PUBLIC COMMENT SUMMARY REPORT

Project Title: Development, Reevaluation, and Implementation of Outpatient Outcome/Efficiency Measures

Dates:

The Call for Public Comment ran from **Monday, August 24, 2020** through **Thursday, September 24, 2020.**

The Public Comment Summary was posted on **Wednesday, December 16, 2020**.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) and its partner, the Lewin Group (Lewin), to respecify an outpatient imaging efficiency measure, *Lumbar Spine Imaging for Low Back Pain* (OP-8). The contract name is Development, Reevaluation, and Implementation of Outpatient Outcome/Efficiency Measures. The contract number is HHSM-HHSM-75FCMC18D0042, the task order number is HHSM-75FCMC19F002. As part of its measure development process, Yale/CORE and Lewin requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project. The project's primary objectives, as they relate to this public comment period, included the following:

- Respecification of OP-8 to further align the measure with current clinical guidelines and practice, incorporating improvements previously suggested by stakeholders, including:
  - Providing feedback on the respecified measure specifications;
  - Making assessments on the measure's importance, face validity, feasibility, and usability; and
  - Recommending improvements as needed.

Information About the Comments Received:

The measure developer solicited public comments by conducting outreach to notify key stakeholders and the general public about the comment period for *Lumbar Spine Imaging for Low Back Pain*. This outreach included the following:

- Posting a notification about the measure on the CMS public comment website and asking for comments, and
- Sending e-mails to the following stakeholders and stakeholder organizations:

- American Academy of Physical Medicine and Rehabilitation
- American College of Radiology
- American Hospital Association
- American Medical Association
- American Nuclear Society
- American Orthopedic Association
- American Osteopathic College of Radiology
- American Roentgen Ray Society
- American Society of Emergency Radiology
- American Society of Neuroradiology
- American Society of Radiologic Technologists
- American Society of Spine Radiology
- American Spinal Injury Association
- Association of University Radiologists
- Clinical Magnetic Resonance Society
- Lumbar Spine Research Society
- North American Spine Society
- Radiological Society of North America
- Society of Nuclear Medicine
- Society of Radiation Oncology Administrators
- Society of Thoracic Radiology

We received seven unique responses from five different organizations on this topic. The following professional organizations submitted responses during the public comment period:

- American Society of Neuroradiology
- American Academy of Physical Medicine and Rehabilitation
- American Medical Association
- American Association of Neurological Surgeons and Congress of Neurological Surgeons
- American College of Radiology

Stakeholder Comments

General Stakeholder Comments:

No general stakeholder comments were received during the public comment period for the *Lumbar Spine Imaging for Low Back Pain* measure.

Measure-Specific Stakeholder Comments:

Appropriateness of Measure Exclusion Conditions

Several commenters recommend updates to the list of excluded conditions.

Two commenters expressed concern that the current list of exclusions may not be sufficient based on previous NQF reviews of the measure.

Four commenters recommended osteoporosis or osteopenia be considered for the list of denominator exclusions.

One commenter recommended the exclusion of conditions related to cancer or infection (including unexplained weight loss, urinary infection, and prolonged use of corticosteroids) and cauda equina syndrome (including acute onset of urinary retention or overflow incontinence, loss of anal sphincter tone or fecal incontinence, saddle anesthesia, and global or progressive motor weakness in the lower limbs). This commenter also suggested extending the look-back period for the trauma exclusion from 45 to 90 days.

One commenter requested that cauda equina syndrome be listed as its own excluded condition, as opposed to being grouped with the neurologic impairment exclusion.

Response: Thank you for providing feedback on the exclusions for the *Lumbar Spine Imaging for Low Back Pain* measure. The measure developer will consider the appropriateness of adding the recommended exclusions, including their impact to the denominator population, to the measure as its technical specifications are finalized.

Elderly Age Exclusion

Feedback about the advanced age exclusion and the age at which a person is considered elderly was equivocal.

Four commenters stated that elderly individuals, without underlying etiology, should be included in the list of denominator exclusion criteria. The age at which a person is considered elderly, however, differed among the individual commenters, with ages ranging from 50 to 70.

One commenter stated that age alone, according to the 2015 *Low Back Pain* Appropriateness Criteria® (published by the American College of Radiology), is not supported as an independent red flag condition. The commenter indicated that

there is no statistically significant difference in primary outcome after one year for older adults who had spine imaging within the six weeks following an initial visit for low back pain when compared to similar individuals who did not undergo early imaging.

Response: Thank you for providing feedback on the exclusions for the *Lumbar Spine Imaging for Low Back Pain* measure. The current measure guideline is based upon the American College of Radiology's Appropriateness Criteria® on Low Back Pain (2015), which does not support age as an independent red-flag condition for early imaging of individuals with low back pain. The list of measure exclusions is designed to capture the underlying etiology for which an individual (including elderly persons) may receive appropriate early imaging for low back pain. The measure development team will continue evaluating the appropriateness of excluding elderly individuals, based on age alone, from the measure.

Imaging Modalities

Feedback about the imaging modalities used to identify the numerator population was equivocal.

Five commenters recommended including CT myelography as an imaging modality within the measure's numerator, as it is often used when MRI is contraindicated.

Two commenters recommended including dynamic films as an imaging modality within the measure's numerator.

One commenter did not recommend the inclusion of CT myelography as an imaging modality within the measure's numerator. The commenter noted that the procedure is uncommonly performed for low back pain alone and is typically used when there is a preexisting condition or if MRI is contraindicated for the patient. The commenter also noted that myelography is an invasive procedure that introduces the patient to the risk of an adverse event.

Response: Thank you for providing feedback about the imaging modalities being considered for the *Lumbar Spine Imaging for Low Back Pain* measure. We will consider the appropriateness of including CT myelography and dynamic films as imaging modalities, given the intent of the measure.

Validity

Two commenters expressed concern about the use of administrative claims data, stating that it cannot be used as a data source to capture all forms of antecedent conservative therapy sufficiently. These commenters recommended the measure developer work with stakeholders to identify alternative data sources from which the measure could be calculated.

Response: Thank you for providing feedback about the validity of *the Lumbar Spine Imaging for Low Back Pain* measure. The measure developer will consider your concerns about using administrative claims data to capture antecedent conservative therapy adequately within the measure's numerator as we finalize the measure's specifications.

Usability

Two commenters stated that unintended consequences of using the measure may include missed or delayed diagnosis and subsequent development of significant pathology (such as infection) that is associated with ambiguous signs and symptoms, including low back pain.

One commenter stated that an unintended consequence of the measure may be delayed imaging caused by the failure of a patient to report a red-flag condition.

One commenter stated that the proposed measure is useful, as there is a relatively poor correlation between imaging findings and symptoms for many patients. Furthermore, unnecessary surgeries are often prompted by and subsequently performed due to misleading imaging findings, resulting in poor patient outcomes and wasteful resource utilization. Implementation of this measure, therefore, may be beneficial in reducing unnecessary healthcare costs.

One commenter stated that the numerator and denominator, as proposed, adequately measure facility compliance with current clinical practice guidelines.

Two commenters stated that the proposed measure specifications may not necessarily reflect inappropriate use of imaging, but instead reflect provider and patient preferences, regardless of performance at the facility level.

Response: Thank you for providing feedback about the usability of the *Lumbar Spine Imaging for Low Back Pain* measure. We will consider your comments, including potential unintended consequences associated with implementation of the measure, as we finalize the technical specifications.

Preliminary Recommendations

The *Lumbar Spine Imaging for Low Back Pain* measure development team will review commenters' suggestions with CMS, identifying potential modifications to the proposed measure specifications to address feedback about the denominator exclusions (including look-back periods), imaging modalities used to identify the numerator population, and measure validity. We will also provide details on measure testing and integrate additional guidance into the measure rationale, as appropriate. We will make recommendations for next steps based on discussions with CMS and the measure's technical expert panel.

Overall Analysis of the Comments and Recommendations

Feedback on the *Lumbar Spine Imaging for Low Back Pain* measure was highly informative—commenters expressed support for the measure's usability and the comprehensive list of exclusions. Several individuals recommended additional exclusion criteria and imaging modalities for consideration, as well as expressed validity concerns given the inability to capture all forms of antecedent conservative therapy using administrative claims data. We thank all of the commenters and organizations for providing their feedback and perspectives on this important measure.

Date Posted/ Received	Name, Credentials, and Organization of Commenter	Text of Comments	Response
9/21/20	Noushin Yahyavi, MD *American Society of Neuroradiology*	Studies have shown that degenerative changes on the spine imaging are not necessarily associated with presence or severity of back pain (1, 2). In addition, imaging findings of degenerative changes in the spine are highly prevalent in asymptomatic individuals with increasing age (2) and are likely part of normal aging. Degenerative disc changes are seen in up to 96% of asymptomatic patients at age 80 (2). Therefore, while imaging spine in elderly patients is sensitive for detecting degenerative changes, findings may not correlate with symptoms or change the outcome/add value. Thus, excluding elderly solely based on age may result in over-imaging and over-treatment of these individuals. In cases of elderly with osteoporosis, osteoporotic compression fractures can be better detected with MRI of lumbar spine and may lead to vertebral augmentation for symptomatic relief. These individuals may experience a fracture without significant trauma which results in back pain. There is approximately 10% prevalence of osteoporosis, and 44% prevalence of low bone mass in adults over 50 in the United States (3). Detection of recent fractures in older individuals with underlying osteopenia or osteoporosis is difficult on CT and often results in performing both CT and MRI. Therefore, MRI is superior for older adults. Age cut-of used can be above 50. If MRI is contraindicated and CT does not provide adequate information (hardware from prior surgery, tumor infiltration in the epidural space, …), CT myelography is a good replacement for MRI. As discussed above, osteoporosis or osteopenia may be added to the list of excluded conditions, if exclusion for elderly is removed from the measure.	Thank you for providing feedback on the specifications for *the Lumbar Spine Imaging for Low Back Pain* measure. The current measure guideline is based upon the American College of Radiology's Appropriateness Criteria® on Low Back Pain (2015), which does not support age as an independent red-flag condition for early imaging of individuals with low back pain. Instead, the list of measure exclusions is designed to capture the underlying etiology for which an individual (including elderly persons) may receive appropriate early imaging for low back pain. The measure development team will continue to evaluate the appropriateness of excluding elderly individuals, based on age alone, from the measure. We will also consider the appropriateness of adding osteoporosis and/or osteopenia as exclusion conditions for the measure, as well as CT myelography as an imaging modality used to identify the numerator population, given the intent of the measure.

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9/21/20	John E. Jordan, MD, MPP, FACR *American Society of Neuroradiology*	I would consider excluding older patients greater than 50-55 years of age. In this age range unforeseen events such as neoplasia or osteoporosis may manifest with significant back pain requiring prompt clinical evaluation and management. Similarly, imaging of headache guidelines have a suggested age cutoff of 50 years of age (see ACR Appropriateness Criteria for imaging and headache). I think this is a reasonable age cutoff as a proxy for somewhat higher risk groups. - CT myelography in combination or myelography alone should also be included in the measure specifications. CT-myelography (CTM) is often ordered in lieu of MR particularly if there is a contraindication to MRI. Moreover, CTM is invasive and has more patient risk of adverse events than noncontrast MRI. Rarely, less experienced practitioners may order myelography alone (which is also invasive, with potential contrast risks). - I think the current list of exclusions is appropriate. - OP-8 is useful as most back pain will resolve with conservative measures. There is a relatively poor correlation between imaging findings and symptoms (and prognosis) in many patients. For example, it is well documented that unnecessary surgeries often are performed and prompted by misleading imaging findings; and imprecise surgeries may result in poor patient outcomes, and a wasteful utilization of resources. Hence the intent and usefulness of the measure in promoting quality care for Medicare beneficiaries is valid in my view. -The problem with the measure is that facility quality and performance are not necessarily reflected by inappropriate use of imaging, which more often reflects provider and often patient preferences irrespective of the facility. Other confounding factors that might affect clinical decision making (and the utility of the measure) include fear of litigation and patient complaints/dissatisfaction. - Unintended consequences could include missing significant pathology such as infection with ambiguous signs and symptoms, or tumors, both of which might warrant immediate attention and management. Delays in diagnosis could negatively impact quality of care and patient outcomes in certain cases.	Thank you for providing feedback on the specifications for *the Lumbar Spine Imaging for Low Back Pain* measure. The current measure guideline is based upon the American College of Radiology's Appropriateness Criteria® on Low Back Pain (2015), which does not support age as an independent red-flag condition for early imaging of individuals with low back pain. Instead, the list of measure exclusions is designed to capture the underlying etiology for which an individual (including elderly persons) may receive appropriate early imaging for low back pain. The measure development team will continue to evaluate the appropriateness of excluding elderly individuals, based on age alone, from the measure. The most recent guidelines from the American College of Radiology (2015) do not recommend the inclusion of CT myelography or myelography alone in cases of patients presenting with uncomplicated low back pain. We will discuss your concerns about the potential for missing data internally to ensure that key data elements are appropriately specified in the measure's development. We will also consider the appropriateness of adding CT myelography as an imaging modality used to identify the numerator population, given the intent of the measure, as well as your comments on the measure's usability (including the potential unintended consequences).
9/21/20	Peter McCreight, MD *American Society of Neuroradiology*	I am in full agreement with Dr. Bradley's article, details and recommendations, please see the article attached in the email.	Thank you for providing feedback on the specifications for the *Lumbar Spine Imaging for Low Back Pain* measure. We will consider the article to which you make reference as we finalize the technical specifications for the measure.

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9/23/20	Joseph Hornyak, MD, PhD *American Academy of Physical Medicine and Rehabilitation*	We question the absence of Cauda Equina Syndrome (and its associated symptoms of saddle anesthesia, bowel/bladder incontinence, etc.) in the exclusion list. The closest exclusion that it could be included with would be possibly "Neurologic impairment" but this is simply too broad, particularly as Cauda Equina is a very specific set of symptoms which often warrants emergent surgical decompression. Cauda Equina deserves to be listed on its own. The list is otherwise fairly comprehensive.	Thank you for your feedback on the specifications for the *Lumbar Spine Imaging for Low Back Pain* measure. Cauda equina syndrome is currently captured under the *Neurologic Impairment* exclusion. We will consider including cauda equina syndrome (and its associated symptoms) as a separate exclusion in the narrative specifications as we finalize the measure.
9/24/20	Koryn Rubin *American Medical Association*	The American Medical Association (AMA) appreciates the opportunity to submit comments on the draft CMS Lumbar Spine Imaging for Low Back Pain measure. The AMA asks that CMS carefully consider the concerns raised during the last two reviews by the National Quality Forum (NQF) when developing and testing of this revised measure (2017). Specifically, the committee questioned whether the list of exclusions were sufficient and expressed concerns that administrative claims data would not capture all of antecedent conservative therapies received by a patient. These questions on the validity of the data must be adequately addressed prior to any implementation of this measure and if claims data do not provide valid information on a facility's performance then the measure should not be finalized. The AMA also recommends that the measure exclude individuals with chronic steroid use and osteoporosis. In addition, we request that the measure exclusions account for the fact that there are circumstances where advanced imaging— particularly dynamic films, CT, and CT myelography— are extremely valuable and should not be excluded from surgical workup. For example, these modalities may be useful for problem solving in cases where MRI is either non-diagnostic or contraindicated.	Thank you for your feedback about the *Lumbar Spine Imaging for Low Back Pain* measure. We will assess the appropriateness of adding osteoporosis and chronic steroid use as exclusion conditions for the measure, as well as CT lumbar spine, CT myelography, and dynamic film as imaging modalities used to identify the numerator population, given the intent of the measure. We will also consider your concerns about using claims data to adequately capture antecedent conservative therapy, as we finalize the specifications for the measure.

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9/24/20	John A. Wilson, MD *American Association of Neurological Surgeons* Brian L. Hoh, MD *Congress of Neurological Surgeons*	In general, the AANS and the CNS request that CMS consider the concerns raised during the last two reviews by the NQF when evaluating this revised measure. Specifically, the NQF committee questioned whether the list of exclusions was sufficient and expressed concerns that administrative claims data would not capture all of the antecedent conservative therapies received by a patient. These issues must be adequately addressed before CMS implements this revised measure. If claims data do not provide valid information on a facility's performance, then the measure should not be finalized, and CMS should work with stakeholders to evaluate alternative data sources. The AANS is collaborating with the American Academy of Orthopaedic Surgeons (AAOS) in sponsoring the American Spine Registry (ASR), a national quality improvement registry for spine care that collects procedural data, postoperative data, and patient-reported outcome measurement (PROM) data. The ASR expands on the formative AANS Quality Outcomes Database (QOD) Spine Registry — previously the nation's largest spine registry — to offer a more far-reaching data collection platform that facilitates the participation of all North American spine surgeons. Data points and metrics supported by the ASR have been informed by clinical experts performing these procedures and are backed by the most current evidence-based literature. We encourage CMS to consider the ASR as a resource for not only best practice, but also for feasible metrics that can be implemented across federal programs nationwide. The AANS and CNS agree that yes, advanced age is a red flag for potentially treatable pathology. As noted below, the current red flag is greater than 64 years. In uncomplicated low back pain in the elderly, plain films are appropriate within the first six weeks. Advanced imaging (CT, MRI, and dynamic films) is appropriate to investigate radiographic findings on the initial films, if red flags for malignancy or osteoporosis are present, or if symptoms persist beyond six weeks. The current red flag is greater than 64 years. Yes, CT myelography should be added. The AANS and the CNS recommend that the measure exclude individuals with chronic steroid use and osteoporosis. The measure exclusions also should account for the fact that there are circumstances where advanced imaging — particularly dynamic films, CT and CT myelography — is extremely valuable and should not be excluded from the surgical workup. For example, these modalities may be useful for problem-solving when MRI is either non-diagnostic or contraindicated. A potential unintended consequence of this measure is that some patients may have imaging delayed due to failure to report a red flag.	Thank you for your feedback about the *Lumbar Spine Imaging for Low Back Pain* measure. We will assess the appropriateness of adding osteoporosis and chronic steroid use as exclusion conditions for the measure, as well as CT lumbar spine, CT myelography, and dynamic films as imaging modalities used to identify the numerator population, given the intent of the measure. We will also consider your concerns about using administrative claims data to adequately capture antecedent conservative therapy, as we finalize the specifications for the measure. Additionally, in regards to the exclusion of elderly individuals, the current measure guideline is based upon the American College of Radiology's Appropriateness Criteria® on Low Back Pain (2015), which does not support age as an independent red-flag condition for early imaging of individuals with low back pain. Instead, the list of measure exclusions is designed to capture the underlying etiology for which an individual (including elderly persons) may receive appropriate early imaging for low back pain. With that said, we will continue evaluating the appropriateness of excluding elderly individuals, based on age alone, from the measure. Lastly, we will consider your comments about the potential unintended consequences of the measure, as we finalize it for implementation.

9/24/20	William T. Thorwarth, MD, FACR *American College of Radiology*	In framing the objectives for updating OP-8, CMS states "re-specification of the measure presents an opportunity to align the updated measure with current clinical guidelines and practice." The ACR strongly recommends use of the most current ACR Appropriateness Criteria (AC) for Low Back Pain, which was revised in 2015. CMS' proposed re-specification continues to identify the 2007 ACR AC for Low Back Pain as a reference guideline for this measure. The 2015 ACR AC for Low Back Pain includes statements that do not support age as an independent red flag for appropriateness of lumbar spine imaging. "Previous guidelines have suggested that imaging be performed in adults >50 years of age who present with LBP. When studied, there was no statistically significant difference in primary outcome after 1 year for older adults who had spine imaging within 6 weeks after an initial visit for care for LBP versus similar patients who did not undergo early imaging," thus, [the current American College of Radiology Appropriateness Criteria for Low Back Pain] does not include age older than 50 as an independent red flag." Based on the current guidelines, the ACR does not recommend excluding elderly patients without previously diagnosed underlying etiology based on their age alone. Our opinion is that a better approach would be to use specific risk conditions as exclusions that would sufficiently remove elderly patients with underlying conditions from the denominator rather than a blanket age exclusion. The exclusions currently identified are relatively comprehensive and are reflective of the most "red flags" considered to raise suspicion for a serious underlying condition as included in the 2015 ACR AC for Low Back Pain. However, the ACR advises CMS to include the additional conditions as exclusions as listed below: - Red flags for Cancer or Infection: unexplained weight loss, urinary infection (if not covered under the current "infectious conditions" exclusion), prolonged use of corticosteroids - Red flags for spinal fracture: minor fall or heavy lift in a potentially osteoporotic or elderly individual, prolonged use of steroids - Red flags for Cauda Equina Syndrome or severe neurologic compromise: acute onset of urinary retention or overflow incontinence, loss of anal sphincter tone or fecal incontinence, saddle anesthesia, global or progressive motor weakness in the lower limbs The ACR does not recommend the inclusion of CT myelography to the measure specifications. This procedure is uncommonly performed for an indication of low back pain alone, and typically when there is a pre-exiting condition or if MRI is contraindicated for a patient. The 2015 ACR AC for Low Back Pain does state "CT myelography could be performed to assess the patency of the	Thank you for your feedback about *the Lumbar Spine Imaging for Low Back Pain* measure. We agree that advanced age, alone, without a previously diagnosed underlying etiology, does not warrant exclusion from the measure; instead, the list of measure exclusions is designed to capture the underlying etiology for which an individual (including elderly persons) may receive appropriate early imaging for low back pain. As we finalize the measure specifications, we will consider the appropriateness of excluding symptoms related to red flag conditions, such as cancer, spinal fracture, and cauda equina syndrome, as well as extending the look-back period for the trauma exclusion to 90 days, given the intent of the measure. We will also assess the appropriateness of adding CT myelography to the list of imaging modalities used to identify the numerator population. Lastly, we will consider your comments about the unintended consequences of the measure, as we finalize it for implementation.

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		spinal canal/thecal sac and of the neural foramen in patients who cannot undergo MRI." However, myelography requires an invasive procedure to introduce intrathecal contrast agents and introduces patient risk of adverse event more so than non-contrast MRI. Overall, the ACR agrees with the current list of excluded conditions. The ACR recommends adding other risk factors for vertebral compression fractures, such as osteoporosis and steroid use, as well as major risk factors for cancer. Additionally, the ACR suggests modifying the current trauma exclusion look-back period from 45 days to 90 days, at minimum. As mentioned above, the ACR advises CMS to review the list of red flags and underlying conditions indicated in the 2015 ACR AC for Low Back Pain to determine the appropriate exclusions. OP-8 is useful, as most back pain will resolve with conservative measures. There is a relatively poor correlation between imaging findings and symptoms (and prognosis) in many patients. It is well documented that unnecessary surgeries often are performed and prompted by misleading imaging findings; and imprecise surgeries may result in poor patient outcomes, and a wasteful utilization of resources. The ACR believes that the numerator and denominator specified will adequately measure facility compliance with guidelines. However, facility quality and performance are not necessarily reflected by inappropriate use of imaging, which more often reflects provider and patient preferences irrespective of the facility. Other confounding factors that might affect clinical decision-making include fear of litigation and patient complaints and/or dissatisfaction. As with any measure, there is the risk of rare occurrence of abnormalities that go undetected because no clinical warning signs are present. These unintended consequences could include missing significant pathology such as infection with ambiguous signs and symptoms, or tumors, both of which might warrant immediate attention and management. However, by adopting this measure, the overall benefits are great with respect to reducing unnecessary health care costs.	