Developing Evidence-Based Appropriate Use Criteria under the Protecting Access to Medicare Act of 2014

Hossein Jadvar, MD, PhD, MPH, MBA, SNMMI President

On March 31, 2014, Congress passed the Protecting Access to Medicare Act of 2014 (PAMA), which tied advanced diagnostics imaging services/physician reimbursement to appropriate use criteria (AUC). Advanced diagnostic imaging services (ADIS) are defined as diagnostic MR imaging, CT, nuclear medicine (including PET), and other diagnostic imaging services specified by the Secretary of the U.S. Department of Health and Human Services (HHS) in consultation with physician specialty organizations and other stakeholders.

Under the new law, a program will be launched by January 2017 that requires the use of AUC for ADIS. Referring physicians will have to consult AUC via a clinical decision support tool, prior to ordering ADIS, for help in determining whether an exam is clinically appropriate for each patient's condition. According to the PAMA legislation, AUC can be created or endorsed only by national medical specialty societies or other provider-led entities. By November 15, 2015, in consultation with various stakeholders, the Secretary of HHS was required to provide a list of 'approved' or 'deemed' AUC to be included in the program. The Centers for Medicare & Medicaid Services (CMS) provided additional guidance on the process of developing AUC and defining 'provider-led entities' in the proposed 2015 Medicare Physician Fee Schedule (MPFS) rules released in July. The final 2015 MPFS rules will be published in November.

Based on the CMS data on high-volume nuclear medicine procedures and lack of existing evidence-based AUCs, the SNMMI Guidance Oversight Committee (GOC) has recommended the following topics for research and AUC development this year: bone scintigraphy in malignant disease, ventilation/perfusion imaging in pulmonary embolism, ^{18}F-FDG PET in restaging of malignancy, and hepatobiliary scintigraphy in abdominal pain. AUC have been developed by other medical societies on these 4 topics; however, they are not entirely evidence-based or have put nuclear medicine at a disadvantage when reviewed objectively.

For example, the existing AUC for bone scintigraphy in malignant disease, developed by another medical society, does not address SPECT/CT as an imaging modality, although it has demonstrated superior diagnostic performance over both planar bone scan and CT. It also fails to mention ^{18}F-NaF PET, which demonstrates high sensitivity and specificity. Similarly, an existing AUC applicable to ventilation/perfusion scans fails to provide the implications of radiation dosimetry in nonpregnant premenopausal women, and the arbitrary scale of radiation symbols provides misleading or incomplete information. In several other examples, nuclear medicine procedures are ranked lower or inappropriate when the published literature provides evidence to the contrary.

Hossein Jadvar, MD, PhD, MPH, MBA

SNMMI is moving away from the current process of developing consensus-based clinical guidelines and instead focusing on developing evidence-based criteria. In an effort to create multidisciplinary, evidence-based guidelines, SNMMI is collaborating with a number of medical societies and has also contracted with Avalere, an industry leader in the field of health care policy, to assist with the methodology of the AUC development process. In addition, the society has contracted with Oregon Health Sciences University's Evidence Practice Center to conduct an objective systematic review of the existing literature. The 4 workgroups have identified draft clinical indications for the respective AUC. Based upon the systematic review of literature and strength of evidence, these indications will be voted upon and finalized. The final AUC document will then be drafted by the appropriate subject matter experts in the workgroups and peer reviewed within SNMMI, as well as externally by other stakeholders.

SNMMI leadership will continue to support the development of additional AUC for high-volume/high-growth-potential nuclear medicine procedures for the foreseeable future. In addition to the development of the 4 AUC currently underway, the SNMMI GOC is finalizing further topic areas for next year. Topics identified so far include lymphoscintigraphy, myocardial perfusion imaging, infection imaging, radioiodine treatment for thyroid diseases, and gastrointestinal transit studies.

For more information regarding the AUC development and approval process, contact the SNMMI Evidence and Quality Department at SMO-Quality@snmmi.onmicrosoft.com.