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CMS Finalizes Next Implementation Phase of Medicare Appropriate Use Criteria Program for Advanced Diagnostic Imaging Services

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In 2015, the Centers for Medicare & Medicaid Services (CMS) announced it would utilize a phased-in approach for implementation of the Medicare Appropriate Use Criteria (AUC) program for select advanced diagnostic imaging services that was enacted in Section 218 of the Protecting Access to Medicare Act of 2014 (PAMA). While many health care providers were scrambling to meet the program requirements by the previously finalized effective date of January 1, 2018, CMS offered a brief reprieve in the CY 2018 Physician Fee Schedule (PFS) Final Rule with its announcement of a further delayed start date and transition period. In that notice, CMS established that professionals must report the consultation of AUC when ordering advanced diagnostic imaging services—defined as diagnostic magnetic resonance imaging, computed tomography, nuclear medicine and positron emission topography services—beginning January 1, 2020. The initial year of reporting is an "education and operations testing" phase where payment for services would not be affected by the reporting requirement, with the payment consequences for failing to report taking effect in 2021. In the recently published CY 2019 Proposed Rule, CMS further clarifies a number of policies and solicits feedback on how to identify outlier ordering professionals. Given the complexity of implementing this program, affected stakeholders should review the proposals and consider implications for existing AUC consultation policies. Affected stakeholders also might consider giving CMS feedback on proposed changes.

For more information, contact Deborah Godes or Eric Zimmerman.

OVERVIEW

Beginning January 1, 2020, when submitting claims to Medicare for advanced diagnostic imaging services under the Medicare PFS, Hospital Outpatient Prospective Payment System or Ambulatory Surgery Center payment system, furnishing professionals and entities (including hospitals) must certify that professionals ordering advanced diagnostic imaging services consulted AUC applicable to the imaging modality. Following the one-year testing phase, providers who fail to report this information on a claim will not receive payment for that service. The original implementation date of this requirement under Section 218 of PAMA was January 1, 2017, but CMS delayed the effective date multiple times and is now including a further transition period to ensure stakeholders are prepared for program implementation.

Providers who fail to report this information on a claim will not receive payment.

Furnishing professionals and entities will be required to specify on the claim which qualified clinical decision support mechanism (CDSM) was used to consult the AUC, and whether the service ordered adheres to those criteria. At least initially, it will not be required that the imaging service furnished actually adhere to the AUC, just that the AUC be consulted. However, compliance with AUC is a potential program requirement in the long term.

CMS has been implementing the AUC program since CY 2016, adding requirements for various elements of program operation and compliance each year. In the CY 2019 PFS Proposed Rule released on July 12, 2018, CMS proposed several AUC policies and/or clarifications, including the following:

- Expanding the definition of applicable setting to include independent diagnostic testing facilities
- Clarifying that AUC consultation may be performed by the ordering professional or clinical staff working under the direction of the ordering professional
- Clarifying that the AUC consultation information must be reported by the furnishing professional AND furnishing facility
- Using G-codes and modifiers to report the required AUC information on Medicare claims (a departure from the agency's previous position that G-codes and modifiers would result in overly complex claims reporting obligations)
- Modifying the previously finalized hardship exceptions criteria in an effort to establish a more straightforward and less burdensome approach

Additionally, CMS is seeking input from stakeholders on the data elements and thresholds that the agency should consider in identifying outlier ordering professionals who would, in the future, be subject to a prior authorization requirement when ordering advanced diagnostic imaging services.

SELECTION OF QUALIFIED PROVIDER-LED ENTITIES

CMS defines "appropriate use criteria" as a collection of individual appropriate use criteria that are 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. Pursuant to the statute, these criteria are either developed or endorsed by provider-led entities (PLEs) and, to the extent feasible, should be evidence-based. CMS defines PLEs as national professional medical specialty societies (such as the American College of Radiology) or organizations that are composed "primarily of providers and [are] actively engaged in the practice and delivery of healthcare."

PAMA requires CMS to assess whether the criteria under the AUC program are "scientifically valid and evidence-based." CMS is relying on AUC that have been developed, modified and/or endorsed by PLEs that are selected through an annual application process. Rather than reviewing each criterion published by a PLE, CMS utilizes a qualification and review process to select qualified PLEs based upon requirements set forth in regulation.

PLEs are required to submit their application by January 31 of each year and, if approved, receive a qualification for a five-year period.

To date, CMS has completed three rounds of review of applications for organizations seeking to become qualified PLEs. Currently, there are 20 organizations—a combination of medical societies and providers—qualified as PLEs; the full list of organizations can be found on the CMS website.

PLE Qualifying Criteria

- ✓ Have an established evidence review process for developing or modifying an AUC
- ✓ Be led by a multidisciplinary team with "autonomous governance" and have strict adherence to a policy on the disclosure of potential conflict of interest
- ✓ Demonstrate transparency in the process for developing the criteria, the grading approach for the criteria, and the pipeline of criteria under consideration
- ✓ Publish each individual criterion on the PLE's website with the title, authors and key references used to establish the evidence
- ✓ Identify each AUC or AUC subset that is relevant to a priority clinical area
- ✓ Identify key points in an individual criterion as evidence-based or consensus-based, and grade such key points in terms of strength of evidence using a formal, published and widely recognized methodology
- ✓ Utilize a transparent process for the timely and continual updating of each criterion
- ✓ Publicly post the process for developing or modifying the AUC
- ✓ Disclose parties external to the PLE when such parties have involvement in the AUC development process

AUC DEVELOPMENT PROCESS

Appreciating the variations in clinical practice across the United States, CMS specifies that the AUC should be consistent with "local circumstances and populations," and allows flexibility in the program in three distinct ways:

- If there are multiple criteria for a specific condition-imaging

combination, the practitioner can choose the criteria that best align with local practice customs.

- When developing the criteria, PLEs can allow for different pathways or options that may come into play depending on clinical practice.
- Local provider organizations can seek to become qualified PLEs and then develop their own AUC.

While CMS has established strict requirements for PLEs, it acknowledges that there is still a risk that non-evidence-based criteria could be developed or endorsed in the program. To minimize that risk, CMS is allowing public stakeholders to submit comments—as part of the standard rulemaking process—on potentially non-evidence-based criteria. Once identified, non-evidence-based criteria will be reviewed by the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), which will make a determination on the details provided.

PRIORITY CLINICAL AREAS

The PAMA legislation requires that CMS identify outlier ordering professionals, defined as professionals with low adherence to applicable AUC in priority clinical areas selected by CMS. In the CY 2017 PFS Final Rule, CMS established eight initial areas that fall into this category based upon considerations such as the prevalence of disease, variability in the volume and utilization of the services, and the strength of the evidence supporting the use of the imaging service. Imaging associated with the eight priority conditions comprises approximately 40 percent of advanced diagnostic imaging furnished under Medicare Part B and includes the following priority clinical areas:

- 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

At a minimum, ordering professionals are required to consult applicable AUC for these areas, and adherence with such criteria will be used, in part, to measure clinicians' utilization for purposes of designating provider outliers. In the future, clinicians who are designated as outliers may be subject to additional prior authorization requirements when placing orders, but CMS has indicated that it will establish specific methods for determining outliers and will specify any resulting requirements in future rulemakings.

CONSULTATION AND REPORTING OF AUC REQUIRED FOR MEDICARE PAYMENT

As noted earlier, PAMA requires that *ordering professionals* consult AUC for applicable advanced diagnostic imaging services, and that *furnishing professionals* report information about the consultation on the claim form for Medicare payment. In the CY 2019 PFS Proposed Rule, CMS has not proposed any changes to the timeline for consulting and reporting AUC under the program. The timeline remains as follows:

- Ordering professionals are required to consult AUC through a qualified clinical decision support mechanism (CDSM) on or after January 1, 2020.
- Furnishing professionals must provide the following details on Medicare claims beginning January 1, 2020:
  - Which qualified CDSM was consulted by the ordering professional
  - Whether the service ordered would or would not adhere to specified applicable AUC, or whether specified applicable AUC were not applicable to the service ordered
  - NPI of the ordering professional (if different from the furnishing professional)

CMS notes that an AUC consultation must take place for every order for an applicable imaging service furnished in an applicable setting and under an applicable payment system. Moreover, qualified CDSMs must make available, at a minimum, AUC that reasonably address common and important clinical scenarios within all priority clinical areas. While a "not applicable" response is possible, CMS expects such response to be limited in scope and to decrease in frequency over time as the PLEs further build out the collection of AUC. CMS also establishes specific exceptions to the consultation and reporting requirement:

AUC Consultation Required if:
- ✓ Applicable imaging service
- ✓ Applicable setting
- ✓ Applicable payment system

Exceptions:
- ✓ Emergency services
- ✓ Inpatient services under Medicare Part A
- ✓ Ordering professionals with hardship exception

- For emergency services furnished to patients with emergency medical conditions
- For an inpatient encounter paid under Medicare Part A
- For ordering professionals who have been granted a significant hardship exception

Significant Hardship Exceptions

In the CY 2019 PFS Proposed Rule, CMS once again acknowledged the need to update the significant hardship exceptions that it previously established in its 2017 rulemaking to exempt select ordering professionals from the requirement to consult and report AUC in certain circumstances. The original criteria for hardship exceptions included the following:

- Insufficient Internet Connectivity (as specified in Section 495.102(d)(4)(i))
- Extreme and Uncontrollable Circumstances (as specified in Section 495.102(d)(4)(iii))
- Lack of Control over the Availability of CEHRT (as specified in Section 495.102(d)(4)(iv)(A))
- Lack of Face-to-Face Patient Interaction (as specified in Section 495.102(d)(4)(iv)(B))

CMS considered modifications to the significant hardship exceptions as part of the CY 2018 rulemaking cycle but did not finalize the proposed changes based in part on stakeholder feedback. After further review and consideration, in the CY 2019 Proposed Rule, CMS has proposed to establish revised significant hardship exceptions for the AUC program. The proposed modified criteria include the following:

- Insufficient internet access where the advanced diagnostic imaging service is ordered by the ordering professional
- Electronic health record (EHR) or CDSM connectivity issues, which CMS expects to be "irregular and unusual"
- Extreme and uncontrollable circumstances

Appreciating the time and burden of obtaining an exception, CMS proposes to allow for the ordering professional to self-attest when experiencing a qualified significant hardship at the time of the order. The ordering professional would communicate the information with the required documentation, and the furnishing professional and facility would reflect that on the claim by appending the appropriate modifier.

Clinical Decision Support Mechanisms

In order to access the library of applicable AUC offered by PLEs in the program, practitioners are required to utilize a qualified CDSM that allows them to electronically interface with available criteria in a streamlined fashion. In the CY 2017 PFS rule, CMS defined a CDSM as "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." The CDSMs may be modules within or accessible through certified EHR technology or private sector tools independent from EHR technology. Initially, CMS has not been prescriptive about specific IT standards for the CDSMs given the continuously evolving IT and EHR environments. There is an emphasis on the need to be integrated as seamlessly as possible.

CMS also defined the requirements and process for becoming a qualified CDSM under the AUC program. The CDSMs must meet the following requirements:

- Make available specified applicable AUC and their related supporting documentation
- Identify the AUC consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario
- Make available, at a minimum, specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas
- Be able to incorporate specified applicable AUC from more than one qualified PLE
- Determine the extent to which the applicable imaging service is consistent with specified applicable AUC
- Generate and provide a certification or documentation at the time of order that documents key information, including the CDSM consulted and details regarding the ordering physician
- Ensure modifications to AUC within the CDSM comply with the key timeline requirements
- Meet privacy and security standards under applicable provisions of law
- Provide to the ordering professional aggregate feedback regarding his or her consultations with specified applicable AUC in the form of an electronic report on at least an annual basis
- Maintain electronic storage of the clinical, administrative and demographic information of each unique consultation for a minimum of six years
- Comply with modification(s) to any requirements made through rulemaking within 12 months of the effective date
- Notify ordering professionals upon de-qualification

Applications for the first round of CDSMs were due in March 2017, with the first list of qualified CDSMs published in June 2017. As of July 2018, 11 CDSM tools have received full qualification, with an additional seven tools receiving preliminary qualification. The list of full and preliminary tools can be found on the CMS website.

OUTLIER ORDERING PROFESSIONALS

The final component of the program that CMS has yet to define is its approach to identifying outlier ordering professionals. Individuals identified as outliers would, at a future point in time, be subject to prior authorization requirements when ordering advanced diagnostic imaging services. While CMS has existing prior authorization programs, these programs have not focused on identifying outliers. Therefore, CMS is seeking input on the different data elements and thresholds that should be considered as CMS defines its methodology.

CMS notes that the first year of data for this analysis would be CY 2021 claims data given that CY 2020 is an operational testing period for the program. As a result, stakeholders should expect further discussions about the outlier methodology and process in the CY 2022 and CY 2023 rulemaking cycle.

For more information contact Deborah Godes or Eric Zimmerman.