compliance

Appropriate Imaging Through Decision Support

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It is an act of Congress, specifically section 218 of the Protecting Access to Medicare Act (PAMA) of 2014, which requires all physicians ordering advanced imaging studies to consult government-approved, evidence-based appropriate use criteria through a clinical decision support system. The goal of these tools is to improve the accuracy of ordering advanced diagnostic imaging and ensure that appropriate studies are performed for the right reasons on the right patients.

Physicians furnishing advanced diagnostic imaging services will only be paid if the claims submitted for reimbursement confirm that this appropriate use criteria (AUC) was consulted, which clinical decision support mechanism (CDSM) was used, and whether the study ordered adhered (or not) to the final recommendation. It's important to note that, as of now, the ordering physician can override the recommendation and order the study anyway. Regardless, the AUC guidelines must be consulted, and there may come a time when ordering-physician compliance with these guidelines is mandatory.

Appropriate Use Criteria
AUC are defined as measures developed or endorsed by national professional medical specialty societies, or other provider-led entities, to assist ordering professionals in making the most appropriate treatment decision for a specific clinical condition for an individual patient. Appropriate use criteria are a collection or library of information presented to the physician in a manner that links a specific clinical condition or symptom with an assessment of the appropriateness of advanced diagnostic imaging services. These criteria would be developed or endorsed by provider-led entities, such as national professional medical specialty societies and organizations that primarily include providers who are actively engaged in the practice and delivery of healthcare.

According to the Centers for Medicare & Medicaid Services (CMS) in the November 16, 2015 Federal Register, (2016 Final Rule, Medicare Physician Fee Schedule):

Experience and published studies alike show that results are best when AUC are built on an evidence base that considers patient health outcomes, weighing the benefits and harms of alternative care options, and are integrated into broader care management and continuous quality improvement (QI) programs.

There is also consensus that AUC programs built on evidence-based medicine and applied in a QI context are the best method to identify appropriate care and eliminate inappropriate care, and are preferable to across-the-board payment reductions that do not differentiate interventions that add value from those that cause harm or add no value.

AUC are intended to be integrated into the clinical workflow and facilitate evidence-based care delivery. In addition, the ideal AUC is an evidence-based guide that starts with a patient's specific clinical condition or presentation (e.g., symptoms, provisional diagnosis, final diagnosis) and assists providers in the overall patient workup, treatment, and follow-up.

As reported by CMS in the Medicare Physician Fee Schedule Final Rule 2016:[1] "The end goal of using AUC is to improve patient health outcomes." In addition, this program is applicable to services billed under the Medicare Physician Fee Schedule (PFS), the Hospital Outpatient Prospective Payment System (OPPS), and the Ambulatory Surgical Center payment system.

Table 1, right, offers a summary of AUC program requirements.

Qualified Provider-Led Entity
A qualified provider-led entity (qPLE) is an organization of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care. CMS will establish its program based on AUC that have been developed, modified, and/or endorsed by provider-led entities. Rather than reviewing each criterion for each imaging study proposed by the qPLEs, CMS will have a qualification and review process for the provider-led entities themselves. To become a qPLE, an organization must meet the following requirements:

- Have an established evidence-review process, using a formal, published, and widely recognized methodology for grading evidence.
- Grade the AUC in terms of strength of evidence.
- Be led by a multidisciplinary team with "autonomous governance" and have strict adherence to a policy on the disclosure of potential conflict of interest.

Table 1. Summary of AUC Program Requirements

Ordering professionals must consult AUC criteria for advanced outpatient imaging (CT, MR, NM, PET) orders.

Ordering professionals must access AUCs through a qualified clinical decision support mechanism.

Only AUC from qualified provider-led entities will be used.

Ordering professionals identified as outliers must obtain preauthorization as soon as Jan. 1, 2020.

Acronym Legend

TERM	DEFINITION
AUC	Appropriate Use Criteria (AUC) are guidelines created or endorsed by qPLEs (see below) intended for use in decision support interactions. These guidelines form the backbone of knowledge that informs every decision support interaction. 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. Essentially, AUC link a specific clinical condition or symptom with an assessment of the appropriateness of advanced diagnostic imaging services.
CDSM	Clinical Decision Support Mechanisms (CDSMs) are the electronic portals through which clinicians would access the AUC during the patient workup. With a fully-embedded CDSM platform, practitioners interact directly with the CDSM through their primary user interface, minimizing interruption to the clinical workflow.
DSN	Every CDSM consultation must record the physician's NPI (national provider identifier) and then assign a unique Decision Support Number (DSN). The DSN serves as the "unique consultation identifier" and provides a reference to details of the CDSM consultation, including adherence and applicability of the selected service with the AUC. It contains all required data elements for a claim. CMS will define how the DSN will be used in the claims process in future rulemaking.
FP	A Furnishing Provider (FP) is the organization or health system that furnishes and bills Medicare for the ordered service provided to the beneficiary.
OP	An Ordering Provider (OP) is the individual who orders an item or service (e.g., imaging services) that will be furnished and billed by another provider or supplier (e.g., laboratory, imaging center).
PAMA	The Protecting Access to Medicare Act (PAMA) of 2014 mandates that starting Jan. 1, 2017, physicians ordering advanced diagnostic imaging exams must consult qualified, evidence-based appropriate use criteria, namely through a Clinical Decision Support Mechanism. CMS unilaterally changed the start date to Jan. 1, 2018 since a 2017 startup was not practicable.
PCA	CMS has defined eight Priority Clinical Areas (PCAs) that will be used as a tool to measure outlier ordering professionals. The PCAs represent a baseline for AUC coverage and will expand annually. In addition, there is still a requirement to document the medical necessity for each advanced imaging service ordered. The final list of PCAs includes 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), and cervical or neck pain.
qPLE	A qualified Provider-Led Entity (qPLE) is responsible for the creation of sets of AUC for use in CDSM interactions. Each organization approved to create or endorse AUC follows strict guidelines and rules for criteria authoring. CMS defines a qPLE as 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."

- Demonstrate transparency of the process for developing the criteria, the grading approach for the criteria, and the pipeline of criteria under consideration.

CMS adds that the agency would expect the literature review to include evidence on analytical validity, clinical validity, and clinical utility of the specified imaging study.

Provider-led entities would be required to apply and, if approved, would receive a qualification for a six-year period. Applications must include a statement regarding how the entity meets the definition of a qPLE, and once accepted, qPLEs must re-apply every five years. According to CMS, qPLEs may endorse the AUC set or individual criteria of other qualified provider-led entities, which means that qPLEs can combine their AUC to create a larger, more clinically encompassing library.

CMS acknowledges that conflicting AUC may be a concern, but generally believes that qPLEs will be using an evidence-based AUC development process that will reduce the likelihood and frequency of conflicting AUC. As a result, there may be some situations where CMS and MEDCAC (the Medicare Evidence Development & Coverage Advisory Committee) will have to review the evidence base. CMS states in the November 16, 2015, Federal Register that MEDCAC has extensive experience in reviewing, interpreting, and translating evidence.

The most recent list of qualified provider-led entities, dated June 2016, includes:[2]

- American College of Cardiology Foundation
- American College of Radiology
- Brigham and Women's Physicians Organization
- Center for Diagnostic Imaging (CDI) Quality Institute
- Intermountain Healthcare
- Massachusetts General Hospital, Department of Radiology
- National Comprehensive Cancer Network (NCCN)

- Society for Nuclear Medicine and Molecular Imaging
- University of California Medical Campuses
- University of Washington Physicians
- Weill Cornell Medicine Physicians Organization

CMS will release a list of newly approved qPLEs by June 30 of every year, so the number of qPLEs will grow over time.

Clinical Decision Support Mechanisms

A clinical decision support mechanism (CDSM) is defined as an interactive electronic tool for use by clinicians that communicates AUC information to users and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. In the 2017 Medicare PFS Final Rule, CMS states that specialists may seek to align themselves with a qualified CDSM that contains AUC more exhaustive in one area of medicine to reflect the imaging services that they order most often.

Clinical decision support has two distinct parts: the appropriate use criteria (clinical guidelines) and an electronic platform that makes the guidelines accessible (an information technology tool). A CDSM may be fully integrated with, or be part of, a provider's certified EHR (electronic health record) system, partially integrated, or a stand-alone system entirely outside of the provider's existing EHR.[3] According to CMS, in the November 15, 2016 Federal Register:

"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 [application programming interface] or other connection. Such integration would minimize burden on practitioners and avoid duplicate documentation."

The requirements for a clinical decision support mechanism include the ability to make available specified AUC and the supporting documentation, while complying with privacy and security standards. This means that the CDSM must identify the AUC source consulted if multiple sources (e.g., AUC from more than one qPLE) are available for a specific clinical scenario. In addition, each CDSM will communicate the appropriateness rating to the physician ordering the diagnostic imaging study. This communication will vary, based on the program, but may include a scale of numeric ratings, indicator lights (e.g., green, yellow, red), or a yes-or-no response.

Each time the CDSM is consulted or queried, the mechanism will provide the provider ID (NPI number), adherence to AUC, and applicable AUC availability, and assign a unique consultation ID number. In addition, the CDSM must provide aggregate feedback to ordering professionals in an electronic record format on at least an annual basis, and notify ordering professionals who have been assigned outlier status. Last, the CDSM will store data electronically for a minimum of six years. According to CMS, six years is an appropriate amount of time across which ordering professionals will want to assess their ordering patterns.

Ordering providers will access the CDSM and issue an imaging order that complies with the AUC. The furnishing provider (e.g., the radiologist, imaging center, or radiology department) will submit documentation with the claim that identifies the CDSM mechanism consulted by the ordering physician, verifies adherence to the AUC, nonadherence to the AUC or whether no criteria in the CDSM were applicable to the patient's scenario, and include the NPI of the ordering professional. CMS is considering the mechanisms for appending the AUC consultation information to various types of Medicare claims (e.g., CMS1500 professional or UB04 hospital claim submissions) and expects to develop requirements for reporting such information in the calendar year 2018 PFS rulemaking process.

The noncompliance penalty for the ordering physician includes the possibility of being classified as an outlier and subsequently required to obtain preauthorization for advanced imaging studies for Medicare patients. In addition, a consequence of noncompliance for the furnishing provider includes claim denials and lack of reimbursement (this applies to both the professional and technical components of the advanced diagnostic imaging studies).

When AUC are updated or modified, CDSMs must make the updated AUC available within 12 months, have protocols in place to remove AUC determined to be potentially dangerous, and make available within 12 months AUC for new priority clinical treatment areas. The current approval timeline for clinical decision support mechanisms is:

- April 2014: PAMA signed into law, requiring provider use of AUC via CDSM for advanced imaging.
- Nov. 2, 2016: The Medicare PFS Final Rule for CY 2017 was released and established the eight clinical priority areas and clinical decision support mechanism requirements and approval process.
- March 1, 2017: Application deadline for the first round of qualified CDSMs.
- June 30, 2017: CMS is scheduled to release the first list of CDSMs.
- Jan. 1, 2018: Ordering professionals begin using CDSMs/AUC and application deadline for the second round of qualified CDSMs.
- Jan. 1, 2022: Application deadline for the first round of qualified CDSM 5-year renewals.

Outliers

Under the law, CMS must identify outlier ordering professionals, defined as professionals with low adherence to the applicable AUC, and implement prior authorization programs. While the penalties for low adherence will not be employed immediately, Section 414.94(e)(5) establishes the following priority clinical areas that will be used to determine ordering

professional outliers:

- 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.

A priority clinical area (PCA) is defined as clinical topics, clinical topics and imaging modalities, or imaging modalities identified by CMS through annual rulemaking and in consultation with stakeholders that may be used in the determination of outlier ordering professionals.

This initial list of priority clinical areas was selected based on diagnostic groups with the highest associated advanced imaging volumes. In addition, a table was made available that provided stakeholders with diagnosis codes that were used to describe the proposed priority clinical areas.[4] All advanced diagnostic imaging requires the use of a clinical decision support mechanism and approved use criteria, but only consistently overriding services in priority clinical areas will result in the need to conform to a preauthorization requirement. Last, CMS plans to increase the number and scope of priority clinical areas annually.

Exceptions

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements. First, the statute provides for an exception when an applicable imaging service is ordered for an individual with an emergency medical condition. CMS believes that this exception is warranted because there can be situations in which a delay in action would jeopardize the health or safety of patients. To meet this exception, the clinician only needs to determine that the medical

condition manifests itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment of bodily functions, or serious dysfunction of any bodily organ or part.

In addition, applicable imaging services ordered for an inpatient and for which payment is made under Medicare Part A are exempt from the requirement to consult AUC. CMS notes that if payment is made under Medicare Part A, the service is not paid under an applicable payment system.

Last, applicable imaging services ordered by an ordering professional for whom consultation with an AUC would result in significant hardship (as determined on a case-by-case basis) are exempt. For example, a hardship may include an ordering professional practicing in a rural area without sufficient Internet access, extreme and uncontrollable circumstances that prevent the healthcare professional from becoming a meaningful EHR user, practicing for less than two years, a primary specialty of anesthesiology, radiology, or pathology that qualifies for a hardship exemption, or practicing at multiple locations with the inability to control the availability of Certified EHR Technology (CEHRT).

Choosing Wisely®

While not guidelines or requirements, there are currently recommendations for advanced imaging relating to cancer care on the Choosing Wisely website (choosing-wisely.org), including:

American College of Preventive Medicine

- Don't use whole body scans for early tumor detection in asymptomatic patients.

American Society of Clinical Oncology

- Don't perform PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.

- Don't perform surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.
- Don't perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.
- Avoid using PET or PET/CT scanning as part of routine follow-up care to monitor for a cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer unless there is high-level evidence that such imaging will change the outcome.

American Society of Hematology
- Limit surveillance CT scans in asymptomatic patients following curative-intent treatment for aggressive lymphoma.
- Don't perform baseline or routine surveillance CT scans in patients with asymptomatic, early-stage chronic lymphocytic leukemia.

American Urological Association
- Don't obtain CT scan of the pelvis for asymptomatic men with low-risk clinically localized prostate cancer.

Society of Gynecologic Oncology
- Avoid routine imaging for cancer surveillance in women with gynecologic cancer, specifically ovarian, endometrial, cervical, vulvar, and vaginal cancer.

Society of Nuclear Medicine and Molecular Imaging
- Don't use PET/CT for cancer screening in healthy individuals.

Society of Surgical Oncology
- Don't perform routine PET/CT in the initial staging of localized colon or rectal cancer or as part of routine surveillance for patients who have been curatively treated for colon or rectal cancer.
- Don't routinely order imaging studies for staging purposes on patients newly diagnosed with localized primary cutaneous melanoma unless there is suspicion for metastatic disease based on history and physical exam.

The Society of Thoracic Surgeons
- Patients with suspected or biopsy-proven stage I NSCLC do not require brain imaging prior to definitive care in the absence of neurological symptoms.

Additional details on these recommendations are available on the Choosing Wisely website (choosingwisely.org).

Future Considerations

The mandate specifies that providers must consult a qualified CDSM for every Medicare diagnostic advanced imaging service (CT, MR, NM, PET) ordered. And, each claim must contain evidence of the CDSM consultation to be payable. According to a 2014 AIM Specialty Health presentation, "All things being equal, the imaging utilization of unmanaged Medicare population was 8.5% higher than managed."[5] This study highlighted that oncology specialties were responsible for 12 percent of total advanced imaging utilization.

CMS clarified in the 2017 Medicare PFS Final Rule that the delay in implementation until Jan. 1, 2018, provides ordering practitioners time to research and align themselves with a qualified CDSM. As a result, oncologists should be prepared to begin reporting data once CMS announces the claim submission details as part of the 2018 PFS Final Rule.

PAMA also introduced the controversial concept of prior authorization into Medicare. While initially limited to the small group of physicians who are image-ordering outliers, this sets a precedent for expanded application to a wider group of high-utilizers in the future.

For providers, implementing this initiative will be considerably more involved than just contacting the IT department to install a new program. Buy-in and commitment from ordering physicians, including medical, radiation, and surgical oncologists, will be critical to the successful implementation of appropriate use criteria. According to radiology specialty societies, referring physicians must be educated on the importance of using these tools and recognize that this will require both time and commitment.

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