



## **Medicare Physician Fee Schedule Final Rule for CY 2018 Appropriate Use Criteria for Advanced Diagnostic Imaging Services Summary**

### *Background and Overview*

The Protecting Access to Medicare Act of 2014 included a provision for the mandatory use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Through the CY 2016 rulemaking process, CMS addressed the initial component of the AUC program, specifying applicable AUC. CMS established a process for the development of AUC, defined provider-led entities (PLEs), and established the process by which PLEs may become qualified to develop AUC. The first list of [qualified PLEs](#) was posted on the CMS website in late June 2016.

The CY 2017 MPFS final rule identified the requirements clinical decision support mechanisms (CDSMs) must meet for qualification including an opportunity for preliminary qualification for mechanisms still working toward full adherence, and established a process by which CDSMs may become qualified. The first list of [qualified CDSMs](#) was posted to the CMS website in conjunction with the CY 2018 proposed rule in July 2017.

In addition, CMS defined applicable payment systems under this program (MPFS, Hospital Outpatient Prospective Payment System (HOPPS), and Ambulatory Surgical Center (ASC) payment system), specified the first list of priority clinical areas for the identification of outlier ordering professionals, and identified exceptions to the requirements that ordering professionals consults specified applicable AUC when ordering applicable imaging services.

The CY 2018 proposed rule included proposals for the start date of the Medicare AUC program, modification of policies related to significant hardship exceptions, and details regarding how AUC consultation information must be included on the Medicare claim. In this final rule, CMS makes changes to the proposals in response to comments received.

### *Program Implementation Date*

#### Proposals

CMS proposed that ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2019. The agency stated that this proposed effective date was necessary to allow time for ordering practitioners not already aligned with a qualified CDSM to research and evaluate the CDSMs so they may make an informed decision.

CMS noted that the proposed implementation date substantially lags the statutory requirement of January 1, 2017. The agency also indicated that unless a statutory exception applies, 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.

Given the delayed start date of the AUC program, CMS anticipated that implementation of the prior authorization component for outlier ordering professionals would also be delayed beyond January 1, 2020. The agency will outline details around outlier calculations and prior authorization in the CY 2019 proposed rule.

### Comments and CMS Response to Comments

1. CMS received comments in support of the January 1, 2019 start date as well as comments from stakeholders who do not want the AUC program implemented in 2019 or at any point in the future. These commenters want the program to be delayed indefinitely, discontinued or modified to the extent that participation is only voluntary as opposed to mandatory. Some of these commenters stated that the quality goals of the AUC program are duplicative of the quality goals of the Quality Payment Program (QPP) and that the AUC program runs counter to the agency's goal of reducing administrative burden for practitioners and providers.

CMS responded by reminding stakeholders that the AUC program and the QPP are the result of two distinct statutory requirements within PAMA and the Medicare Access and CHIP Reauthorization Act (MACRA) respectively. The agency agrees that the goals of the QPP are consistent with those of the AUC program. In addition, the AUC program promotes AUC to ensure the patient gets the right test at the right time and reduces inappropriate imaging.

2. Some commenters who support the AUC program suggested that CMS participate in additional stakeholder engagement, including creation of an advisory panel, listening sessions, town hall meetings and open door forums.

CMS agrees that additional stakeholder engagement would be beneficial and intends to establish these opportunities over the coming months.

3. CMS received comments requesting clarification on who is required to perform the AUC consultation and whether a designee within an ordering professional's practice could consult on behalf of the ordering professional and/or whether an ordering professional could delegate the consultation to another individual, third party vendor or contracted agent.

CMS reiterated the statutory requirement that an "ordering professional" consult with a qualified CDSM. The agency will consider developing policy to address this issue.

4. Some commenters requested clarification on how imaging order changes by the furnishing professional or radiology technician will be handled under the AUC program. Commenters recommended that furnishing professionals have the flexibility to adjust exam parameters or modify orders without consulting AUC, submit orders themselves if

they have relevant patient clinical information and occasionally use AUC as appropriate to demonstrate that a test was warranted.

CMS does not believe it was the intent of the PAMA to reverse existing rules around imaging order changes and ordering of additional studies by furnishing professionals. The agency will establish a means to account for instances when the order must be updated or modified in future rulemaking.

**In response to public comments, CMS is further delaying the effective date for the AUC consultation and reporting requirements to January 1, 2020. The agency is also finalizing a voluntary reporting period where early adopters can begin to report some consultation information on Medicare claims from July 2018 through December 2019.**

On January 1, 2020, the program will begin with an educational and operations testing period and during this time CMS will continue to pay claims whether or not they correctly include such information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020, and furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020.

#### *Claims Processing*

CMS notes that furnishing professionals are required to report the following information on Medicare claims for applicable imaging services:

1. Which qualified CDSM was consulted by the ordering professional;
2. Whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC were not applicable to the service ordered;
3. The NPI of the ordering professional (if different from the furnishing professional).

This information is required for both the technical and professional component claims for applicable advanced diagnostic imaging services in all three applicable payment systems (MPFS, HOPPS and ASC).

The rule acknowledges the possibility that AUC may not be available in a particular qualified CDSM to address every applicable imaging service that might be ordered and as such, the furnishing professional can meet the requirement to report information on the ordering professional's AUC consultation by indicating that AUC is not applicable to the service ordered. CMS points out that qualified CDSMs must make available, at a minimum, AUC that reasonably address common and important clinical scenarios within all priority clinical areas, which represent about 40 percent of advanced diagnostic imaging services paid for by Medicare in 2014. Additionally, the agency notes that they expect the "not applicable" situations to be limited in scope and number and to decrease over time as qualified PLEs continue to build out their AUC libraries and qualified CDSMs update their content and collaborate with more PLEs.

To implement the reporting requirement, CMS proposed to establish a series of HCPCS level 3 codes. These G-codes would describe the specific CDSM that was used by the ordering professional. Ultimately there would be one G-code for every qualified CDSM with the code description including the name of the CDSM. CMS also proposed to establish a G-code to identify circumstances where there was no AUC consultation through a qualified CDSM. The description of this code would indicate that a qualified CDSM was not consulted by the ordering professional.

These G-codes would be a line-item on both practitioner and facility claims. CMS would expect that one AUC consultation G-code would be reported for every advanced diagnostic imaging service on the claim. Each G-code would be expected, on the same claim line, to contain at least one new HCPCS modifier. CMS proposed to develop a series of modifiers to provide necessary information on whether or not the service would adhere to the applicable AUC or whether an exception is met.

Due to the complex nature of the program, CMS proposed an “educational and operations testing period” of one year, beginning January 1, 2019. During this period, ordering professionals would consult AUC and furnishing professionals would report AUC consultation information on the claim, but CMS would continue to pay claims whether or not they correctly include the information. This educational period allows providers to actively participate in the program while avoiding claims denials during the first year. It also gives CMS the opportunity to make any needed claims processing adjustments before payments are impacted.

CMS sought comment on whether the program should be delayed beyond the proposed start date of January 1, 2019 and/or if the educational and operations testing period should be longer than one year. The agency expected a voluntary reporting period to be available prior to January 1, 2019, possibly in July 2018, depending on the readiness of the Medicare claims system to accept and process claims that include AUC consultation information.

#### Comments and CMS Response to Comments

1. While some commenters agreed with the proposed G-code and modifier approach to capture AUC consultation information on Medicare claims, numerous other commenters expressed concern that the proposal would be excessively burdensome to practitioners. Several recommendations were made to CMS to avoid this burden, including the ACR’s recommendation that CMS require the use of a unique consultation identifier. This would allow CMS to match the claim with the more robust consultation data that is collected within the CDSM. This information may then be used for the identification of outlier ordering professionals. Commenters indicated that this would be the least administratively burdensome method approach. Other commenters suggested development of a registry to hold all AUC consultation information across CDSMs.

**CMS agreed with commenters that a less burdensome approach should be considered. In response to the comments received, the agency decided not to move forward with the G-code and modifier approach and will instead further explore and**

**pursue the use of the unique consultation identifier for reporting on Medicare claims. CMS will conduct stakeholder outreach during 2018 to develop a standard taxonomy and will discuss such changes in future rulemaking ahead of the 2020 effective date. CMS does expect that limited use of modifiers will be required in the future to identify exceptions to AUC consultation requirements.**

During the voluntary reporting period, one HCPCS modifier will be available to furnishing professionals and facilities reporting AUC consultation information. This modifier will identify only that AUC was consulted and not the result of the consultation and will be temporary as CMS moves forward to implement reporting with the unique consultation identifier.

2. One commenter asked whether claims for physicians billing Medicare Part B services for the professional component of advanced imaging services will require AUC consultation when the patient is an inpatient.

CMS responded that the physician's Part B professional claim would not require reporting of an AUC consultation when the technical component is billed under Medicare Part A.

3. A few commenters asked if orders for advanced diagnostic imaging services for patients in critical access hospitals (CAHs) are subject to the AUC consultation and reporting requirement.

CMS responded that any advanced diagnostic imaging service furnished within a CAH would not be furnished in an applicable setting. Applicable settings currently include physician offices, hospital outpatient departments and ambulatory surgical centers. CAH patients who are furnished an advanced diagnostic imaging service in an applicable setting but the claim for that imaging service is not paid under one of the applicable payment systems would not require consultation and reporting of the AUC consultation. This may apply in situations when a CAH has elected Method II billing.

4. CMS received several comments on the communication of AUC consultation information between the ordering and furnishing professionals.

CMS recognizes that there is a burden placed on furnishing professionals since ultimately they will be penalized if AUC consultation information is not provided; however, the PAMA specifically requires that the information be reported on the furnishing professional's claim. CMS will continue to seek opportunities to reduce the reporting burden.

5. CMS received numerous other comments on detailed aspects of communication of AUC consultation information and claims reporting. The agency responded that these comments are helpful and important as they develop and build out the outreach and education strategies.

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.

CMS indicated that if they adopt a policy to require reporting of the unique AUC consultation identifier on the furnishing professional's claim, they would expect the ordering professional to include that identifier on the order for the advanced diagnostic imaging service. Additional guidance will be provided once the details of the unique consultation identifier taxonomy are developed.

### *Voluntary and Educational and Operations Testing Periods*

CMS recognizes that there are many areas for potential missteps and errors in the implementation of this new AUC program. For these reasons, an educational and operations testing period is needed. During this period, ordering professionals would consult AUC and furnishing professionals would report AUC consultation information on the claim, but CMS would continue to pay claims whether or not they correctly include such information. This educational and operations testing period allows professionals to actively participate in the program while avoiding claims denials during the learning curve. It also gives the agency an opportunity to make any needed claims processing adjustments before payments are impacted. CMS does not expect to continue this educational and operations testing period beyond the first year of the AUC program.

In addition, CMS expects a voluntary reporting period to be available prior to the beginning of the operations and testing period in July 2018. CMS will make announcements through their educational channels (i.e. listservs and website) when the voluntary reporting period becomes available.

### Comments and CMS Response to Comments

1. Many stakeholders commented on the burden of the program and the need to further delay implementation.

CMS believes this program can be implemented in a manner that would minimize burden, but this will require additional stakeholder outreach, collaboration and time. **For practitioners and facilities that are ready to use qualified CDSMs or that are new to CDSMs and want to practice and refine their workflow, CMS will provide the voluntary period starting in July of 2018 that runs through CY 2019.**

**Given the agency's intention to use the educational and operations testing period to make needed adjustments to the program as well as identify any needs for further guidance and education, CMS will evaluate whether a second educational and operations testing year is necessary. The agency would like to retain this option in the event that, to be responsive to stakeholder feedback and the lessons learned, it is expedient to take additional time to fully implement the AUC consultations and reporting requirements.** However, since there are currently qualified PLEs and

qualified CDSMs, CMS expects to be prepared to quickly begin a voluntary participation period. Since the educational and operations testing period will not start until 2020, CMS is extending the voluntary participation period to 18 months from July 2018 through December 2019.

2. Some commenters asked for clarification on what is expected/required during the voluntary reporting period and the educational and testing period.

Since the first year of required AUC consultation and reporting will be an educational and operations testing period, CMS will not deny claims that fail to properly include AUC consultation information. The agency expects to adopt and communicate additional details and expectations for AUC consultation and reporting during the educational and operations testing period through further rulemaking and guidance before January 1, 2020.

#### *Alignment with Other Medicare Quality Programs*

The CY 2018 Quality Payment Program final rule included a finalization of the proposal to give Merit-based Incentive Payment System (MIPS) credit to ordering professionals for consulting AUC using a qualified CDSM as a high-weight improvement activity for the performance period beginning January 1, 2018. The agency believes this will incentivize early use of qualified CDSMs to consult AUC by motivated eligible clinicians looking to improve patient care and better prepare themselves for the AUC program.

CMS is also considering how the AUC program could serve to support a quality measure under the MIPS quality performance category and they seek feedback from the public regarding feasibility and value of pursuing this idea further. The agency will consider suggestions made in the public comment period as they continue to collaborate with other quality improvement programs and engage in future rulemaking.

#### *Significant Hardship Exceptions to Consulting and Reporting Requirements*

CMS proposed to modify the significant hardship exceptions to reflect the sunset of the payment adjustments under the Medicare EHR Incentive Program substituted an alignment with the advancing care information performance category of MIPS. The agency proposed the following categories for the AUC program significant hardship exceptions:

- Insufficient Internet Connectivity
- Extreme and Uncontrollable Circumstances
- Lack of Control over the Availability of CEHRT
- Lack of Face-to-Face Patient Interaction

The agency proposed to remove the hardship exception for those practicing for less than two years. CMS noted that only the ordering professional is allowed to seek a significant hardship exception, not the furnishing professional.

CMS proposed to establish a process for identifying ordering professionals in need of a significant hardship exception to the Medicare AUC requirements that is outside of the MIPS re-weighting process. A significant hardship exception for this program would be granted for no longer than 12 months, with the option to establish an exception for a shorter period where warranted by the circumstances. Further information on this process will be provided in future rulemaking.

#### Comments and CMS Response to Comments

Many commenters supported CMS' proposals to align the hardship exception with the QPP program and many also expressed concern. Other commenters expressed concern about the burden to the furnishing professional of identifying, tracking and reporting which ordering professionals have significant hardship exceptions.

**In response to public comments that varied widely, CMS decided not to finalize the proposed changes to the significant hardship exceptions in this final rule. The agency will take time to consider both the public comments on the proposals and the policies adopted in the CY 2018 QPP final rule and will revisit the issue in rulemaking for CY 2019.**

Some of the specific suggestions for expansion of the hardship exceptions included:

- Imaging services ordered as part of clinical research
- Emergency clinicians attempting to meet the current exclusion criteria
- Physicians nearing retirement or dealing with hardships who may not have data systems, capital, or the desire to invest in a qualified CDSM system
- Any time when a PLE or CDSM is de-qualified
- Complex medical systems
- Any physician who does not have access to free integrated CDSMs
- Physicians whose EHR cannot integrate into an existing qualified registry
- Ordering professionals that order a low-volume of advanced imaging services

More than one commenter cited the GAO's 2015 evaluation of the Medicare Imaging Demonstration which reported frustration on the part of ordering professionals when decision support was not integrated with their EHRs.

CMS agreed with concerns raised that the communication about a significant hardship exception from an ordering professional to a furnishing professional introduces potential challenges. The agency will continue to explore opportunities to use a more automated process for providing additional information to ordering and furnishing professionals in a timely manner in order to facilitate such communication and make the information readily accessible.

#### *Unintended Consequences and Other Comments*

CMS notes that some stakeholders have expressed concern that AUC program requirements may inadvertently encourage physicians to order imaging services that they do not believe are right for their patients. The goal of the evidence-based AUC is to assist clinicians in ordering the most



appropriate imaging services for their patients' specific clinical scenarios. To ensure the program is implemented effectively, CMS asked for public comment on such potential unintended consequences. The **agency** also sought comments on how they can continue to engage interested participants in developing AUC in a transparent and scientifically robust manner. CMS was particularly interested in how qualified PLEs develop or modify AUC in collaboration with non-PLE entities and what additional challenges such entities might face.

### Comments and CMS Response to Comments

#### 1. Comments on unintended consequences included:

- Decreased patient access or choices
- Inappropriate underutilization of imaging studies and harm to patients because of such a reduction
- Delays in beneficiaries receiving needed tests or even denial of services by furnishing professionals and facilities if AUC is not consulted or information is not provided by the ordering professional
- Healthcare rationing
- Shift in referral patterns
- Disruptions in physicians' practices and workflows
- Reduction in patient facing time for providers
- Unwarranted financial penalties for imaging facilities
- Increases in the cost of tests as CDSMs may recommend higher cost imaging
- Risk of impeding clinical research involving imaging

CMS stated that they appreciate being alerted to these potential unintended consequences so that they can closely monitor and mitigate these issues should they arise during the voluntary and educational and operations testing as the agency proceeds to implement this program.

#### 2. Some commenters expressed concerns regarding the definition of PLE codified in regulations in the CY 2016 MPFS final rule and the avenues by which entities not meeting the definition PLE can participate in the AUC program. These commenters reiterated their previously expressed opposition to the regulatory definition of PLE and requested revisions to allow participation by more organizations, inclusive of independent content developers, which they deem to be more reflective and in the spirit of the language in the statute describing a PLE.

CMS continues to believe the definition of PLE as established in the CY 2016 final rule is an accurate and appropriate interpretation of the statute. The agency does not feel a modification to the regulatory definition is necessary.

#### 3. Commenters questioned the endorsement pathway whereby qualified PLEs may endorse the AUC of other qualified PLEs, under agreement by the respective parties, to enhance an AUC set. Some commenters stated that independent content developers and third party entities cannot participate in the AUC program under the current definition and requested

that the regulations be revised to reflect the intent and language in the statute and to allow PLEs to endorse AUC from any author or developer.

CMS does not believe that AUC endorsed by any organization that could not meet the definition of PLE should be considered specified AUC under this program.

CMS strongly believes that non-PLE organizations can play a valuable role under the AUC program. This has already been demonstrated by collaboration arrangements between qualified PLEs and third party organizations such as independent content developers, and CMS expects these collaborations to continue to grow and evolve. The agency encourages stakeholders to explore options for collaboration under the guidelines of this policy.

4. Some commenters expressed opposition to the transparency requirements for qualified PLEs. These commenters stated that the transparency requirements are inappropriate because they require developers to place their intellectual property in the public domain. Commenters recommended instead that CMS allow alternative methods for making AUC information available upon request. For example, commenters suggested that requirements can be met by granting access to providers, beneficiaries and CMS to AUC on an as-needed basis or to customers through password protected portals.

CMS believes that to assure the public that all the statutory considerations are taken into account, transparency of the process is essential. This includes making publicly available the people, methodologies, and evidence used by developers. Failing to be transparent calls into question the degree to which AUC are indeed evidence based. AUC developed using non-evidence based sources could result in physicians and patients making the wrong decisions to guide care. Transparency allows AUC to be vetted by all stakeholders, including the patient and his/her physician, therefore allowing them to make informed decisions.

### *Summary*

CMS continues to believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDSM developers.

The following changes were made to the policies proposed in the CY 2018 MPFS proposed rule:

1. Extending the voluntary reporting period to 18 months starting July 2018 and continuing through CY 2019.
2. Making the AUC consultation and reporting requirements effective for an educational and operations testing period beginning on January 1, 2020, instead of January 1, 2019 as proposed, to last through CY 2020.
3. Not finalizing the changes to the significant hardship exceptions in this final rule as further evaluation is necessary. This will be addressed in rulemaking for CY 2019.

4. CMS will reevaluate the claims processing instructions and will further explore opportunities for stakeholder engagement.