May 29, 2012

Patrick Conway, M.D.
Chief Medical Officer
Director, Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mail Stop S3-02-01
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Dr. Conway:

The Advanced Medical Technology Association (“AdvaMed”) would like to bring to your attention a matter of concern among AdvaMed members. At least eight Medicare Administrative Contractors (MACs) have adopted (or are adopting) local coverage determinations (“LCDs”) relating to CPT Category III codes that automatically create non-coverage policies for items and services described by those codes.¹ We are concerned that this approach does not follow the current instructions to MACs to consider “particular” items or services, and may have the effect of restricting Medicare beneficiaries’ access to valuable technologies.

AdvaMed’s member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

The American Medical Association’s (AMA) CPT Editorial Panel establishes and maintains Category III CPT codes for tracking new procedures and services and to allow for additional data collection. The assignment of a Category III code to a device or procedure should not serve as the sole basis for non-coverage. In fact, on its website, the AMA describes categorical denial of payment for Category III codes as “not reasonable.”² Category III codes may describe

¹ See Centers for Medicare & Medicaid Services Medicare Coverage Database, http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx, Document IDs L31711 (Palmetto GBA); L25275 (NGS); L20194 (Pinnacle); L18917 (NHIC); L31686 (Highmark); L26811 (Trailblazer); L24473 (Noridian); and DL32569 (WPS).
procedures that have established peer-reviewed literature, specialty or subspecialty support or practice guidelines, and the procedures may be commonly used to treat Medicare beneficiaries. However, for a number of reasons, including low procedure volume or low incidence of the disease, a Category I code may not yet be warranted.

Local contractor policies that automatically non-cover Category III codes do not comport with the Social Security Act’s (the Act) definition of LCD\(^3\) or with CMS’ specific guidance to its contractors regarding the development of local coverage determinations.\(^4\) The Act defines an LCD as a determination regarding whether or not a particular item or service is covered as reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. CMS’ policies require contractors to base their LCDs on the strongest evidence available, including searches of published scientific literature and consideration of standard of practice in the medical community.

**Blanket non-coverage of Category III codes, whether by a categorical statement or by automatically listing all Category III codes in an LCD that non-covers them, is not appropriate.** MACs have the discretion to individually review new services and procedures and to make coverage decisions regarding specific services and procedures.

We recognize that these policies were promulgated by, and fall within the purview of, the various local MACs. However, because there appears to be a pattern across multiple contractors, we ask that CMS central office undertake a review of the approach used by the various MACs in developing Category III LCD policies. Some of the current MAC policies contain language clarifying that while the contractor may consider an item or service described by a CPT Category III code to not be reasonable and necessary, the contractor may reserve the right to review the available evidence and make a determination of local coverage.\(^5\) Other policies direct interested parties that disagree with any aspect of an LCD for non-covered services to use the MAC’s reconsideration process and provide relevant documentation or evidence that supports coverage to the contractor.\(^6\)

**Recommendations:**

Based on the existence of multiple LCDs across multiple contractors that non-cover Category III CPT codes, and the variation in instructions regarding the process for appealing non-coverage of a specific code affected by these policies, AdvaMed recommends that CMS instruct all of its contractors to include clarifying language in LCDs for non-covered Category III CPT codes stating that the MACs have the discretion to review the available evidence and provide coverage.

\(^3\) See Social Security Act (SSA) §1869(f)(2)(B).

\(^4\) See Medicare Program Integrity Manual, Publication 100-08, Chapter 13, Section 13.7.1 “LCD Development Process: Evidence Supporting LCDs.”

\(^5\) See, e.g., Highmark Medicare Services, Inc., LCD L31686, “Services That Are Not Reasonable and Necessary.”

\(^6\) See, e.g., Noridian Administrative Services, LCD L24473, “Local Coverage Determination (LCD) for Non-Covered Services.”
for Medicare beneficiaries with respect to specific Category III codes. Additionally, CMS should instruct contractors that they must follow LCD processes (i.e., public posting, opportunity for comment) when issuing an LCD to non-cover an item or service described by a Category III code.

We appreciate your consideration of our recommendation and would be happy to discuss this issue with you in more detail. Please contact Chandra Branham on my staff at cbranham@AdvaMed.org or (202) 434-7219 if you have any additional questions. Thank you for your attention to this matter. We look forward to hearing from you.

Sincerely,

[Signature]
Ann-Marie Lynch
Executive Vice President, Payment and Health Care Delivery Policy

cc: Louis Jacques, M.D.
Tamara Syrek-Jensen, J.D.