CMS Issues New Instructions on PET Coverage

The Centers for Medicare & Medicaid Services (CMS) on February 6 released 2 sets of instructions related to coverage with evidence development (CED) requirements for ^{18}F-FDG PET in solid tumors and for amyloid-β PET imaging in dementia and neurodegenerative disease.

Claims Processing and ^{18}F-FDG PET in Solid Tumors

In the first announcement, CMS released instructions to Medicare administrative contractors for processing of claims pursuant to the June 11, 2013, final decision to end CED requirements for certain ^{18}F-FDG PET studies in solid tumors. These transmittals instructed contractors to cover a single PET scan for initial antitumor treatment strategies (designated by appending the "PI" modifier with the claim) and to cover 3 scans when used to guide subsequent antitumor treatment strategy (designated by appending the "PS" modifier) after completion of initial anticancer therapy for the same cancer diagnosis. Counting in contractor systems begins on July 1, 2014; contractors are not required to search their past files. However, contractors who become aware of past ^{18}F-FDG PET studies for the same cancer diagnosis, such as via the appeal process, are allowed to count earlier studies dating back to June 11, 2013. The count begins again for any ^{18}F-FDG PET scans related to a different cancer diagnosis.

Providers who perform more than a single initial treatment strategy PET or more than 3 subsequent treatment strategy PET studies for the same cancer indication should ensure that these studies are medically necessary and are not being performed for screening (surveillance). For medically necessary, nonscreening studies, providers must append a "KX" modifier, in addition to all other appropriate modifiers. The KX modifier will bypass contractor edits and allow the claim to be paid. However, providers should consider having a patient sign an Advanced Beneficiary Notice of Noncoverage (ABN) when more than 3 subsequent treatment strategy ^{18}F-FDG PET studies have been performed, because payment for such studies will be at contractor discretion. Only limited information is currently available as to which clinical circumstances contractors will consider to be medically necessary and which claims will be paid. Claims should include a "GA" modifier when an ABN has been signed and a "GZ" modifier when no ABN is on file.

Because CED for certain ^{18}F-FDG PET studies of solid tumors ended for claims with dates of service on or after June 11, 2013, CMS has officially removed the requirement for the provider to append a "Q0" modifier to any ^{18}F-FDG PET claims.

Providers will know when they have exceeded the limit on scans, because the claim rejection will identify such claims lacking a KX modifier with remark codes CARC 96, RARC N435, MSN 23.17, Group Code PR, or CO. Appending the KX modifier documents that a scan performed beyond the limit is considered by the provider to be medically necessary. Providers must maintain adequate documentation of medical necessity of such scans, because they may be asked to provide documentation in a postpayment review by the Medicare contractor.

The CMS transmittal also noted that "contractors shall deny subsequent treatment strategy (PS) claims for oncologic FDG PET scans when no initial treatment strategy (PI) claim is present in history," when appropriate. Prostate cancer is an exception, because ^{18}F-FDG PET is not covered for initial treatment strategy in prostate cancer. The transmittal also stated that, to avoid nonpayment of appropriate subsequent treatment strategy claims for which the initial treatment strategy scan may have been provided before June 11, 2013, or prior to the patient's enrollment as a Medicare beneficiary, contractors should not reject PS claims. In its summary overview of the CMS transmittal, SNMMI Government Relations staff noted "concerns regarding this mixed language and regarding contractor implementation." These concerns were communicated to CMS and several contractors. The SNMMI overview pointed out that the wording "when appropriate" may allow contractors to pay a claim when no PI is present in history and that providers may have to supply documentation to support the rationale and append the KX modifier to bypass edits in place. SNMMI will provide updates on its website as more information on this issue becomes available from CMS or the contractors. The CMS announcements are available at www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2873CP.pdf and www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R162NCD.pdf. The CMS Medicare Learning Network also offers a summary at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8468.pdf.

Instructions on NCD for β-Amyloid PET

CMS announced in 2013 that, after consideration, evidence was insufficient to conclude that the use of PET amyloid-β imaging improves health outcomes for Medicare beneficiaries with dementia or neurodegenerative disease. However, CMS indicated that sufficient evidence is available to suggest that PET amyloid-β imaging could be promising in certain scenarios. The result is that CMS will only allow coverage for PET amyloid-β imaging (a single PET scan per patient) to: (1) develop better treatments or prevention strategies for Alzheimer disease (AD) or as a strategy to identify subpopulations at risk for developing AD; or (2) resolve clinically difficult differential diagnoses (e.g., to differentiate frontotemporal dementia from AD) in which the use of PET amyloid-β imaging appears to improve health outcomes. In both cases, patients must be enrolled in an approved clinical study under CED. Instructions released to contractors on February 6 addressed

the use of PET amyloid-β under CED. Several groups, including SNMMI, warned that it is important to note that these billing instructions are not currently relevant, because no CMS-approved CED programs for such studies are in place.

SNMMI, along with the Alzheimer's Association, reported active work toward developing a registry for CMS approval. Such efforts often take months to approve and implement. SNMMI will provide additional updates on its website. The February 6 CMS transmittal is available at www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R160NCD.pdf. The CMS Medicare Learning Network also offers a summary at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8526.pdf.

House of Delegates Votes for Task Force on SNMMI Governance

At the Mid-Winter Meeting in Palms Springs, CA, in February, the House of Delegates (HOD) discussed issues regarding the governance of SNMMI, including the role and function of the HOD and the makeup of the Board of Directors (BOD).

Concerns expressed were that the society bylaws give the HOD a very small role in governance, mainly to make recommendations to the BOD. The BOD, although made up of dedicated individuals, is not truly representative of the society as a whole. Most members of the BOD are academicians and technologists. Many segments of the SNMMI were felt to be underrepresented. Concern was expressed that the BOD needs to hear from all segments of the society, which is made up of diverse individuals with different expertise and perspectives. This interaction of all segments of the society is what has made nuclear medicine great. In addition, it was of concern that the chairs of 3 of 5 of the important committees overseen by the HOD (Committee on Chapters and Centers, Committee on Councils, and Nominations Committee) are not selected by the committees or the HOD.

After discussion of these and other issues, the HOD voted to "establish an HOD task force to examine the state of the SNMMI governance, including the role of the HOD and membership representation on the BOD."

Harvey A. Ziessman, MD
Speaker of the House of Delegates