



September 2015

# MEDICARE

## Considerations for Expansion of the Appropriate Use Criteria Program

## Why GAO Did This Study

PAMA required the establishment of a Medicare AUC program for advanced diagnostic imaging services. The Act also included a provision for GAO to report on the extent to which AUC could be used for other Medicare services, such as radiation therapy and clinical diagnostic laboratory services.

In this report, GAO describes (1) CMS's plans for implementing the imaging AUC program and (2) examples of questionable- or low-value nonimaging services where provider-led entities have developed AUC, among other objectives. GAO reviewed CMS's July 2015 Federal Register notice of proposed rulemaking outlining its initial plans for implementing components of the imaging AUC program and also interviewed CMS and AHRQ officials. To identify services for potential AUC program expansion, GAO focused on 36 nonimaging services deemed to be of questionable or low value as identified by the American Society for Radiation Oncology, the American Society for Clinical Pathology, and a 2014 study by researchers at Harvard Medical School. GAO also examined AHRQ's National Guideline Clearinghouse to determine whether AUC developed by provider-led entities were associated with those 36 services. GAO did not evaluate the extent to which the associated AUC are suitable for program implementation. Also, the resulting set of services is illustrative and not a comprehensive list of candidates for potential AUC program expansion.

HHS provided technical comments on a draft of this report, which were incorporated where appropriate.

View [GAO-15-816](#). For more information, contact James C. Cosgrove at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov).

## MEDICARE

### Considerations for Expansion of the Appropriate Use Criteria Program

## What GAO Found

The Centers for Medicare & Medicaid Services (CMS)—an agency within the Department of Health and Human Services (HHS)—has proposed initial plans and timeframes for implementing the Medicare appropriate use criteria (AUC) program for advanced diagnostic imaging services, such as computed tomography, magnetic resonance imaging, and positron emission tomography. AUC are a type of clinical practice guideline intended to provide guidance on whether it is appropriate to perform a specific service for a given patient. Under the Protecting Access to Medicare Act of 2014 (PAMA), a health care provider ordering advanced diagnostic imaging services generally must consult AUC as a condition of Medicare payment for providers who furnish imaging services. Consulting AUC involves entering patient clinical data into an electronic decision tool to obtain information on the appropriateness of the service. The agency's July 2015 notice of proposed rulemaking focused largely on the process for specifying applicable AUC to be used in the program and a policy for identifying providers who must obtain authorization from CMS before ordering imaging services due to their low adherence to appropriate ordering.

- CMS has proposed to qualify provider-led entities—such as national professional medical specialty societies—such that all AUC developed, endorsed, or modified by these entities would be eligible for use in the imaging program. To become a qualified source of AUC, provider-led entities must adhere to CMS standards for AUC development. The agency does not plan to evaluate and select imaging AUC itself because of the volume of those potentially available, according to CMS officials.
- CMS plans to establish priority clinical areas, and providers with low adherence to appropriate ordering—as determined by the AUC—in those areas will be subject to prior authorization. The agency intends to establish a number of priority clinical areas—potentially including low back pain, nontrauma headache, or acute chest pain—through rulemaking beginning in 2016. CMS officials stated that, given the variety of clinical scenarios for which imaging services may be ordered, the aim of establishing priority clinical areas is to narrow the potential scope of prior authorization.

Medicare services with associated AUC developed by provider-led entities represent potential candidates for AUC program expansion. Medical specialty societies and health care researchers—including the American Society for Radiation Oncology, the American Society for Clinical Pathology, and researchers at Harvard Medical School—have compiled lists of services considered to be of questionable or low value in certain clinical circumstances. GAO reviewed 36 of these services and found that provider-led entities have developed associated AUC for more than half of them, according to a database of clinical practice guidelines maintained by Agency for Health Research Quality (AHRQ). Specifically, GAO found associated AUC across several service categories, including radiation therapy, clinical pathology, cardiovascular testing and procedures, cancer screenings, diagnostic and preventive testing, and preoperative testing.

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## Abbreviations

AHRQ	Agency for Healthcare Research and Quality
AUC	appropriate use criteria
CDSM	clinical decision support mechanism
CMS	Centers for Medicare & Medicaid Services
HHS	Department of Health and Human Services
PAMA	Protecting Access to Medicare Act of 2014
UCLA	University of California Los Angeles

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September 30, 2015

The Honorable Orrin G. Hatch  
Chairman  
The Honorable Ron Wyden  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Paul D. Ryan  
Chairman  
The Honorable Sander M. Levin  
Ranking Member  
Committee on Ways and Means  
House of Representatives

Many researchers—including those at the Institute of Medicine, Medicare Payment Advisory Commission, and Dartmouth Institute for Health Policy and Clinical Practice—have reported considerable variation in how health care services are used and that patients are likely receiving some unnecessary services. In response, a number of national professional medical societies have identified tests and procedures that offer minimal benefit or that could even harm under certain circumstances and have made recommendations to improve the quality of health care. However, because a particular service may be appropriate for some patients but not for others, difficulties arise in customizing population-based recommendations to individual patients. Provider efforts to develop and apply appropriate use criteria (AUC)—a more patient-focused approach

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to reducing inappropriate care—may help enhance the quality of care and lead to health care savings.<sup>1</sup>

Over the past decade, questions have been raised about the potential overuse of advanced diagnostic imaging services—including magnetic resonance imaging, computed tomography and positron emission tomography—among other services and supplies covered by Medicare. In a 2008 report, we found that Medicare spending on advanced diagnostic imaging services more than doubled from 2000 through 2006, growing far faster than other imaging services, such as ultrasound and x-rays.<sup>2</sup> We recommended that Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) that administers the Medicare program—examine the feasibility of adding more front-end approaches, including prior authorization, to manage the spending growth.<sup>3</sup> However, according to CMS, the general consensus among health care providers and researchers is that the use of AUC to guide clinical practice is preferable to across-the-board utilization management controls that do not differentiate interventions that add value from those that cause harm or add no value. To test the impact AUC may have on advanced imaging service use, CMS conducted a 2-year Medicare imaging demonstration from 2011 through 2013, as required by law.<sup>4</sup> The Protecting Access to Medicare Act of 2014 (PAMA) directed HHS to establish an AUC program for advanced imaging services

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<sup>1</sup>AUC are a subset of clinical practice guidelines intended to provide guidance on whether it is appropriate to perform a specific service for a given patient. Clinical practice guidelines are generally considered broader and may apply to the overall management of particular diseases or conditions, whereas AUC are more targeted to a specific service for a specific patient.

<sup>2</sup>GAO, *Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices*, [GAO-08-452](#) (Washington, D.C.: June 13, 2008). Also see GAO *Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions*, [GAO-12-966](#) (Washington, D.C.: Sept. 28, 2012).

<sup>3</sup>Prior authorization is a utilization management tool where providers must seek coverage approval from payers before providing the service in order to be reimbursed.

<sup>4</sup>Medicare Improvements for Patients and Providers Act of 2008, Pub L. No. 110-275, § 135(b), 122 Stat. 2494, 2535 (2008).

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furnished to Medicare fee-for-service beneficiaries.<sup>5</sup> The law stipulated that providers who order imaging services must consult with AUC as a condition of payment for providers who furnish imaging services. Consulting with AUC involves entering patient data into an electronic decision tool to obtain information on the appropriateness of the service. The law further required that AUC must be developed or endorsed by national medical professional societies or other provider-led entities. Under the program, providers with a history of low adherence to appropriate ordering will be subject to prior authorization from CMS.

In addition to requiring the Medicare imaging AUC program, PAMA included a provision for us to report on the extent to which AUC could be used for other Part B services, such as radiation therapy and clinical diagnostic laboratory services. For purposes of this report, we will refer to advanced diagnostic imaging services as imaging services. In this report, we describe

1. CMS's plan for implementing the imaging AUC program,
2. examples of questionable- or low-value nonimaging services where provider-led entities have developed AUC to assist providers in making the most appropriate treatment decisions, and
3. considerations that would facilitate AUC program implementation and potential expansion to other services.

To describe CMS's plan for implementing the imaging AUC program, we reviewed the agency's July 2015 Federal Register notice of proposed rulemaking.<sup>6</sup> We also interviewed CMS officials responsible for managing the program to clarify the agency's proposed definitions and phased rollout of the program.

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<sup>5</sup>Pub. L. No. 113-93 § 218(b), 128 Stat. 1040, 1065 (2014) (codified at 42 U.S.C. § 1395m(q)). The law applies to Part B services, such as those provided in physician offices, hospital outpatient departments, and ambulatory surgical centers. The traditional fee-for-service Medicare program accounts for about 70 percent of all beneficiaries.

<sup>6</sup>Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 41,686 (proposed Jul. 15, 2015). According to CMS officials, the final rule is expected to be published on November 1, 2015.

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To describe examples of questionable- or low-value nonimaging services where provider-led entities have developed AUC, we took a two-step approach. First, we selected eight radiation therapy and nine clinical diagnostic laboratory services that the American Society for Radiation Oncology and the American Society for Clinical Pathology, respectively, considered of questionable value when provided in certain clinical situations.<sup>7</sup> We also selected 19 Medicare services considered to be of low value included in a 2014 study prepared by researchers at Harvard Medical School (hereafter referred to as the Harvard study).<sup>8</sup> We reviewed the methodologies used to identify questionable- and low-value services and considered them to be sufficiently reliable for the purposes of our report.

Second, we determined whether any of these 36 questionable- and low-value services had associated AUC developed by provider-led entities.<sup>9</sup> To do this, a physician on our study team examined the National Guideline Clearinghouse—a database of clinical practice guidelines maintained by HHS’s Agency for Healthcare Research and Quality (AHRQ).<sup>10</sup> Based on our review of related documentation and an interview with knowledgeable agency officials, we determined that the data in the National Guideline Clearinghouse were sufficiently reliable for the purposes of this report. We considered an AUC to be associated with a service if it closely corresponded to the questionable- or low-value application of the service as described by the medical specialty societies

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<sup>7</sup>Services identified by the American Society for Radiation Oncology and the American Society for Clinical Pathology were included in *Choosing Wisely*®, an initiative of the American Board of Internal Medicine Foundation which identified over 300 potentially wasteful or unnecessary medical services from more than 70 medical specialty societies. Because they were described only in general terms, we excluded 2 of the 10 services listed by American Society of Radiation Oncology and 1 of the 10 services listed by the American Society for Clinical Pathology.

<sup>8</sup>See Aaron L. Schwartz, Bruce E. Landon, Adam G. Elshaug, et al., “Measuring Low-Value Care in Medicare,” *Journal of the American Medical Association Internal Medicine*, vol. 174, no. 7 (published online May 12, 2014).

<sup>9</sup>We used definitions of AUC and provider-led entity as described in CMS’s notice of proposed rulemaking, while recognizing the tentative nature of these definitions pending CMS’s adoption of a final rule.

<sup>10</sup>The National Guideline Clearinghouse may not include all existing clinical practice guidelines. For example, some organizations may choose not to submit their clinical practice guidelines to the clearinghouse for inclusion, or alternatively, some guidelines may not meet AHRQ’s criteria for inclusion in the clearinghouse.



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or Harvard researchers. We also considered an AUC to be associated with a service if the AUC addressed a clinically specific use of a service that was broadly described.<sup>11</sup> The resulting set of services found to have associated AUC is for illustrative purposes and does not represent a comprehensive list of potential candidates for AUC program expansion. In addition, the associated AUC we found had varying levels of comprehensiveness in terms of the range of clinical scenarios to which the AUC may be applied. We did not evaluate the extent to which the associated AUC are in a format suitable for program implementation.

To describe considerations that would facilitate AUC program implementation and potential expansion to other services, we reviewed the 2014 evaluation of CMS's 2-year Medicare imaging demonstration performed by RAND.<sup>12</sup> To supplement this information, we reviewed medical professional publications related to the use of AUC by providers. In addition, we interviewed officials from CMS and AHRQ regarding participant experience with the Medicare imaging demonstration and the format and scope of AUC, respectively.

We conducted this performance audit from May 2015 to September 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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<sup>11</sup>For example, proton beam therapy for prostate cancer describes a specific procedure for a particular diagnosis. On the other hand, routine preoperative lab tests prior to elective surgical operations is much broader and can refer to many possible tests and procedures.

<sup>12</sup>Justin W. Timbie, Peter S. Hussey, Lane Burgette, et al., *Medicare Imaging Demonstration Evaluation Report for the Report to Congress*, prepared for CMS by the RAND Corporation (Santa Monica, CA: April 2014). We reviewed the RAND report and considered it to be sufficiently reliable for our purposes.

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## Background

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### AUC Development and Use

RAND and the University of California at Los Angeles (UCLA) School of Medicine developed a process for determining the appropriateness of a specific health care service for a particular patient, known as the RAND/UCLA appropriateness method.<sup>13</sup> An appropriate service was defined as one in which the expected health benefit exceeds the expected negative consequences by a sufficiently wide margin that the procedure is worth doing, exclusive of cost. In selecting services for AUC development, the RAND/UCLA authors outlined the following factors for consideration. A service should

- be frequently used,
- be associated with a substantial amount of morbidity and/or mortality,
- consume significant resources,
- exhibit wide variations among geographic areas in rates of use, or
- be controversial.

Numerous groups—including provider-led entities, such as medical specialty societies, and government or non-profit entities, such as the Centers for Disease Control and Prevention or the American Cancer Society—have developed AUC to assist providers in making the most suitable treatment decision for a particular patient.

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### Testing AUC for Imaging Services under Medicare Part B

From October 2011 through September 2013, CMS conducted the Medicare imaging demonstration to estimate the impact applying AUC would have on provider ordering practices and utilization. AUC were programmed into clinical decision support mechanisms (CDSM)—electronic tools in which providers enter patient characteristics, such as symptoms, diagnoses, prior test results, and demographic information. From the CDSM, providers received a rating on the degree of

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<sup>13</sup>The process involves reviewing the available scientific literature, developing a list of indications and definitions, convening an expert panel to review the information, identifying the collective opinion of experts, and classifying the appropriateness for a specific service as appropriate, uncertain, or inappropriate. See Kathryn Fitch, Steven J. Bernstein, Maria Dolores Aguilar, et al., *The RAND/UCLA Appropriateness Method User's Manual* (Santa Monica, CA: 2001).

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appropriateness of their imaging order (appropriate, equivocal or uncertain, or inappropriate). If the order could not be linked to any criteria in the CDSM, no rating would be assigned. Instead, the CDSM would notify the provider that the order was not covered by the guidelines.

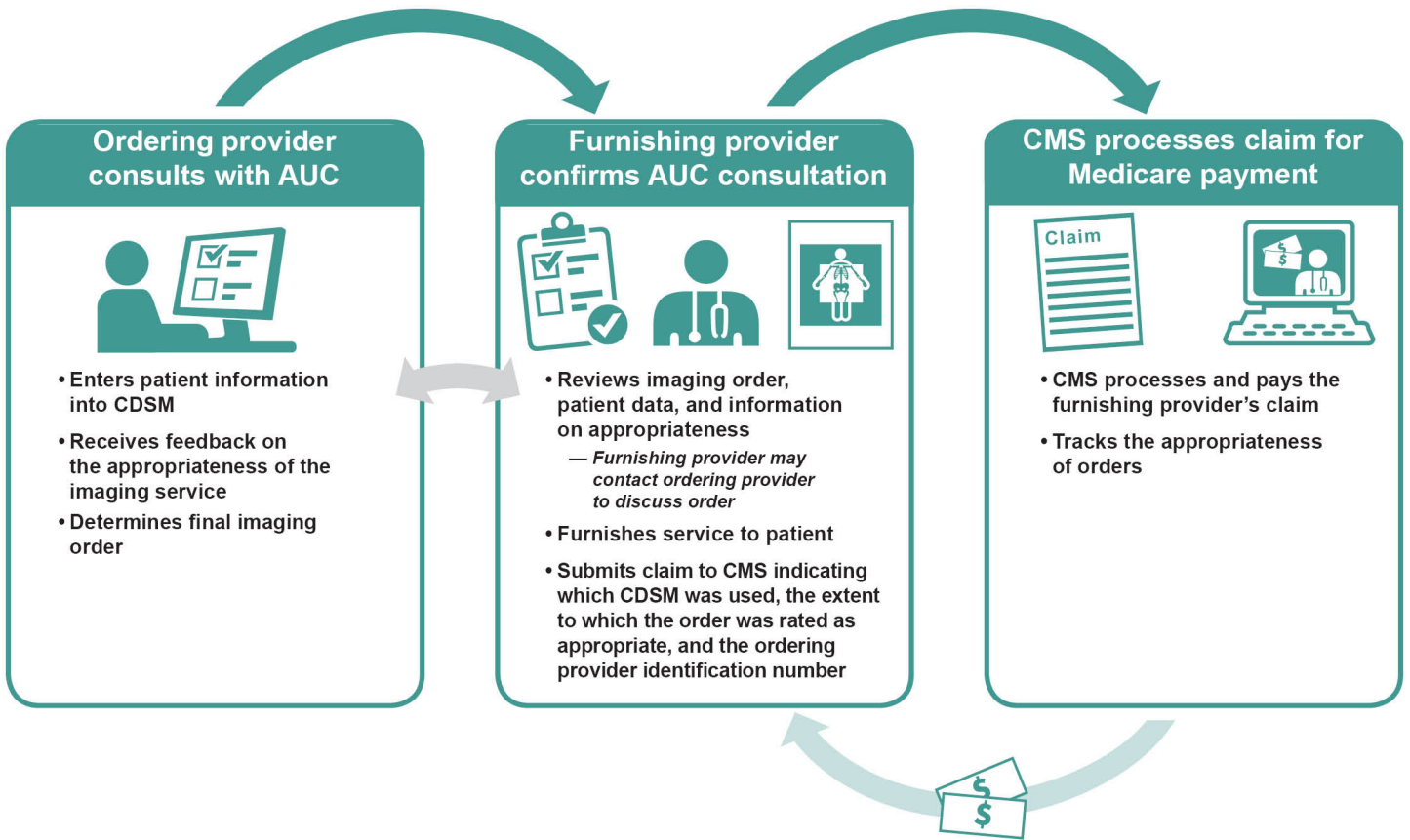
The RAND evaluation of the demonstration found an increase in the percentage of orders that were rated as appropriate over the course of the demonstration. However, the authors noted that, due to the large proportion of orders that could not be linked to any criteria, the results do not necessarily indicate an improvement in the rate of appropriate ordering. For this reason, among others, the evaluation of the demonstration recommended against expanding the use of AUC for imaging services to a broader population of Medicare beneficiaries.

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## Legislative Requirements for the Imaging AUC Program

PAMA stipulated that, as of January 2017, providers ordering imaging services (including primary care and specialty care providers) generally will be required to consult AUC through a qualified CDSM. The results of the AUC consultation generally must be documented on the claim submitted by providers furnishing imaging services (typically radiologists) in order to be paid by Medicare. (See fig. 1.)

**Figure 1: Use of Clinical Decision Support Mechanisms (CDSM) and Payment of Claims under the Medicare Imaging Appropriate Use Criteria (AUC) Program**



Legend: AUC = Appropriate Use Criteria; CDSM = Clinical Decision Support Mechanism; CMS = Centers for Medicare & Medicaid Services.

Sources: GAO analysis of CMS information (data); GAO and Art Explosion (clipart). | GAO-15-816

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To fully implement the imaging AUC program, CMS must complete several components over the next 5 years, as outlined in PAMA:

- **Specify applicable AUC by November 15, 2015.** Through rulemaking, and in consultation with stakeholders, CMS must specify one or more AUC. The AUC may only be developed or endorsed by national professional medical specialty societies or other provider-led entities, not by CMS. The agency must take into account whether the AUC have stakeholder consensus, are scientifically valid and evidence-based, and are derived from studies that are published and reviewable by stakeholders. CMS must annually review AUC to determine the need for any updates or revisions.
- **Publish a list of qualified CDSMs by April 1, 2016.** With stakeholder input, CMS must specify one or more qualified CDSMs that may be used by ordering providers for AUC consultation. Mechanisms may include modules in certified electronic health record technology, other private sector CDSMs, or mechanisms established by CMS. The CDSMs must be able to execute certain functions, such as generating and providing a certification or documentation that the CDSM was used by the ordering provider. The list must be updated periodically and include one or more CDSMs per imaging service that are available free of charge.<sup>14</sup>
- **Roll out imaging AUC program by January 1, 2017.** Ordering providers generally must provide to the furnishing provider certification that they have consulted with specified AUC using a qualified CDSM. Furnishing providers generally will only be paid if their Medicare claims for imaging services indicate which CDSM was used, whether the order would or would not adhere to any applicable AUC, and the ordering provider identification number.<sup>15</sup>

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<sup>14</sup>Some researchers have pointed out that more data on the potential harms of using CDSMs are needed before widespread adoption can be recommended. For example, see Caroline Lubick Goldzweig, et al., "Electronic Health Record-Based Interventions for Improving Appropriate Diagnostic Imaging," *Annals of Internal Medicine*, vol. 162, no. 8 (Philadelphia, PA: Apr. 21, 2015).

<sup>15</sup>CMS officials stated that Medicare payment is not limited to imaging services rated as appropriate by specified AUC. Furthermore, it may be clinically desirable under certain circumstances for ordering providers to recommend a service rated as inappropriate and for a furnishing provider to render that service. For example, the evaluators of the demonstration raised concerns about the limited applicability of AUC for patients with comorbid conditions.

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- **Begin the process for identifying outlier ordering providers on January 1, 2017.** For services furnished beginning in 2017, CMS must annually determine up to 5 percent of all ordering providers who are outliers based on their low adherence to appropriate ordering. In making these determinations, CMS must use 2 years of data starting from January 1, 2017 and consult with stakeholders in order to develop methods to identify outlier ordering providers. CMS must also establish a process for determining when a provider's outlier designation should be removed.
  - **Implement prior authorization beginning January 1, 2020.** Imaging services ordered by an outlier provider will be subject to prior authorization from CMS. In applying prior authorization, the agency may only use specified AUC.

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## CMS's Initial Implementation Plan Focuses on the Process for Specifying Applicable AUC and Establishing Priority Clinical Areas for Future Prior Authorization

In its July 2015 notice of proposed rulemaking, CMS outlined its initial plan and timeframes for implementing the imaging AUC program. While CMS's initial plan touches on each implementation component of the program, it focused largely on the process for specifying applicable AUC and establishing priority clinical areas for future prior authorization policy. Given the need to consider stakeholder comments and that progress on early components affects the timing of subsequent components, CMS's initial plans to implement certain components of the program extend beyond the dates outlined in PAMA.

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### Specifying Applicable AUC

To respond to the PAMA requirement of specifying applicable AUC, CMS is proposing to qualify provider-led entities such that all AUC developed, endorsed, or modified by these entities may be eligible for use in the imaging program. The agency does not intend to evaluate and select AUC itself because of the volume of those potentially available, according to CMS officials. Once an entity is qualified by CMS, all applicable AUC developed, endorsed, or modified by that entity would become specified applicable AUC under the program. In addition, CMS is proposing recertification every 6 years. The agency's proposed definition for a provider-led entity is a national professional medical specialty society or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of health care, such as hospitals and health systems.

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CMS has proposed that individual AUC must link a specific clinical condition, one or more imaging services, and an assessment of the appropriateness of the service(s). To respond to PAMA's requirement for AUC development, the agency proposed that, to become qualified, provider-led entities must demonstrate that their process for developing, endorsing, or modifying AUC includes certain elements such as

- a rigorous evidentiary review process whereby key decision points within each criteria are graded according to the strength of evidence using a formal, published, and widely recognized methodology;
- a multidisciplinary team with autonomous governance to lead the AUC consideration process;
- a publicly transparent process for identifying and disclosing potential conflicts of interest;
- public postings of their AUC and their AUC development process on the entity's website; and
- a transparent process for the timely and continual updating of each AUC.

Under PAMA, CMS is required to specify applicable AUC by November 15, 2015. However, CMS does not anticipate posting its initial set of qualified entities on its website until the summer of 2016. As a result, the agency does not expect to specify applicable AUC until at least 7 months after the PAMA-specified timeframe.

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## Prior Authorization Policy

To respond to PAMA's requirement that prior authorization be applied to ordering providers with low adherence to appropriate ordering, CMS plans to establish priority clinical areas and limit its identification of outlier ordering providers to these areas. In developing the priority clinical areas, CMS may consider incidence and prevalence of diseases, volume and variability of utilization, strength of evidence for imaging services, and applicability to a variety of care settings and to the Medicare population. According to agency officials, given the variety of clinical scenarios for which imaging services may be ordered, the aim of establishing priority clinical areas is to narrow the potential scope of prior authorization. They also stated that low back pain, nontrauma headache, and acute chest pain are examples of potential priority clinical areas. CMS expects to identify the first set of priority clinical areas in the rulemaking cycle that begins in 2016 in consultation with stakeholders and to further develop its

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policy to identify outlier ordering providers. Additional priority clinical areas may be added during each rulemaking cycle.

In addition, the agency is proposing a process by which it will be made aware of potentially nonevidence-based AUC associated within the established priority clinical areas. CMS is planning to have a standing request for public comments in all future AUC-related rulemaking notices so the public has ongoing opportunities to assist the agency in identifying AUC that may not be sufficiently evidence-based. CMS may consult the Medicare Evidence Development and Coverage Advisory Committee in reviewing any potentially nonevidence-based AUC.<sup>16</sup> If, through this process, AUC are determined to be insufficiently evidence-based, and the provider-led entity that produced the criteria does not make a good faith attempt to correct the issue, this information could be considered when the provider-led entity applies for requalification.

According to CMS officials, the proposed process does not include review of potentially nonevidence-based AUC outside of the established priority clinical areas. To respond to PAMA's requirement that specified applicable AUC be reviewed each year, they stated that, in addition to accepting public comments regularly on potentially nonevidence-based AUC associated with the established priority clinical areas, they will also review the requirements and process for AUC development as a part of CMS's annual rulemaking.

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## Status of Identifying Qualified CDSMs

Under PAMA, CMS is required to publish a list of qualified CDSMs by April 1, 2016. To do so, CMS must determine which CDSMs are suitable for use in the program. The agency's July 2015 notice of proposed rulemaking did not contain specifics on this implementation component. The agency plans to provide clarifications, develop definitions, and establish the process by which it will specify qualified CDSMs through the rulemaking process in 2016. The agency stated that it does not plan to publish a list of qualified CDSMs until after November 1, 2016, at least 7 months after the PAMA-specified timeframe.

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<sup>16</sup>The Medicare Evidence Development and Coverage Advisory Committee is composed of experts on specific clinical topics, evidence-based medicine, epidemiology, clinical trial design, and ethics, according to CMS officials.



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## Provider-Led Entities Have Developed AUC Related to a Number of Services Deemed of Questionable or Low Value

Medical specialty societies and health care researchers have undertaken efforts to identify services that are of questionable or low value under certain circumstances and therefore have the potential to be used inappropriately. Based on our examination of the AHRQ National Guideline Clearinghouse, we found that provider-led entities—as defined in CMS’s notice of proposed rulemaking—have developed AUC associated with a number of these services. These questionable- and low-value services with associated AUC are potential candidate services if the AUC program were to expand beyond imaging services.

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## Many Services Have Been Identified As Having Questionable Or Low Value

Since 2012, as a part of the *Choosing Wisely*® initiative, national medical specialty societies have identified health care services of questionable value. Among the hundreds of services included in the *Choosing Wisely*® initiative, we reviewed 17 radiation therapy and clinical pathology services of questionable value under certain circumstances. The following are among those we reviewed:

- The American Society for Radiation Oncology surveyed its members to collect a list of potential services, convened a work group to select key services from the initial list, conducted literature reviews, and received input from its board of directors to inform its final selection. For example, the group recommended against routine follow-up mammography more often than annually for women who have had radiotherapy following breast conserving surgery. In addition, it recommended that providers not routinely prescribe proton beam therapy over other forms of definitive radiation therapy for prostate cancer.
- The American Society for Clinical Pathology convened a review panel of pathology and laboratory medicine experts to evaluate the literature and identify services that are frequently performed; that are of no benefit or harmful; that are costly and do not provide higher quality care; and where eliminating the service or alternatives are within the control of the provider. Among the services identified, the group recommended against prescribing testosterone therapy without laboratory evidence of testosterone deficiency. The group also recommended avoiding routine preoperative testing for low-risk elective surgeries without a clinical indication.

In addition, researchers at Harvard Medical School compiled a list of 26 low-value Medicare-covered services, of which we reviewed 19 nonimaging services. The researchers deemed a service to be of low value if, on average, it provided little to no clinical benefit, either in

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general or in specific clinical scenarios. They developed their set of low-value services from the *Choosing Wisely*<sup>®</sup> initiative, the U.S. Preventive Services Task Force ratings of services with a ‘D’ grade, the National Institute for Health and Care Excellence “do not do” recommendations, the Canadian Agency for Drugs and Technologies in Health technology assessments, and peer-reviewed literature.<sup>17</sup> The 19 nonimaging services fell into 5 categories: cardiovascular testing and procedures, cancer screening, diagnostic and preventive testing, preoperative testing, and other surgery. In addition, the Harvard study estimated the proportion of Medicare beneficiaries receiving the low-value services and total spending devoted to these services.

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### Provider-Led Entities Have Developed AUC For Some, But Not All, Questionable- And Low-Value Services

We found that provider-led entities have developed AUC for some, but not all, of the questionable- or low-value services we reviewed. Our analysis of AHRQ’s National Guideline Clearinghouse indicated that provider-led entities have developed AUC for more than half of the 36 questionable- or low-value services included in our review. Specifically, 23 services had at least 1 associated AUC developed by a provider-led entity.<sup>18</sup> For the remaining 13 services, we did not find any associated AUC in the National Guideline Clearinghouse.

Among the 17 radiation therapy and clinical pathology questionable-value services identified by the respective medical specialty societies, 12 services had an associated AUC developed by a provider-led entity. (See table 1.) For example, the American College of Radiology has developed an AUC for appropriate radiation therapy following hysterectomy for endometrial cancer patients. In other cases, we found multiple associated AUC for a single questionable service. For instance, the American College of Obstetricians and Gynecologists and the American Society for

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<sup>17</sup>The task force recommends against furnishing services with a “D” grade because there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. In a 2012 report, GAO suggested that Congress consider requiring beneficiaries to share the cost of a service if the task force recommends against use of that particular service for those beneficiaries. See GAO, *Medicare: Use of Preventive Services Could Be Better Aligned with Clinical Recommendations*, [GAO-12-81](#) (Washington, D.C.: Jan. 18, 2012).

<sup>18</sup>Associated criteria may have been developed or endorsed by multiple provider-led entities. In addition, the National Guideline Clearinghouse contains criteria submitted by other entities, such as government-affiliated entities (U.S. and foreign), and disease-specific organizations.

Colposcopy and Cervical Pathology have each developed criteria for the appropriate use of human papilloma virus testing for low-risk abnormal pap smears.

**Table 1: Examples of Questionable-Value Services for which Provider-Led Entities Have Developed Appropriate Use Criteria, as of June 2015**

<i>Radiation therapy</i>
Whole breast radiotherapy
Proton beam therapy for prostate cancer
Intensity modulated radiotherapy as a part of breast conservation therapy
Radiation following hysterectomy for endometrial cancer patients
Radiation therapy for patients with resected early-stage, non-small cell lung cancer
Mammograms in follow-up of breast cancer
Whole brain radiation for metastases
<i>Clinical pathology</i>
Human papilloma virus testing of low-risk abnormal pap smears
Routine preoperative lab tests prior to elective surgical operations
Testosterone therapy in the absence of laboratory evidence of testosterone deficiency
Creatine kinase (muscle-brain) in the diagnosis of acute myocardial infarction
Multiple tests in initial evaluation of a patient with suspected non-neoplastic thyroid disease

Source: GAO analysis of the American Board of Internal Medicine Foundation's *Choosing Wisely*® and the Agency for Healthcare Research and Quality's National Guideline Clearinghouse. | GAO-15-816

In addition, we found associated AUC developed by provider-led entities for 11 of the 19 low-value services identified in the Harvard study. (See table 2.) For example, the American College of Physicians has developed AUC regarding the appropriate use of stress testing for those with stable coronary disease. In addition, the American College of Radiology has developed criteria outlining the appropriate conditions under which inferior vena cava filters may be used to prevent pulmonary embolism.

**Table 2: Examples of Medicare Services Deemed of Low Value by Researchers for which Provider-Led Entities Have Developed Appropriate Use Criteria as of June 2015, and Estimated 2009 Spending and Service Use**

Services <sup>a</sup>	2009 spending (millions of dollars) <sup>b</sup>	2009 Medicare beneficiary use (count per 100 beneficiaries) <sup>b</sup>
<i>Cardiovascular testing and procedures</i>		
Stress testing for stable coronary disease	\$212 to 2,065	0.8 to 7.8
Renal artery angioplasty or stenting	139 to 705	0.1 to 0.4
Carotid endarterectomy for asymptomatic patients	110 to 263	0.1
Inferior vena cava filters to prevent pulmonary embolism	43	0.2
<i>Cancer screening</i>		
Cervical cancer screening for women aged 65 years and older	111 to 120	6.5 to 7.0
Colorectal cancer screening for older elderly patients <sup>c</sup>	7 to 573	0.9 to 7.7
Prostate-specific antigen testing for men aged 75 and older	23 to 98	2.8 to 12.0
<i>Diagnostic and preventive testing</i>		
Bone mineral density testing at frequent intervals	17 to 20	0.8 to 1.0
<i>Preoperative testing</i>		
Preoperative chest radiography	22 to 75	1.6 to 5.5
<i>Other surgery</i>		
Vertebroplasty or kyphoplasty for osteoporotic vertebral fractures	196 to 199	0.3
Arthroscopic surgery for knee osteoarthritis	63 to 143	0.1 to 0.2

Source: GAO analysis of Aaron L. Schwartz et al., "Measuring Low-Value Care in Medicare," *Journal of the American Medical Association Internal Medicine*, vol. 174, no. 7 (published online May 12, 2014) and the Agency for Healthcare Research and Quality's National Guideline Clearinghouse. | GAO-15-816

Notes:

<sup>a</sup>The services listed are measure descriptions. The Harvard study provides more specific operational definitions of low-value occurrences.

<sup>b</sup>The range of spending and use estimates reflect two sets of calculations. One set was based on higher specificity, a more narrow approach which was less likely to misclassify appropriate use as inappropriate. The other set focused on higher sensitivity, a broader approach capturing more inappropriate use (but also some potentially appropriate use). Spending calculations included payments from Medicare, beneficiary coinsurance amounts, and payments from other primary payers. Use calculations are based on fee-for-service Medicare beneficiaries aged 65 years or older.

<sup>c</sup>Older elderly was defined as 85 years and older under the higher specificity calculation and 75 years and older under the higher sensitivity calculation.

As indicated in the RAND/UCLA report, the selection of services for an AUC program generally takes into account the service's frequency of use and resources consumed, among other factors. The Harvard researchers used claims and enrollment data—such as procedural codes, beneficiary diagnoses, and age—to determine the extent to which the low-value services were used and the associated expenditures. The researchers reported their results as a range using two approaches. The more narrow approach was based on higher specificity and was less likely to misclassify appropriate use as inappropriate. The broader approach

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focused on higher sensitivity, capturing more inappropriate use but also some potentially appropriate use. For example, in 2009, estimated inappropriate spending for colorectal cancer screening ranged from \$7 million for beneficiaries 85 years and older to \$573 million for those 75 years and older and affected 0.9 to 7.7 percent of beneficiaries of each group, respectively.<sup>19</sup> The wide range in inappropriate service use, as measured by the two approaches, indicates how difficult it may be to select services for program expansion that have the most potential for improving health care quality and reducing wasteful spending.

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## Clinical Decision Tool Capabilities and Provider Confidence Are Among Key Considerations for an Effective AUC Program

We identified several issues that are key to the effective implementation of the imaging AUC program or any future expansion of the program, including the utility of the CDSM and provider confidence in the applicable criteria. Such issues surfaced during the Medicare imaging demonstration and, according to the RAND evaluation of the demonstration, may have limited its success. Because they are not specific to imaging services, they likely would apply to services considered for program expansion as well.

- **Effectively mapping clinical indications to applicable AUC.** Programming an adequate variety of patient characteristics into CDSMs would allow the mapping of clinical indications to available AUC to be sufficiently robust.<sup>20</sup> During the demonstration, almost two-thirds of orders placed by providers could not be linked to any criteria in CDSMs; therefore, providers did not receive an appropriateness rating (appropriate, uncertain or equivocal, or inappropriate) for these orders. Providers reported issues with locating a diagnosis or clinical scenario relevant to their patient or that the clinical information they

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<sup>19</sup>Spending calculations in the Harvard study included payments from Medicare, beneficiary coinsurance amounts, and payments from other primary payers, and use calculations are based on fee-for-service Medicare beneficiaries aged 65 years or older. The Harvard study calculations do not reflect the full extent of low-value care spending or use of additional tests or procedures—also known as downstream services—that may result from the initial service.

<sup>20</sup>The format and scope of AUC have important implications for efficient use and broad clinical applicability in a CDSM. For example, CMS officials told us that not all AUC employ decision trees—a tree-like graph or model of multiple options and their corresponding decision end points—which are conducive to an efficient, algorithmic logic for CDSMs. In addition, CMS officials said that providers use a variety of AUC approaches with some developed for a specific imaging service and others developed for a specific clinical condition.

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did successfully enter about their patients into the CDSM did not result in any matches to AUC. The evaluators of the demonstration cited technical issues with mapping clinical indications to the distinguishing features of each AUC programmed into the CDSMs.

- **Enhancing clinical decision making.** Only well-developed CDSMs can adequately assist providers with meaningful clinical decisions. Many providers in the demonstration found the CDSM feedback presented to them—that is, the appropriateness rating or the links to the AUC, if applicable—was not specific enough to assist with decisions for specific patients or situations. Providers said that they expected detailed, actionable feedback about their orders to guide them in their decision making. In addition, providers reported that the CDSMs would have been more helpful if they had provided feedback before the order was placed, rather than after; specifically, some said they would have preferred entering the clinical indication or other patient information first in order to receive guidance on what to order.
- **Designing CDSMs for ease of use.** Whether CDSMs are integrated with electronic health record systems or web-based or stand-alone software applications, providers prefer those that can be used quickly and efficiently. In the demonstration, providers using web-based or stand-alone software applications experienced frustration with the lack of integration between the CDSM and their electronic health record system. For example, providers had to click out of their electronic health record system and go through an entirely new platform to order imaging services. Additionally, providers wanting to change orders would have to start from the beginning and go through the entire process again. This process caused workflow inefficiencies for busy providers.
- **Ensuring provider confidence in appropriateness ratings and their underlying evidence.** To secure provider buy-in, it is important that ratings not be based on outdated evidence or conflict with local guidelines or other best practice guidelines. Providers who participated in the demonstration were not always comfortable with the appropriateness ratings that were assigned to their orders and wanted more transparency than was available about how the ratings were assigned, especially when evidence was known to be limited. Providers wanted more information regarding the quality of evidence used to generate AUC and more detail about the level of agreement associated with appropriateness ratings.
- **Allowing sufficient preparation time for implementation.** Due to the complex and wide scope of changes associated with implementing AUC, allowing adequate preparation time for

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stakeholders is critical. Providers who participated in the demonstration noted that all phases of the demonstration were too short to address the large number of challenges related to successfully engaging providers and staff, aligning existing and new workflow patterns, and introducing providers and staff to the CDSM software and guidelines. Providers reported inadequate time for set up, planning, pilot testing, implementation, internal evaluation, and change. Efforts to move forward rapidly during the demonstration were confounded by CDSM software challenges beyond the control of participants and their practices, as well as escalating frustrations and disengagement by providers.

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## Agency Comments and Our Evaluation

The Department of Health and Human Services reviewed a draft of this report and provided technical comments, which we incorporated where appropriate.

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We are sending copies of this report to appropriate congressional committees and the Administrator of CMS. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix I.



James C. Cosgrove  
Director, Health Care

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# Appendix I: GAO Contact and Staff Acknowledgments

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## GAO Contact

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## Staff Acknowledgments

In addition to the contact named above, Rosamond Katz, Assistant Director; Kye Briesath; Stella Chiang; Maria A. Maguire; Vikki L. Porter; and Jennifer M. Whitworth made key contributions to this report.



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*Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions.* [GAO-12-966](#). Washington, D.C.: September 28, 2012.

*Medicare: Use of Preventive Services Could Be Better Aligned with Clinical Recommendations.* [GAO-12-81](#). Washington, D.C.: January 18, 2012.

*Medicare Part B Imaging Services: Rapid Spending and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices.* [GAO-08-452](#). Washington, D.C.: June 13, 2008.

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