The Protecting Access to Medicare Act (PAMA – see pages 3-8 herein for the text of this federal law) authorizes Medicare to promote the use of “appropriate use criteria” (AUC) before ordering advanced diagnostic tests for Medicare patients. Medicare has not launched an educational campaign at this time because this program is only partially implemented.


Appropriate Use Criteria include evidence-based guidelines for diagnostic imaging selection, radiotherapy protocols, and image guided interventional procedures. Initially, claims for advanced imaging studies within eight “priority clinical areas” will be evaluated for payment according to the physician’s use of appropriate use criteria as reported on the claim. The method of reporting this information on claims is not yet formed; CMS is considering G-codes and/or modifiers.

CMS identified the following list of priority clinical areas for which physicians will be expected to consult clinical decision support mechanisms (CDSMs):

- 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.

While an implementation date is not set, CMS concedes that the earliest an entity may be able to comply with the unformed reporting requirements will be January 1, 2018.
CMS Developing Appropriate Use Criteria Regulations

According to the 2017 Medicare Physician Fee Schedule Final Rule,

“We are considering the mechanisms for appending the AUC consultation information to various types of Medicare claims and expect to develop requirements for appending such information in the CY 2018 PFS rulemaking process. ...We were particularly interested in receiving feedback on, for example, whether the information should be collected using HCPCS level II G codes or HCPCS modifiers.”

CMS has approved some Qualified Provider-Led Entities (qPLE) to develop “clinical decision support mechanisms” (CDSMs). A CDSM is a functionality that provides persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care. At the earliest, the first qualified CDSM(s) will be specified on June 30, 2017.

Multiple CDSM sets may be approved; at this time, Medicare expects that claims for advanced imaging studies for patients within one of the eight priority clinical areas will report which qualified CDSM was consulted by the ordering professional for the service; whether the service, based on the CDSM consultation, adheres to specified applicable AUC, does not adhere to specified applicable AUC or whether no criteria in the CDSM were applicable to the patient's clinical scenario.

The American College of Radiology has announced its approval by Medicare as a qPLE:

https://www.acr.org/Quality-Safety/Appropriateness-Criteria
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While the law allows the requirements to be implemented beginning January 1, 2017, CMS stated in the 2017 Medicare Physician Fee Schedule Final Rule that “At the earliest, the first qualified CDSM(s) will be specified on June 30, 2017. We anticipate that some ordering professionals could be able to begin consulting AUC through qualified CDSMs very quickly as some may already be aligned with a qualified CDSM.”

A link and an excerpt of the pertinent portion of the PAMA law is provided below:

https://www.govtrack.us/congress/bills/113/hr4302/text

218. Quality incentives for computed tomography diagnostic imaging and promoting evidence-based care

(b) Promoting evidence-Based care.—

(1) In general. — Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by subsection (a), is amended by adding at the end the following new subsection:

(q) Recognizing appropriate use criteria for certain imaging services.—

(1) Program established.—

(A) In general.—The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

(B) Appropriate use criteria defined.—In this subsection, the term “appropriate use criteria” means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

(C) Applicable imaging service defined.—In this subsection, the term “applicable imaging service” means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines—

(i) one or more applicable appropriate use criteria specified under paragraph (2) apply;

(ii) there are one or more qualified clinical decision support mechanisms listed under paragraph (3)(C); and
(iii) one or more of such mechanisms is available free of charge.

(D) Applicable setting defined.— In this subsection, the term “applicable setting” means a physician’s office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

(E) Ordering professional defined.— In this subsection, the term “ordering professional” means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service.

(F) Furnishing professional defined.— In this subsection, the term “furnishing professional” means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service.

(2) Establishment of applicable appropriate use criteria.—

(A) In general.— Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

(B) Considerations. — In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria—

(i) have stakeholder consensus;

(ii) are scientifically valid and evidence based; and

(iii) are based on studies that are published and reviewable by stakeholders.

(C) Revisions.— The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

(D) Treatment of multiple applicable appropriate use criteria.—

In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.
PAMA - continued

(3) Mechanisms for consultation with applicable appropriate use criteria.—

(A) Identification of mechanisms to consult with applicable appropriate use criteria.—

(i) In general. — The Secretary shall specify qualified clinical decision support mechanisms that could be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

(ii) Consultation. — The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

(iii) Inclusion of certain mechanisms.—Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1848(o)(4)).

(II) Use of private sector clinical decision support mechanisms that are independent from certified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

(III) Use of a clinical decision support mechanism established by the Secretary.

(B) Qualified clinical decision support mechanisms.—

(i) In general.— For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

(ii) Requirements.— The requirements described in this clause are the following:

(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.
(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

(VI) The mechanism meets privacy and security standards under applicable provisions of law.

(VII) The mechanism performs such other functions as specified by the Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.

(C) List of mechanisms for consultation with applicable appropriate use criteria.—

(i) Initial list.—Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

(ii) Periodic updating of list.—The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

(4) Consultation with applicable appropriate use criteria.—

(A) Consultation by ordering professional.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall—

(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

(B) Reporting by furnishing professional.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)),
payment for such service may only be made if the claim for the service includes the following:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

(II) whether the service ordered would not adhere to such criteria; or

(III) whether such criteria was not applicable to the service ordered.

(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

(C) Exceptions.—The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

(i) Emergency services.—An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1867(e)(1)).

(ii) Inpatient services.—An applicable imaging service ordered for an inpatient and for which payment is made under part A.

(iii) Significant hardship.—An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

(D) Applicable payment system defined.—In this subsection, the term “applicable payment system” means the following:

(i) The physician fee schedule established under section 1848(b).

(ii) The prospective payment system for hospital outpatient department services under section 1833(t).

(iii) The ambulatory surgical center payment systems under section 1833(i).
(5) Identification of outlier ordering professionals.—

(A) In general.—With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

(B) Outlier ordering professionals.—The determination of an outlier ordering professional shall—

(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

(ii) include data for ordering professionals for whom prior authorization under paragraph (6)(A) applies.

(C) Use of two years of data.—The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

(D) Process.—The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

(E) Consultation with stakeholders.—The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

(6) Prior authorization for ordering professionals who are outliers.—

(A) In general.—Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

(B) Appropriate use criteria in prior authorization.—In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

(C) Funding.—For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.
CMS Developing Appropriate Use Criteria Regulations

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(7) Construction. — Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.

Excerpts from the Federal Register/2017 Medicare Physician Fee Schedule Final Rule (AUC discussion begins on page 80403):


“…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. We further believe that section 1834(q)(4)(B) of the Act accounts for the possibility that AUC may not be available in a particular qualified CDSM to address every applicable imaging service that might be ordered; and thus, 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.

“We are considering the mechanisms for appending the AUC consultation information to various types of Medicare claims and expect to develop requirements for appending such information in the CY 2018 PFS rulemaking process. We encouraged stakeholders interested in sharing feedback related to reporting and claims processing to do so as part of the comment period to inform this final rule. We were particularly interested in receiving feedback on, for example, whether the information should be collected using HCPCS level II G codes or HCPCS modifiers.”