerned about the revisions' potential negative impact on patient access to medically appropriate molecular testing. In Chapter 10, Section F of the NCCI manual (code set 8000-89999), there are several updates that are of significant concern to AMP membership (Section F.7-Section F.9) and run counter to current laboratory practice. These changes will be highly disruptive to molecular pathology laboratory practice coding and payment and were finalized without the opportunity for stakeholders to provide comment. Therefore, AMP recommends that these changes be withdrawn and that NCCI contractors (Correct Coding Solutions and Capitol Bridge, LLC) and the Centers for Medicare & Medicaid Services (CMS) consult with AMP and other relevant stakeholders to understand the effects of these changes.

Below we address each section in more detail. Due to the change in NCCI contractors and the resulting need to update them on our previous correspondence, we have attached previous letters to NCCI, which addressed specific procedure to procedure (PTP) edits to NCCI. The letters provide additional explanation why certain molecular codes are often billed together and how those practices reflect current medical practice.

## Section F.7

Section F.7. reads:

A Tier 1 or Tier 2 molecular pathology procedure CPT code shall not be reported with a genomic sequencing procedure, molecular multianalyte assay, multianalyte assay with algorithmic analysis, or proprietary laboratory analysis CPT code where the CPT code descriptor includes testing for the analyte described by the Tier 1 or Tier 2 molecular pathology code.

AMP strongly disagrees with this overly broad, limiting coding guidance for the molecular pathology CPT code set. This language will no longer allow for sequential testing algorithms where common variants are first tested

and then, only if negative, more comprehensive analysis may be performed. Depending on the clinical scenario, laboratories should be permitted to bill the single analyte codes and mulitanalyte codes when necessary.

## Section F.8

The revised language within Section F.8 is as follows:

If one laboratory procedure evaluates multiple genes utilizing a next generation sequencing procedure, the laboratory shall report only one unit of service of one genomic sequencing procedure, molecular multianalyte assay, multianalyte assay with algorithmic analysis, or proprietary laboratory analysis CPT code. If no CPT code accurately describes the procedure performed, the laboratory shall report CPT code 81479 (unlisted molecular pathology procedure) with one unit of service. The laboratory shall not report multiple individual CPT codes describing the component test results. If a single procedure is performed, only one HCPCS/CPT code with one unit of service may be reported for the procedure.

The broad policy instruction within this section runs counter to AMA CPT<sup>®</sup> codebook instruction that states the following for the "Genomic Sequencing Procedures and Other Molecular Multianalyte Assays" section:

When all of the components of the descriptor are not performed, use individual Tier 1 codes, Tier 2 codes, or 81479 (unlisted molecular pathology procedure).

This language is contradictory to what is stated within the Section F.8, which requires that only the unlisted molecular pathology procedure code be used. In many cases, it may be more appropriate and mandated by a specific Medicare Administrative Contractor (MAC) to bill codes specific to certain analytes. As a result of the language within Section F.8, laboratories and MACs will face significant and needless administrative burden.

## Section F.9

Section F.9 addresses procedure-to-procedure (PTP) edits, which prevent inappropriate payment of services that should not be reported together. The revised language states:

Procedure-to-procedure edits bundling two Tier 1 molecular pathology procedure CPT codes describe procedures that should not routinely be performed and reported together. For example CPT code 81292 describes full sequence gene analysis of MLH1, and CPT code 81294 describes duplication/deletion variant gene analysis of MLH1. In evaluating a patient with colon carcinoma (vs. constitutional genetic disorder), it may be appropriate to perform duplication/deletion testing if the disease variant(s) is (are) not identified by performing full gene sequencing. The same principle applies to other code pair combinations of testing for the same gene (e.g., 81295/81297, 81298/81300).

AMP expressed concern with similar revisions in a letter to NCCI dated June 5, 2018 that we still have today. The language within F.9 stating that these types of codes should not be reported together is incorrect and inconsistent with established medical practice. Full sequence analysis and duplication and deletion analysis procedures are distinct services, requiring separate protocols and analysis, but are commonly performed at the same time. In accordance with current medical practice, full gene sequencing and duplication/deletion codes for the same analyte are often used on the same patient on the same day to comprehensively assess changes in the order, number, organization, and irregular arrangements within a gene relevant to the patient's condition or disease.

AMP reiterates that these additions to the NCCI policy manual be withdrawn and request that NCCI contractors and CMS consult with AMP and other stakeholders to understand the effects of these changes. AMP looks forward to discussing this issue further with you. AMP is appreciative of your consideration of and attention to this matter. Please direct your correspondence to Tara Burke, AMP Senior Director of Public Policy and Advocacy, at <u>tburke@amp.org</u>.

Sincerely,

Victoria M. Pratt, PhD, FACMG

President, Association for Molecular Pathology