Appropriate Use Criteria for Advanced Diagnostic Imaging Services

MPFS Final Rule CY 2016

Background:

In Section 218 of the Protecting Access to Medicare Act of 2014 (PAMA), Congress required that providers that order advanced diagnostic imaging services consult with appropriate use criteria (AUC) via a clinical decision support mechanism by 2017. CMS was directed to establish such appropriate use criteria from among those developed or endorsed by national medical professional specialty societies and other provider-led entities.

MPFS Final Rule 2016:

With regard to the timeline for the "Medicare AUC Program", CMS indicated that it would not be able to implement the program at the beginning of 2017 given the tight timeframe and number of steps involved.

It is important to note that CMS is only postponing the provider implementation deadline, not the program altogether. CMS is continuing to implement the program through a "step wise" process. This year's rule finalized the AUC approval process, while CY 2017 and 2018 rules will finalize the additional components of the program.

The CY 2016 MPFS Final Rule establishes which organizations are eligible to develop, modify or endorse appropriate use criteria, the evidence-based requirements for appropriate use criteria development, and the process CMS will follow for qualifying Provider-Led Entities.

CMS finalized most aspects of the proposed rule provisions regarding AUC with some modest revisions (see our summary of the proposed rule on this website). CMS finalized a majority of the definitions as they were proposed. However, based on public comment, CMS changed the definitions of AUC, provider-led entity (PLE), and priority clinical area.

Definition of AUC: CMS revised the last two sentences of the definition in response to public comments that expressed confusion regarding the AUC terminology used in the proposed rule. In the final rule, an "AUC Set" is defined as a collection of individual appropriate use criteria. An individual "criterion" is information presented in a manner that links: a specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service.

Definition of Provider-Led Entity (PLE): In the proposed rule, CMS defined a provider-led entity as one that would include national professional societies (for example ACR and AAFP) or an organization that is

comprised primarily of providers and is actively engaged in the practice and delivery of healthcare (for example hospitals and health systems).

CMS modified the proposed definition of PLE in the final rule to focus on the practitioners and providers that comprise an organization and not on whether the organization, as an entity, delivers care. This includes national professional medical specialty societies, as well as alliances and collaboratives of hospitals and hospital systems and other organizations like the National Comprehensive Cancer Network (NCCN). This approach subsumes national professional medical specialty societies whose members are actively engaged in delivering care in the community and eliminates the need to establish a separate definition for national professional medical specialty societies as they are now an example of a PLE.

Definition of Priority Clinical Areas: CMS proposed to define priority clinical area as clinical topics, clinical topics and imaging modalities, or imaging modalities identified by CMS through annual rulemaking and in consultation with stakeholders which may be used in the determination of outlier ordering professionals. In the final rule, CMS changed the language to better describe the breadth of clinical areas that may be the focus of priority clinical areas. The finalized definition better reflects that priority clinical areas may identify clinical conditions, diseases or symptom complexes and their associated advanced diagnostic imaging services.

CMS will solicit public comment and finalize clinical priority areas through the PFS rulemaking process beginning in CY 2017

AUC Development by Provider-Led Entities: PLEs must demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. CMS provided clarification around what is expected for a systematic literature review and changed the requirements for the autonomous multidisciplinary team that must be used in the AUC development process from a minimum of three members to a minimum of seven members. They also added more granular requirements regarding the expertise that the members of the multidisciplinary team must possess.

Process for Provider-Led Entities to Become Qualified to Develop, Endorse or Modify AUC: PLEs must submit an application to CMS for review that documents adherence to each of the AUC development requirements. CMS reiterated that there will be no "form" for the application but did not elaborate on the process. It did adhere to a January 1st annual deadline for applications and changed the time for re-application from six years to five.

Identifying Priority Clinical Areas: To identify priority clinical areas, CMS may consider incidence and prevalence of diseases, as well as the volume, variability of utilization, and strength of evidence for imaging services. CMS may also consider applicability of the clinical area to a variety of care settings, and to the Medicare population. CMS will solicit public comment and finalize clinical priority areas through the PFS rulemaking process beginning in CY 2017.

Identification of Non-Evidence Based AUC: CMS will not limit review to AUCs that correspond to priority clinical areas in order to broaden the scope of which potentially non-evidence-based AUC may be reviewed by the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). CMS may also independently identify AUC of concern.