Protecting Access to Medicare Act of 2014
Clinical Decision Support (CDS)/Appropriate Use Criteria (AUC)

Background and Frequently Asked Questions

Background[i]

Section 218(b) of the Protecting Access to Medicare Act of 2014 directed the Centers for Medicare and Medicaid Services (CMS) to establish a program to promote consultation of appropriate use criteria (AUC) by ordering physicians prior to referring Medicare beneficiaries for advanced diagnostic imaging services beginning on January 1, 2017. AUC are defined as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decisions for a specific clinical condition.

While the statutory language mandated an effective date of January 1, 2017, the timing of the rulemaking process used by CMS made it extremely difficult to achieve this implementation date. In the 2017 Medicare Physician Fee Schedule (MPFS) final rule, CMS indicated that they continue to aggressively move forward to implement this AUC program and that the first qualified clinical decision support mechanisms (CDSMs) will be announced on June 30, 2017. The Agency expects that furnishing professionals will be required to begin reporting AUC consultation on January 1, 2018.

Definitions[ii]

Applicable imaging service means an advanced diagnostic imaging service (i.e. CT, MR and nuclear medicine, including PET) for which the Secretary determines (i) One or more applicable appropriate use criteria apply; (ii) There are one or more qualified clinical decision support mechanisms listed; and (iii) One or more of such mechanisms is available free of charge. X-ray, ultrasound, mammography, and fluoroscopy are explicitly excluded from the mandate.

Applicable payment system means the physician fee schedule, the hospital outpatient prospective payment system and the ambulatory surgical center payment system.

Applicable setting means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. Settings that are explicitly exempt from the policy are outlined in the below frequently asked questions.

Appropriate use criteria (AUC) means criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria must be

evidence-based. An AUC set is 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(s).

Clinical decision support mechanism (CDSM) means the following: an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified electronic health record (EHR) technology or private sector mechanisms independent from certified EHR technology or established by the Secretary. While the statutory language initially established an April 1, 2016 deadline, CMS, in subsequent regulations, indicated that it will publish a list of qualified CDSMs on June 30, 2017.

Furnishing professional means a physician or a practitioner who furnishes an applicable imaging service.

Ordering professional means a physician or a practitioner who orders an applicable imaging service.

Priority clinical areas means clinical conditions, diseases or symptom complexes and associated advanced diagnostic imaging services identified by CMS through annual rulemaking and in consultation with stakeholders which may be used in the determination of outlier ordering professionals. This concept was not included in the statutory language.

Provider-led entity (PLE) means a national professional medical specialty society or other organization that is comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care.

Specified applicable appropriate use criteria means any individual appropriate use criterion or AUC set developed, modified or endorsed by a qualified PLE.

Qualified provider-led entity*:* To be qualified by CMS, a PLE must adhere to the evidence-based processes described in the 2016 MPFS Final Rule when developing or modifying AUC. A qualified PLE may develop AUC, modify AUC developed by another qualified PLE, or endorse AUC developed by other qualified PLEs. CMS published the list of qualified PLEs on June 30, 2016.

Frequently Asked Questions

When will this mandate go into effect?

While the statutory language mandated an effective date of January 1, 2017, the timing of the rulemaking process used by CMS made it impossible to achieve this implementation date. In the 2017 MPFS final rule, CMS indicated that they continue to aggressively move forward to implement this AUC program and that the first qualified clinical decision support mechanisms (CDSMs) will be announced on June 30, 2017. The Agency expects that furnishing professionals will be required to begin reporting AUC consultation on January 1, 2018.

That said, CMS also indicated in the CY2017 final rule that there will be further rulemaking for calendar year (CY) 2018 issued and completed in 2017. The Agency announced the 2018 implementation date because they expect physicians and other stakeholders to prepare themselves to begin reporting as early as January 1, 2018. Specific claims processing instructions will be discussed in the CY 2018 rulemaking, with the proposed rule, subject to comment, expected to be published in early July.

What should I be doing to prepare?

The ACR recommends that radiologists communicate with their referring physicians to ensure that they are aware of the forthcoming mandate. Referring physicians should become familiar with the available CDS options; however, CMS will not announce the list of qualified decision support mechanisms (software) until June 30, 2017. ACR Select is one of the currently available options, including a free online portal.

The ACR also encourages providers to participate in the Radiology Support, Communication and Alignment Network (R-SCAN), a collaborative action plan that brings radiologists and referring clinicians together to improve imaging appropriateness through the use of CDS. There is no cost to participate in this program. R-SCAN also has been approved by CMS as an improvement activity under the Merit-based Incentive Payment System.

Will AUC consultation be required for all advanced diagnostic imaging or just the priority clinical areas?

The PAMA legislation mandates that AUC be consulted for all advanced diagnostic imaging services. CMS stated in the 2017 MPFS final rule that they do not have statutory authority to limit the consultation requirement to priority clinical areas. PAMA requires that ordering physicians must consult AUC prior to referring Medicare beneficiaries for any advanced diagnostic imaging services.

What is the purpose of the priority clinical areas and what are they?

The statute requires the identification of outlier ordering professionals, who will be subject to a prior authorization requirement beginning on January 1, 2020. The list of priority clinical areas will serve as the basis for identifying outlier ordering professionals.

The final list of priority clinical areas includes the following clinical conditions:

- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and non-traumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury)
- Cancer of the lung (primary or metastatic, suspected or diagnosed)

- Cervical or neck pain

Future MPFS rules are expected to provide further clarity behind the concept of "prior authorization."

Are Emergency Departments exempt from the AUC requirement and are there any other exemptions?

Consulting and reporting requirements are not required for orders for applicable imaging services made by ordering professionals under the following circumstances:

- Emergency services when provided to individuals with emergency medical conditions as defined in section 1867(e)(1) of the Act.
- For an inpatient and for which payment is made under Medicare Part A.
- Ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year.

The CY 2017 MPFS Final Rule addresses the emergency medical condition exemption. CMS indicates while they acknowledge that most of these exempt emergent situations will occur primarily in the emergency department, these situations may arise in other settings as well. Further, they recognize that most encounters in the ED are NOT for an emergency medical condition. The rule states, "To meet the exception for an emergency medical condition, the clinician only needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: placing the health of the individual (or a woman's unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part." In the 2018 rulemaking cycle, CMS will detail how this exception will be indicated on the Medicare claim.

When will CMS provide claims processing instructions to providers?

CMS will provide details on the claims processing instructions in the CY 2018 rulemaking process. The proposed rule is expected to be published in late June or early July 2017, with the final rule published in late October/early November.

Where can I find additional information?

Changes to the AUC program can be monitored through the CMS website. Please also monitor the ACR's website, specifically the Advocacy in Action eNews, where additional information will be published as we receive additional information.

If you have additional questions, please contact Katie Keysor at kkeysor@acr.org.

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[i] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program/index.html

[ii] https://www.ecfr.gov/cgi-bin/text-idx?SID=63d8f5754203d441fccc5582cd0cab13&mc=true&node=se42.3.414_194&rgn=div8