SNMMI Begins Release of AUC for High-Value Nuclear Medicine Procedures

This month Newsline includes a summary and excerpts from the SNMMI *Appropriate Use Criteria (AUC) for Bone Scintigraphy in Prostate and Breast Cancer*, released in March. This is the first in a series of new AUC developed by SNMMI in its role as a qualified provider-led entity (PLE) under the Medicare Appropriate Use Criteria program for advanced diagnostic imaging. These AUC are intended to assist referring physicians and ordering professionals to fulfill the requirements of the 2014 Protecting Access to Medicare Act (PAMA).

Section 218(b) of PAMA established a new program under the statute for fee-for-service Medicare to promote the use of AUC for advanced diagnostic imaging services, including CT and MR imaging and all nuclear medicine procedures, including PET. The Centers for Medicare & Medicaid Services (CMS) published the first of the 4 components of this program in the CY 2016 Physician Fee Schedule final rule, focusing on requiring an evidence-based and transparent process for developing AUC. AUC under this program may be developed only by qualified PLEs. PAMA requires referring physicians to consult AUC developed by a PLE to ensure cost-effective and appropriate utilization of advanced diagnostic imaging services. Final implementation of the program has been delayed until 2018, in part so that CMS can issue more substantive guidance on required clinical decision support tools to be used in ordering imaging services. In a statement issued in July 2016, CMS noted that the agency is focusing on "proposals for priority clinical areas, clinical decision support mechanism (CDSM) requirements, the CDSM application process, and exceptions for ordering professionals for whom consultation with AUC would pose a significant hardship." CMS also confirmed that the third component of the program (when ordering professionals must begin consulting CDSMs and furnishing professionals must append AUC-related information to the Medicare claim) will not begin earlier than January 1, 2018.

To provide a comprehensive library of AUC for the most common nuclear medicine procedures, the SNMMI Guidance Oversight Committee (GOC) identified several high-priority areas for AUC development and release in 2017, including: bone scintigraphy for prostate and breast cancer, ventilation/perfusion imaging in pulmonary embolism, hepatobiliary scintigraphy in abdominal pain, and ^{18}F-FDG PET restaging of malignant disease. An additional 6 topics have been identified for near-term AUC development: gastrointestinal transit, infection imaging, PET myocardial perfusion imaging, prostate cancer imaging, somatostatin imaging, and thyroid imaging and therapy.

The process for SNMMI AUC development was modeled after the RAND/University of California at Los Angeles Appropriateness Method and includes a systematic review of evidence followed by development of AUC for various clinical scenarios using a modified Delphi process. This process is also consistent with the Institute of Medicine's standards for developing trustworthy clinical guidance. The process includes identification of relevant clinical scenarios, a systematic synthesis of available evidence, individual and group ratings of the scenarios using a formal consensus process, and document drafting based on final group ratings and discussions. The GOC has set a goal of developing 4–5 AUC each year for the next several years.

Each expert workgroup selected to develop an SNMMI AUC has a minimum of 7 members, including (in addition to nuclear medicine subject matter experts) a primary care practitioner, an expert in clinical trial design, and an expert in statistical analyses. Other stakeholders, including patient representatives, industry experts, and members of other medical specialties are also consulted.

SNMMI has contracted with an outside organization to conduct independent and objective systematic reviews of relevant evidence to inform the AUC workgroups. The primary purpose of these systematic reviews is to assess the diagnostic accuracy and comparative effectiveness of selected nuclear medicine procedures in clinical decision making and clinical outcomes. These reviews include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. Key research questions are formulated for each topic to guide the systematic reviews, with inclusion and exclusion criteria based on study parameters established by the expert workgroup using the PICOTS (Population, Intervention, Comparisons, Outcomes, Timing, and Setting) approach. The strength of overall evidence is graded as high, moderate, low, or very low based on quality of evidence, consistency, directness, precision, and reporting bias. Working with a series of clinical scenarios representing those most likely to be encountered in practice, the workgroups score use of specific procedures as appropriate, maybe appropriate, and rarely appropriate. These scenarios and resulting summary tables are included in each complete AUC.

The GOC will conduct annual reviews of all AUC developed by SNMMI, evaluating the most recent medical literature to ensure that the AUC reflect current evidence. SNMMI is committed to the transparency of this process, and all AUC will be available to the general public and posted on the SNMMI website at http://www.snmmi.org/auc. New AUC will be published in Newsline and/or as complete articles in other sections of *The Journal of Nuclear Medicine.*