

Deadlines for Appropriate Use Criteria Loom; Resolutions Remain Unclear

As the first of several deadlines associated with new Centers for Medicare & Medicaid Services (CMS) Appropriate Use Criteria (AUC) approaches in 2015, physicians and professional groups are voicing concerns about the ways in which these criteria will be developed, validated, accepted by CMS, and revised over the long term. “This is a very real concern for the nuclear medicine community,” said Alan Maurer, MD, cochair of the Evidence Development Working Group of the SNMMI Industry Forum. “Many key issues relative to implementation of AUC in clinical decision support remain unresolved even as we rapidly approach the dates on which CMS has indicated that it will make choices with the potential to affect the daily practice of nuclear medicine well into the future.”

AUC: Past, Present, and Future

AUC are statements that contain indications describing when and how often a procedure should be performed and are created by experts with consideration of scientific evidence, clinical judgment, and patient values, as well as the avoidance of unnecessary procedures and services. AUC are a natural “practice quality metric” outgrowth of the consensus clinical practice guidelines created for many years by professional societies. SNMMI has been active in developing AUC, notably for β -amyloid PET imaging and for cardiac radionuclide imaging, often in close collaboration with other medical specialty societies.

The passage of the Protecting Access to Medicare Act (PAMA; H.R. 4302) in March 2014 radically changed expectations about AUC and the ways in which CMS would incorporate these into requirements for advanced imaging reimbursement. Although intended to serve as the annual “patch” to forestall physician reimbursement cuts required by the Medicare Sustainable Growth Rate mechanism, PAMA also contained legislation tying advanced diagnostic imaging services (ADIS) and physician reimbursement to AUC. ADIS are defined as diagnostic MR, CT, nuclear medicine (including PET), and other diagnostic imaging services specified by the Secretary of Health and Human Services (HHS) in consultation with physician specialty organizations and other stakeholders.

The new law directed the HHS Secretary to launch by January 1, 2017, a program that promotes the use of AUC for ADIS. Ordering professionals will be required to consult AUC via a clinical decision support tool prior to ordering any ADIS. The purpose of this consultation will be to determine and verify whether an imaging procedure is appropriate for a specific clinical condition for an individual. PAMA indicated that AUC should “to the extent feasible” be evidence based and can only be created or endorsed by national professional medical specialty societies or other “provider-led entities” such as physician

groups (wording specifically intended to exclude insurers, patient advocacy groups, and other nonprofessional entities). The legislation specified that no later than November 15, 2015, the HHS Secretary should identify applicable AUC that will be ‘deemed’ (allowed) in the program. The secretary was directed to take into account whether each appropriate use criterion: (1) has “stakeholder consensus”; (2) is scientifically valid and evidence based; and (3) is based on studies that are published and reviewable by stakeholders. In addition, the Secretary was directed to perform annual reviews of AUC to determine the need for updates or revisions and, in cases of multiple AUC relative to a single imaging service, “to apply 1 or more applicable AUC...for this service.” The legislation went on to describe the qualified decision support mechanisms that would serve as vehicles for communication of AUC to practitioners.

“The integration of AUC into quality practice requirements by CMS was well intentioned and widely supported by physicians and their representative professional groups,” said Maurer. “The problem was and remains a lack of clarity in how these AUC will be generated, in what ways ‘evidence based’ approaches will be interpreted and valued, what will happen when AUC devised by different groups conflict, and, ultimately, how use of AUC will fit into routine patient care activities.”

SNMMI Action on AUC

In a letter sent on April 8 to CMS by SNMMI CEO Virginia Pappas, the society urged better definition of the term “evidence based” and clarification of the ways in which new AUC will be developed and/or updated, expressing additional concerns about potential conflicts when an appropriate use criterion for a specific imaging modality is “developed by 2 separate medical specialty societies that use separate processes and ‘evidence based’ criteria.” The society also requested clarification on whether approved clinical decision support mechanisms will incorporate all “deemed” or approved AUC regardless of copyright issues.

The request came at a time when SNMMI was accelerating its AUC-related activities in response to the PAMA legislation. The society had already established a new department of Evidence and Quality and a Guidance Oversight Committee (GOC) in late 2013, with several short-term goals, including the creation of clinical guidance documents like AUC. To identify topic areas for AUC the GOC in 2014 prioritized the highest-volume nuclear medicine procedures based on CMS data and conducted an environmental scan of existing clinical guidelines and AUC developed by other organizations. The committee prepared a list of those high-volume nuclear medicine procedures in which nuclear medicine is at a disadvantage and/or AUC are not evidence based. The GOC recommended the following topics for SNMMI

research and AUC development: bone scintigraphy in malignant disease, ventilation/perfusion imaging in pulmonary embolism, hepatobiliary scintigraphy in abdominal pain, and ^{18}F -FDG PET for restaging malignant disease.

The GOC committee then formed 4 AUC working groups to focus on these topics. To create multidisciplinary, evidence-based guidelines, the SNMMI reached out to other specialty societies, including the American Society for Clinical Oncology, American Society for Radiation Oncology, American College of Hematology, American Urological Association, American College of Emergency Physicians, Society of Thoracic Surgeons, American Gastroenterological Association, Society of Pediatric Radiology, European Association for Nuclear Medicine, Canadian Association for Nuclear Medicine, and American College of Nuclear Medicine, to participate in AUC development. The society also contracted with Avalere, a health care policy consultant company, to assist with the AUC development process. In addition, the society is in the process of finalizing a contract with an Agency for Healthcare Research and Quality–designated Evidence Practice Center to conduct systematic reviews and develop evidence profiles that will form the basis of AUC development and final recommendations. The anticipated completion date for the 4 AUC is September 30, 2015. Once developed and accepted in the National Guidelines Clearinghouse, a 5-year window for revisions and update is allowed.

AUC development is a time-consuming and costly endeavor. Following the Institute of Medicine criteria for developing validated guidelines can require from 6 to 12 months and cost as much as \$125,000 for each appropriate use criterion.

Key Questions Remain

“Given the effort, cost, and professional time and expertise needed to develop AUCs—and the very crucial role

these will play in our practices—it’s vitally important that key questions be answered as we move toward CMS deadlines,” said Maurer. “The question of what forms the approved clinical decision support mechanisms and tools will take remains entirely unclear. The status of existing AUC that pertain to nuclear medicine but have not been vetted or approved by the nuclear medicine community also remains unresolved.”

Among the questions that Maurer and SNMMI leadership and staff cited as unresolved are: Does CMS have the authority to phase in the program, and, if so, which ADIS will be affected first? Does CMS have a well-codified position on resolution when 2 AUC on the same procedure disagree—and, in such cases, will only 1 apply? What criteria will CMS use in determining the need for annual reviews or updates? How will societies disseminate such updates? The questions related to clinical decision support mechanisms are even more wide ranging: What criteria should CMS use to provide a free clinical decision support mechanism to smaller societies? How will this clinical decision support mechanism be implemented? How will it be incorporated into electronic medical records? Will all approved clinical decision support mechanisms incorporate all ‘deemed’ AUCs?

“The November 15 deadline for HHS to ‘deem’ or approve AUC is only 5 months away, and both clarification and resolution of our concerns as a profession are urgently needed,” said Maurer. “It is important that the nuclear medicine and molecular imaging community support SNMMI efforts to secure clarification from CMS on these and other issues related to AUC implementation. Without clear answers and a unified response, implementation of AUC may radically affect the ways in which physicians are able to order our imaging studies in the very near future.”

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Biology and the Chinese Society of Nuclear Medicine on educational initiatives. SNMMI also collaborated with the American College of Radiology on a task force that developed a joint credentialing and privileges statement for PET/MR for brain imaging; head and neck scanning will be the next area for consideration.

SNMMI has moved this year to strengthen its long-time relationship with the Education and Research Foundation for Nuclear Medicine and Molecular Imaging (ERF). We are collaborative partners committed to improving patient care through nuclear medicine and molecular imaging. SNMMI

is very grateful to ERF for its generous support of our grants and awards program.

SNMMI held its second annual Future Leaders Academy in January during the Mid-Winter Meeting. The goal for participants was to develop skills and organizational expertise and ultimately become leaders within SNMMI and nuclear medicine in general.

As I turn the leadership of SNMMI over to Dr. Hossein Jadvar, I am encouraged by all the advances in our field and within SNMMI. I wish Dr. Jadvar all the best. He has an exciting year ahead!