

Appropriate Use Criteria for Advanced Diagnostic Imaging Services Requirements

March 2017

Key Takeaways:

1. New requirements call for clinicians ordering advanced imaging studies to use clinical decision software (CDS) when placing orders.
2. The Centers for Medicare and Medicaid Services (CMS) is late to operationalize the requirements on how this will work.
3. CMS envisions that a number generated as part of the use of the CDS will need to be placed on a healthcare claim by the clinician furnishing the service.
4. The deadline for clinicians to consult an approved CDS has been delayed to January 1, 2018.
5. A list of CDS systems that have been approved for use will be posted to the CMS website by June 30, 2017.

WHAT are the requirements?

Background

New requirements call for clinicians to employ “**appropriate use**” **criteria (AUC)** when ordering **advanced imaging studies**. The requirement is being put into place to address inappropriate uses of imaging and overuse. CMS envisions these requirements will be met through the use of a clinical decision support mechanism (CDSM). They state, “While CDSMs can be standalone applications that require direct entry of patient information, they may be more effective when they automatically incorporate information such as specific patient characteristics, laboratory results, and lists of co-morbid diseases from Electronic Health Records (EHRs) and other sources. Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.”

CMS also envisions that the CDSM will be interactive such that the provider ordering the image would input information about the patient into the system and the system would provide immediate feedback to the user about the appropriateness of the image

order. CMS has said that qualified CDSMs must be able to generate a unique identifier at the time the system is consulted that ultimately will be required for placement by the furnishing clinician on a healthcare claim form.

CMS has also said, “Ideally, CDSMs would be integrated within or seamlessly interoperable with existing health IT systems and would automatically receive patient data from the EHR or through an API or other connection.” The law allows the CDSM to be CDS modules within certified EHRs or ones that are separate from certified EHRs. The law also says CMS can establish their own CDSMs (CMS has not yet done this). CMS also notes that not every CDSM is required to supply every available AUC. Further, CMS has not named any specific IT standards associated with CDSM though they reserve this option for the future. They do require, however, that qualified CDSMs must be able to incorporate AUC from more than one qualified **provider-led entities (PLEs)**.

CMS is required to consult with clinicians and other stakeholders in developing AUC and selected criteria can only originate from those developed or endorsed by professional medical societies or other **provider-led entities (PLEs)**. PLEs must apply to CMS to be qualified to develop, endorse or modify AUC.

The program only applies to applicable imaging services as defined in section 1834(q)(1)(C) of the Social Security Act. These are advanced diagnostic imaging services for which one or more applicable AUC apply, one or more qualified CDS mechanisms is available, and one of those mechanisms is available free of charge.

Definitions

- **Advanced Diagnostic Imaging Services:** Includes diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and other diagnostic imaging services as specified by CMS. Excludes excluding x-ray, ultrasound and fluoroscopy services.
- **AUC:** Appropriate use criteria is defined in the law as, “criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals. CMS has said defined this to be, “A set of individual criteria that present information 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). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context.”
- **Provider-led Entities (PLE):** National professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. A list of provider-led entities thus far named can be found [here](#).
- **Qualified CDS Mechanisms:** CMS will post a list of qualified CDSMs to their [website](#) by June 30, 2017. CDSMs will be qualified for a period of five years. It is CMS’ expectation that all qualified CDSMs that are approved by June 30, 2017,

should be capable of supporting AUC for all priority clinical areas that are finalized in the CY 2017 Physician Fee Schedule (PFS) final rule. CDSM must make available updated AUC content within 12 months from the date the qualified PLE updates AUC. CMS has said they do not plan on requiring a specific CDSM standard but as work in this area evolves (i.e. with Fast Healthcare Interoperability Resources (FHIR)) they will consider moving to a standard.

- **Priority Clinical Areas:** CMS finalized an initial list of priority clinical areas in the CY 2017 Physician Fee Schedule Final Rule which mimics the priority clinical areas named in the law:
 - Coronary artery disease (suspected or diagnosed)
 - Suspected pulmonary embolism
 - Headache (traumatic and nontraumatic)
 - 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
 - For more information, go [here](#).
- **Unique consultation identifier:** CMS says, “Documentation or certification provided by the qualified CDSM must include a unique consultation identifier. This would be a unique code issued by the CDSM that is specific to each consultation by an ordering professional. This type of unique code may serve as a platform for future collaboration and aggregation of consultation data across CDSMs.” CMS also notes that the CDSM must be able to document which qualified CDSM was consulted, the name and national provider identifier (NPI) of the ordering professional that consulted the CDSM, whether the service ordered would adhere to specified applicable AUC, whether the service ordered would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered. Requirements around the use of these identifiers for placement on claims by clinicians furnishing the service will be addressed in future rulemaking.

WHERE does this apply?

Applies

Outpatient settings like doctor’s offices, hospital outpatient departments (including an emergency department), ambulatory surgical centers, and any provider-led outpatient setting determined appropriate by CMS. The inpatient hospital setting is not an applicable setting.

CMS says, “The number of clinicians impacted by the scope of this program is massive as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast.”

Exceptions

The law affords certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who believe meeting the AUC requirements would result in a significant hardship (i.e. in the case of a professional practicing in a rural area without sufficient Internet access). CMS will grant, for those who file for a Meaningful Use hardship, an automatic hardship for meeting AUC. The year for which the eligible professional is excepted from the EHR Incentive Program payment adjustment is the same year that the ordering professional is excepted from the requirement to consult AUC through a qualified CDSM. However, ordering professionals with a primary specialty of anesthesiology, radiology or pathology will not be categorically excepted from AUC consultation requirements.

CMS plans to create a separate process to handle significant hardship requests from non-physician practitioners that order advanced imaging tests as they are not currently included in the EHR Incentive Program. They will revisit this process after 2018 once the Medicare-based Incentive Program (MIPS) has been stood up.

WHEN are the compliance deadlines?

Starting January 2017 by law, CMS was supposed to begin reimbursing for advanced imaging only after qualifying decision support had been consulted. The law applies to services delivered on or after January 1, 2017. However, CMS is behind in implementing the requirements and has said at the present time they do not plan to enforce the requirements of the law by this date. More details on timing are discussed below.

WHY do I have to do this?

Section 218(b) of the [Protecting Access to Medicare Act \(PAMA\)](#) signed into law in April 2014 amends Section 1834(q)(1)(B) of the Social Security Act (see end of this document for the statute) requiring CMS to establish a program to promote the use of AUC for advanced diagnostic imaging services.

There are four major components of the AUC program each with their own implementation dates:

- (1) Establishment of AUC by November 15, 2015;
- (2) Mechanisms for consultation with AUC by April 1, 2016;
- (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017; and
- (4) Annual identification of outlier ordering professionals for services furnished after January 1, 2017

HOW will this work?

Step 1 – CMS Establishes New Criteria Behind Appropriate Use by November 15, 2015.

Status: delayed.

As noted above, CMS is behind in standing up these new requirements. In the [final PFS rule for 2016](#) published November 16 2015, CMS discusses their plans for the first of the four aforementioned requirements and definitions in the law. CMS envisions clinicians using “CDS mechanism for consultation with AUC as an interactive tool that communicates AUC information to the user.” The way this would work is the clinician ordering the imaging would enter information associated with the patient into a CDS tool, “which may be a feature of or accessible through an existing system, and the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, multiple CDS mechanisms would be available that could integrate directly into, or be seamlessly interoperable with, existing health information technology (IT) systems.” The law calls on CMS to name qualified CDS mechanisms after consultation with the industry.

Step 2 – CMS Establishes Mechanisms for Implementing AUC (i.e. CDS) by April 1, 2016.

Status: delayed.

In the 2016 final PFS rule, CMS said, “We anticipate that the initial list of specified applicable CDS mechanisms will be published sometime after the CY 2017 PFS final rule. If we were to follow a similar process for CDS as we have for specifying AUC, the initial list of CDS mechanisms would be available in the summer of 2017. In advance of these actions, we will continue to work with stakeholders to understand how to ensure that appropriate mechanisms are available, particularly with respect to standards for certified health IT, including EHRs, that can enable interoperability of AUC across systems.”

Step 3 – Clinicians Required to Consult AUC by January 1, 2017:

Status: delayed.

In the 2016 final PFS rule, CMS discusses their initial plans for how clinicians will consult AUC. CMS plans to have the clinician furnishing the image to include on the claim form information provided by the ordering clinician stemming from their use of the CDSM. Again, the intent being that the ordering clinician and the clinician performing the image are often two different people. However, since CMS has not yet named a list of qualified CDSM yet, they offer few other details other than to say that the above deadline need not be met by providers at this time.

Step 4 – Annual Identification of Outlier Ordering Professionals after January 1, 2017:

Status: delayed.

The final set of requirements concerns identifying those clinicians who order images who are considered “outliers” with respect to the priority clinical areas. CMS says that the identification of outlier ordering professionals helps meet the prior authorization requirement for outlier professionals beginning January 1, 2020 required by law. CMS will identify these clinicians in future rulemaking.

WHERE to go for more information?

- CMS has set up an email box. Questions regarding this program may be submitted to the CMS Imaging AUC resource box: ImagingAUC@cms.hhs.gov.
- CMS’ AUC website can be found [here](#).
- Discussion in physician fee schedule rules can be found [here](#) (2015) and [here](#) (2016).

Section [1834\(q\)\(1\)\(B\)](#) of the Social Security Act

(b) Promoting Evidence-Based Care.--

(1) In general.--Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by subsection (a), is amended by adding at the end the following new subsection:

“(q) Recognizing Appropriate Use Criteria for Certain Imaging Services.--

“(1) Program established.--

“(A) In general.--The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

“(B) Appropriate use criteria defined.--In this subsection, the term ‘appropriate use criteria’ 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 shall be evidence-based.

“(C) Applicable imaging service defined.--In this subsection, the term ‘applicable imaging service’ means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines--

“(i) one or more applicable appropriate use criteria specified under paragraph (2) apply;

“(ii) there are one or more qualified

clinical decision support mechanisms listed under paragraph (3)(C); and

``(iii) one or more of such mechanisms is available free of charge.

``(D) Applicable setting defined.--In this subsection, the term `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.

``(E) Ordering professional defined.--In this subsection, the term `ordering professional' means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service.

``(F) Furnishing professional defined.--In this subsection, the term `furnishing professional' means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service.

``(2) Establishment of applicable appropriate use criteria.--

``(A) <<NOTE: Deadline. Regulations. Consultation.>> In general.--Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

``(B) Considerations.--In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria--

``(i) have stakeholder consensus;

``(ii) are scientifically valid and evidence based; and

``(iii) are based on studies that are published and reviewable by stakeholders.

``(C) <<NOTE: Review. Deadline.>> Revisions.--The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

``(D) Treatment of multiple applicable appropriate use criteria.--In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.

``(3) Mechanisms for consultation with applicable

appropriate use criteria.--

``(A) Identification of mechanisms to consult with applicable appropriate use criteria.--

``(i) In general.--The Secretary shall specify qualified clinical decision support mechanisms that could be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

``(ii) Consultation.--The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

``(iii) Inclusion of certain mechanisms.--Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

``(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1848(o)(4)).

``(II) Use of private sector clinical decision support mechanisms that are independent from certified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

``(III) Use of a clinical decision support mechanism established by the Secretary.

``(B) Qualified clinical decision support mechanisms.--

``(i) In general.--For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

``(ii) Requirements.--The requirements described in this clause are the following:

``(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

``(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.

``(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

``(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

``(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

``(VI) The mechanism meets privacy and security standards under applicable provisions of law.

``(VII) The mechanism performs such other functions as specified by the Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.

``(C) <<NOTE: Deadlines.>> List of mechanisms for consultation with applicable appropriate use criteria.--

``(i) <<NOTE: Publication.>> Initial list.-- Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

``(ii) Periodic updating of list.--The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

``(4) Consultation with applicable appropriate use criteria.--

``(A) Consultation by ordering professional.-- Beginning <<NOTE: Effective date.>> with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall--

``(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

``(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

``(B) <<NOTE: Effective date.>> Reporting by furnishing professional.--Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), payment for such service may only be made if the claim for the service includes the following:

``(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

``(ii) Information regarding--

``(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

``(II) whether the service ordered would not adhere to such criteria; or

``(III) whether such criteria was not applicable to the service ordered.

``(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

``(C) Exceptions.--The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

``(i) Emergency services.--An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1867(e)(1)).

``(ii) Inpatient services.--An applicable imaging service ordered for an inpatient and for which payment is made under part A.

``(iii) Significant hardship.--An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

``(D) Applicable payment system defined.--In this subsection, the term 'applicable payment system' means the following:

``(i) The physician fee schedule established under section 1848(b).

``(ii) The prospective payment system for hospital outpatient department services under section 1833(t).

``(iii) The ambulatory surgical center payment systems under section 1833(i).

``(5) Identification of outlier ordering professionals.--

``(A) <<NOTE: Effective date. Determination.>> In general.--With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

``(B) Outlier ordering professionals.--The determination of an outlier ordering professional shall--

``(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

``(ii) include data for ordering professionals for whom prior authorization under paragraph

(6)(A) applies.

((C) Use of two years of data.--The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

((D) Process.--The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

((E) Consultation with stakeholders.--The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

((6) Prior authorization for ordering professionals who are outliers.--

((A) <<NOTE: Effective date.>> In general.-- Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

((B) Appropriate use criteria in prior authorization.--In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

((C) Funding.--For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of \$5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.

((7) Construction.--Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.''

(2) Conforming amendment.--Section 1833(t)(16) of the Social Security Act (42 U.S.C. 1395l(t)(16)) is amended by adding at the end the following new subparagraph:

((E) Application of appropriate use criteria for certain imaging services.--For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1834(q).''

(3) Report on experience of imaging appropriate use criteria program.--Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that includes a description of the extent to which appropriate use criteria could be used for other services under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.), such as radiation therapy and clinical diagnostic laboratory services.

