CONSULTING APPROPRIATE USE CRITERIA
For Advanced Diagnostic Imaging

Objectives
- Learn what Appropriate Use Criteria is and how to access it
- Discover what a Provider Led Entity is and which organizations have been approved as such
- View the requirements for Clinical Decision Support Mechanisms
- Identify which priority clinical areas are included in this mandate
- Realize the impact on ordering and furnishing professionals
- Understand the impact on claims submissions, claims processing, and MIPS
- Find out the plan for outlier ordering professionals

Regulatory Background
- Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) amended Title XVIII of the SSA to add section 1834(q) directing CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services.
**Regulatory Background**

- The CY 2016 PFS final rule
- The CY 2017 PFS final rule
- The CY 2018 PFS proposed rule
- The CY 2018 PFS final rule with comment period
- The CY 2019 PFS final rule with comment period

**Why Appropriate Use Criteria?**

- Appropriateness criteria has been in use for years and has been shown to improve quality, reduce unnecessary imaging, and lower costs.
- CMS has noted increased utilization of high cost diagnostic tests and the OIG included medical necessity for high cost tests in their 2012, 2013, 2014 and 2015 Work Plans.

**Components**

- Four major components of the AUC program:
  - Establishment of AUC, defined PLEs and which PLEs may modify or endorse AUC;
  - Identification of mechanisms for consultation with AUC (CDSM);
  - AUC consultation by ordering professionals, and reporting on AUC consultation by furnishing professionals; and
  - Annual identification of outlier ordering professionals.
AUC – Appropriate Use Criteria

- 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.

- 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

AUC – Appropriate Use Criteria

<table>
<thead>
<tr>
<th>Radiologic Exam Procedure</th>
<th>Appropriateness Rating</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No intra-articular contrast</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Intra-articular contrast</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without intra-articular contrast</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Arthrogram, pos, contrast</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Arthrogram, air only</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Arthrogram, double contrast</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Tomography</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
CDSM – Clinical Decision Support Mechanism

- 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 EHR technology or private sector mechanisms independent from certified EHR technology or established by the Secretary of DHHS.

CDSM Requirements

- Makes available to the ordering professional applicable AUC and the supporting documentation for the applicable imaging service ordered.
- In the case where there is more than one applicable AUC for an applicable imaging service, the CDSM indicates the criteria that it uses for the service.
- Determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.
- 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.

CDSM Requirements

- Is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.
- Meets privacy and security standards under applicable provisions of law.
- Performs such other functions as specified by the DHHS Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.
CDSM

- CDSMs may return a response of "not applicable" if a qualified CDSM does not contain specified applicable AUC for the service ordered.
- These situations should be limited in scope and number, and to decrease over time.

The first list of qualified CDSMs was published in July, 2017 at:


Provider Led Entities

- 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.
Provider Led Entities

To be qualified by CMS, a PLE must adhere to the evidence-based processes described in 42 CFR 414.94(c)(1) when developing or modifying AUC. PLEs must apply to CMS to become qualified. The application must include a statement as to how the entity meets the definition of a PLE and document adherence to each of the qualification requirements.

Once a PLE is qualified the AUC that are developed or endorsed by the entity would be considered to be specified applicable AUC.

All qualified PLEs must re-apply every 5 years and their applications must be received by January 1 during the 5th year of their approval.


In order to be considered a qualified PLE, the PLE’s AUC development process must be led by a multidisciplinary team.

The multidisciplinary team must include 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.

The multidisciplinary team must have at least seven members, including a primary care practitioner.

The required expertise in the clinical topic and imaging service related to the AUC that are being developed must be provided by practicing physician.

The multidisciplinary team must have clinical trial expertise.

Ordering Professional

<table>
<thead>
<tr>
<th>Role</th>
<th>Professional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>Certified Registered Nurse Anesthetist</td>
</tr>
<tr>
<td>Physician Assistant</td>
<td>Clinical Psychologist</td>
</tr>
<tr>
<td>Advanced Registered Nurse Practitioner</td>
<td>Clinical Social Worker</td>
</tr>
<tr>
<td>Certified Nurse Specialist</td>
<td>Registered Dietician or nutrition professional</td>
</tr>
</tbody>
</table>

A physician or professional who orders an applicable imaging service
Furnishing Professional

<table>
<thead>
<tr>
<th>Physician</th>
<th>Certified Registered Nurse Anesthetist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Assistant</td>
<td>Clinical Psychologist</td>
</tr>
<tr>
<td>Advanced Registered Nurse Practitioner</td>
<td>Clinical Social Worker</td>
</tr>
<tr>
<td>Certified Nurse Specialist</td>
<td>Registered Dietician or nutrition professional</td>
</tr>
</tbody>
</table>

A physician or professional who furnishes an applicable imaging service.

Priority Clinical Areas

- 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

Workflow

- The AUC is an evidence-based guide that starts with a patient’s specific clinical condition or presentation (symptoms) and assists the provider in the overall patient workup, treatment and follow-up.
- Imaging would appear as key points within the clinical management decision tree.
- Providers may encounter AUC through a CDSM for the first time at the point of image ordering.
- The CDSM would ideally bring the provider back to that specific clinical condition and work-up scenario to ensure and simultaneously document the appropriateness of the imaging test.
Consultation Requirement

Beginning with January 1, 2020, 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, an ordering professional shall:

- consult with a qualified CDSM; and
- provide to the furnishing professional the following information:
  - which qualified CDSM was consulted for the service;
  - whether the service ordered would adhere to the applicable AUC;
  - whether the service ordered would not adhere to the applicable AUC;
  - whether such AUC was not applicable to the service ordered; and
  - the ordering professional’s NPI (if different from the furnishing professional).
Who Must Consult the AUC?

- Requirement that only the ordering professional could consult AUC was changed in the CY 19 PFS Final Rule.
- Now, ordering professionals may delegate to clinical staff acting under the direction of the ordering professional.

Ordering Provider Communication

- Ordering professional's responsibility to consult applicable AUC through a qualified CDSM and communicate information on that consultation to the furnishing professional.
- Information related to the AUC consultation would be communicated as part of the order.
- If policy adopted to require reporting of the unique AUC consultation identifier on the furnishing professional's claim, then CMS would expect the ordering professional to include that identifier on the order for the advanced diagnostic imaging service.
- First step may be to standardize the taxonomy of the unique consultation identifier before determining the extent to which CMS will establish guidance.

Claim Reporting Requirements

- Payment may only be made if the claim for the advanced diagnostic imaging service includes the required information.
- Required across claim types (including both the furnishing professional and facility claims).
- Required across all three applicable payment systems (PFS, hospital outpatient prospective payment system and ambulatory surgical center payment system).
- Required information is to be included on the practitioner claim that includes the professional component of the imaging service.
- Required information is to be included on the hospital outpatient claim for the technical component of the imaging service.
Claim Reporting Requirements

- CMS proposed using unique AUC consultation identifiers in the form of G-codes to identify the consulted CDSM.
- CMS proposed creating modifiers to be submitted on the claim to identify AUC consultation result conditions.
- Both of these ideas were nixed for now.
- Furnishing professionals and facilities reporting AUC consultation information during the voluntary reporting period will have one HCPCS modifier available to them to report on the line level with the CPT code for the advanced diagnostic imaging service.
- CMS will evaluate a simplified method of reporting during the voluntary reporting period using a single modifier while they work with stakeholders to explore using a standardized unique AUC consultation identifier.

Reporting by FURNISHING Professional

- Payment for an applicable service, in an applicable setting, and paid for under an applicable payment system may only be made if the claim for the service includes the following:
  - information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service;
  - whether the service ordered would adhere to the applicable appropriate use criteria;
  - whether the service ordered would not adhere to such criteria; or
  - whether such criteria was not applicable to the service ordered; and
  - the national provider identifier of the ordering professional (if different from the furnishing professional).

Consultation & Reporting Requirements Delayed

- CMS has delayed the effective date for the AUC consultation and reporting requirements from January 1, 2019 as proposed to January 1, 2020.
- Early adopters can begin reporting limited consultation information on Medicare claims from July, 2018 through December, 2019 on a voluntary basis.
Educational/Operations Testing vs. Voluntary Reporting Period

- Educational/Operations testing period is separate from the voluntary reporting period.
- During the voluntary reporting period, AUC consultation and reporting are not required. However, for applicable imaging services ordered on and after January 1, 2019, ordering professionals are required to consult specified applicable AUC and furnishing professionals would be required to report AUC consultation information on the Medicare claim.
- The initial year of the AUC consultation and reporting requirement would be an educational and operations testing period during which CMS would continue to pay claims whether or not they correctly include the required information.

Applicable Settings

- Physician's office
- Hospital outpatient department (including an emergency department)
- Ambulatory surgical center
- Any other provider-led outpatient setting determined appropriate by the DHHS Secretary
- IDTFs

Applicable Imaging Systems

- Diagnostic magnetic resonance imaging
- Computed tomography
- Nuclear medicine (including positron emission tomography)
- Other diagnostic imaging services CMS may specify in consultation with physician specialty organizations and other stakeholders
- Excludes x-ray, ultrasound and fluoroscopy services.
Applicable Payment Systems

- Physician fee schedule established under section 1848(b) of the Act.
- Prospective payment system for hospital outpatient department services under section 1833(t) of the Act.
- Ambulatory surgical center payment system under section 1833(i) of the Act.

Exceptions to Consulting & Ordering Requirements

- Inpatient services paid under Medicare Part A
- For emergency services when provided to individuals with “emergency conditions”
- Ordering professionals who obtain an exception due to a significant hardship

Significant Hardships

- Insufficient internet connectivity
- Extreme and uncontrollable circumstances
- Lack of control over availability of CEHRT
- Lack of face to face patient interaction
- Case by case basis
**Emergency Medical Condition**

The term "emergency medical condition" means:

- a medical condition manifesting 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, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,
  - serious impairment to bodily functions, or
  - serious dysfunction of any bodily organ or part; or
- with respect to a pregnant woman who is having contractions—
  - that there is inadequate time to effect a safe transfer to another hospital before delivery, or
  - that transfer may pose a threat to the health or safety of the woman or the unborn child.

**Outlier Ordering Professionals**

- Identified outlier ordering professionals will be subject to prior authorization for these services beginning January 1, 2020.
- Given that CMS proposed a program start date of January 1, 2019, they anticipate that implementation of the prior authorization component would be delayed.
- CMS expects to discuss details around outlier calculations and prior authorization in the CY 2019 PFS proposed rule.
- Ultimately, outlier ordering professionals could be subject to prior authorization requirements.

**Identification of Non-Evidence-Based AUC**

- CMS proposed a process by which they would identify and review potentially non-evidence-based criteria that fall within one of the identified priority clinical areas.
- Public can comment through annual PFS rulemaking to assist in identifying AUC that are potentially not evidence-based.
- Proposed using the MEDCAC to further review the evidentiary basis of these identified AUC, as needed.
- If through this process, a number of criteria from an AUC library are identified as being insufficiently evidence-based, and the PLE that produced the library does not make a good faith attempt to correct these in a timely fashion, this information could be considered when the PLE applies for re-qualification.
Imaging Replacement Orders

- In certain situations updates or modifications to orders for advanced diagnostic imaging services may be warranted once the beneficiary is under the care of the furnishing professional.
- The AUC consultation information provided by the ordering professional with the original order should be reflected on the Medicare claim to demonstrate that the requisite AUC consultation occurred.

Orders Prior to Effective Date

- Orders placed for services that are furnished prior to January 1, 2020 are not subject to the AUC consultation and reporting requirement.
- At this time, CMS is exploring claims-reporting options for situations when the imaging service is ordered before January 1, 2020 but furnished after January 1, 2020 and AUC consultation information is not available for inclusion on the claim.

MIPS and AUC

- CMS proposed in the CY 2018 Updates to the Quality Payment Program proposed rule (82 FR 30010) to develop a direct tie between MIPS and the AUC program. This was finalized.
- CMS is considering further opportunities for alignment between the AUC program and the Quality Payment Program, but did not propose additional policies in rulemaking for CY 2018.
- Clinicians attest that they are consulting specified applicable AUC through a qualified CDSM for all applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2018.
Timeline Recap

- Voluntary reporting period extended to 18 months starting 07/01/2018 through 12/31/2019.
- AUC consultation and reporting requirements for educational and operations testing from 01/01/2020 through 12/31/2020. During this time period claims will not be denied for lack of claims indicator supporting AUC consultation.
- Beginning 01/01/2021 claims submitted by furnishing professionals will require AUC consultation indicator (yet to be determined) on claim in order to be reimbursed.

Questions?

The views and opinions expressed here today are solely my own and do not express the views or opinions of my employer -- the University of Florida Jacksonville Physicians, Inc. or its affiliated organizations.

The information presented should not be construed as all inclusive. Websites and the regulations posted on them change frequently and should be checked periodically for the most up-to-date information.

Maryann C. Palmeter, CPC, CPCO, CPMA, CENTC, CHC, AAPC FELLOW

maryannpalmeter@yahoo.com
Ordering Professional Workflow

Ordering Professional wants to order advanced diagnostic imaging service.

STEP 1: Ordering Professional enters patient clinical information and proposed dx test into CDSM?

YES

CDSM analyzes AUC in conjunction with information provided by Ordering Professional.

CDSM provides response to Ordering Professional.

“Not Appropriate” result received?

YES

Ordering Professional submits order to Furnishing Professional with required claim information (i.e., CDSM result).

+++ Ordering Professional may be deemed by CMS to be an outlier. Future orders may be subject to pre-authorization.

NO

GO TO PAGE 2

Ordering Professional submits order to Furnishing Professional without required claim information.

***

END

+++ Furnishing Professional may reject order without required claim information as Furnishing Professional’s claim will not be reimbursed without required claim information.

END
CONTINUED FROM PAGE 1: Ordering Professional decides on next steps.

CDSM response is that proposed test is appropriate?

YES

Ordering Professional sends order to Furnishing Professional with required claim information (i.e., CDSM result)?

YES

Ordering Professional amends order?

YES

RETURN TO STEP 1

END

NO

***

Ordering Professional sends order to Furnishing Professional with required information?

YES

END

NO

***

CDSM proposes alternative dx test?

YES

Ordering Professional amends order?

YES

RETURN TO STEP 1

END

NO

***

Furnishing Professional may reject order without required claim information as Furnishing Professional's claim will not be reimbursed without required claim information.