



ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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Marge Watchorn
Director, Division of Coding and Diagnosis Related Groups
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Delivered electronically to HCPCS@cms.hhs.gov

Re: AMP Comments on Agenda Item #41 – Next Generation Sequencing (IHC251030N8UFD)

Dear Ms. Watchorn:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to provide comments in response to revisions to the HCPCS Level II code set for non-drug and non-biological items and services. AMP appreciates CMS's engagement with stakeholders and submits the following comments regarding **Agenda Item #41, Next Generation Sequencing (NGS) – IHC251030N8UFD**.

AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical technologists who perform or are involved with 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 diagnostic industry. AMP has been heavily involved in CPT codes, working with CMS to help develop codes in the sphere of molecular pathology.

CMS has proposed the creation of two new HCPCS Level II modifiers intended to distinguish NGS testing performed for early-stage cancers (Stages I and II) from testing performed for advanced (Stages III and IV), recurrent, relapsed, refractory, or metastatic cancers. CMS indicates that these modifiers are intended to align claims submission with coverage criteria under National Coverage Determination (NCD) 90.2. While AMP recognizes CMS's objective to support accurate claims processing, we have significant concerns regarding the design, implementation, and unintended downstream consequences of these modifiers.

AMP is particularly concerned that the introduction of early- and late-stage modifiers will enable payers to impose unnecessary administrative burdens by shifting responsibility for stage-specific documentation onto laboratories. While laboratory professionals are integral members of the patient care team, they do not directly manage patients, determine staging, or control how treating physicians document clinical findings. Requiring laboratories, often external to the treating institution, to obtain and verify detailed staging information would be extremely

burdensome and operationally impractical. Such requirements risk delaying access to clinically actionable genomic information, which is essential for evidence-based treatment decisions, and often, when time is of the essence for many cancer patients.

AMP members routinely experience private payer requests for additional documentation that are duplicative, unreasonable, or unrelated to medical necessity. In many cases, payers disregard clinical information already provided through test requisition forms. The HHS Office of Inspector General has documented similar practices among Medicare Advantage Organizations, including requests for additional documentation that delay payment despite the presence of sufficient information to support coverage.¹ Though not intended as such, the creation of these modifiers risks providing payers with yet another mechanism to delay or deny reimbursement inappropriately. Due to the reasons stated above, AMP cautions the creation of these modifiers without further stakeholder input and feedback.

Specifically, AMP is concerned that they will be broadly adopted by private payers and used in ways that create unnecessary administrative barriers to patient care and application of these modifiers by laboratories is not possible. We agree that cancer stage is not readily identifiable through ICD-10 diagnosis codes alone. However, it is often clinically appropriate - and medically necessary - for NGS testing to be performed even when precise staging information is unavailable at the time of testing. Cancer staging is a complex, multimodal determination that integrates multiple data sources and may evolve over time. Laboratories routinely receive test orders before all staging elements are finalized, and unspecified ICD-10 codes are routinely used in these circumstances. Importantly, the absence of finalized staging information does not diminish the clinical value of genetic analysis for patient management in many circumstances. AMP is also concerned about the operational challenges laboratories will face in implementing these modifiers. Billing departments will require time to update systems, educate staff, and develop new workflows to obtain staging information that may not be readily available or clinically relevant at the time of testing. For these reasons, if CMS opts not to withdraw this proposal, AMP strongly urges CMS to, at a minimum, delay the effective date of the proposed modifiers to allow laboratories sufficient time to prepare and avoid disruptions to patient care.

Further, AMP is concerned that inclusion of Next Generation Sequencing within the description of the modifiers is repetitive and confusing. If the intention of these modifiers is to complement claims submission with coverage criteria under National Coverage Determination (NCD) 90.2, the specification of Next Generation Sequencing testing method in the modifier is unnecessary. If CMS continues to move forward with this modifier, AMP recommends removal of the next generation sequencing from the modifier description.

We are also concerned that these modifiers will be misinterpreted as applying to germline testing, in addition to somatic testing. In the summary of applicant submission in Agenda Item #41, CMS incorrectly stated that 90.2 does not cover early-stage cancers. While NCD 90.2 established the coverage criterion that a patient has “either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer” for *somatic* testing, the coverage criteria for germline testing do not restrict coverage based on the cancer stage. In addition to delaying the effective date, CMS should clarify that the use of the modifiers is only applicable to somatic

¹ <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp>

testing and not germline testing. Absent such clarification, laboratories and payers may incorrectly apply stage-based requirements in ways that conflict with existing coverage policy.

As an additional note, AMP joins other stakeholders in expressing interest in reopening NCD 90.2 to update its coverage to align with advancements in the field. Given that the NCD coverage criteria may change, these modifiers could be logistically challenging and unnecessary.

AMP appreciates CMS's consideration of these comments as it finalizes revisions to the HCPCS Level II code set. We would welcome the opportunity to discuss these issues further and provide additional technical or clinical insight as needed. Please contact Annie Scrimenti at Ascrimenti@amp.org with any questions.

Sincerely,

Jay Patel, MD
Chair of Economic Affairs Committee
Association for Molecular Pathology