**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0514

**Measure Title**: MRI Lumbar Spine for Low Back Pain

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 03/03/2014 (2014 Submission) | 11/03/2016 (2016 Submission)

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| **Instructions**  *Complete 1a.1 and 1a.12 for all measures.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Overuse of magnetic resonance imaging (MRI) lumbar-spine studies for patients with low back pain for which there is no evidence of attempts at antecedent conservative therapy (2016 Submission).

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

Other: Efficiency (2014 Submission)

**1a.12** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

The process of identifying MRI studies of the lower back for patients for which antecedent conservative therapy has not yet been performed demonstrates instances of over usage. This awareness has led to incremental improved outcomes, , including attempts at non-invasive therapeutic procedures, better coordination of patient care, reduced exposure to contrast agents, and more efficient use of imaging resources.

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES- State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process (e.g., intervention, or service).**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | **2014 Submission:**  1 - Bussieres AE, Taylor JA, Peterson C. Diagnostic imaging practice guidelines for musculoskeletal complaints in adults-an evidence-based approach-part 3: spinal disorders. J Manipulative Physiol Ther. 2008 Jan; 31(1):33–88. Guideline available at <http://www.ncbi.nlm.nih.gov/pubmed/18308153>.  2 - Chou R, Qaseem A, Snow V, et al. Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007; 147(7):478–91. Guideline available at <http://www.ncbi.nlm.nih.gov/pubmed/17909209>.  3 - Daffner RH, Wippold FJ II, Bennett DL, et al. Expert Panels on Musculoskeletal and Neurologic Imaging. ACR Appropriateness Criteria® suspected spine trauma. [online publication]. Reston (VA): American College of Radiology (ACR). 2012. Guideline available at <http://www.guideline.gov/content.aspx?id=37931>.  4 - Daffner RH, Weissman BN, Appel M, et al. Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® stress (fatigue/insufficiency) fracture, including sacrum, excluding other vertebrae. [online publication]. Reston (VA): American College of Radiology (ACR). 2011. Guideline available at <http://www.guideline.gov/content.aspx?id=32618>.  5 - Davis PC, Wippold FJ II, Cornelius RS, et al. Expert Panel on Neurologic Imaging. ACR Appropriateness Criteria® low back pain. [online publication]. Reston (VA): American College of Radiology (ACR). 2011. Guideline available at <http://www.guideline.gov/content.aspx?id=35145>.  6 – Goertz M, Thorson D, Bonsell J, et al. Institute for Clinical Systems Improvement (ICSI). Adult acute and subacute low back pain. Bloomington (MN): ICSI. 2012. Guideline available at <http://www.guideline.gov/content.aspx?id=39319>.  7 - Low back disorders. Occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery in workers. 2nd ed. Elk Grove Village (IL): American College of Occupational and Environmental Medicine (ACOEM). 2007. Guideline available at <http://www.guideline.gov/content.aspx?id=38438>.  8 - Michigan Quality Improvement Consortium. Management of acute low back pain. Southfield (MI): Michigan Quality Improvement Consortium; 2012. Guideline available at <http://www.guideline.gov/content.aspx?id=37956>.  9 - Morrison WB, Zoga AC, Daffner RH, et al. Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® primary bone tumors. [online publication]. Reston (VA): American College of Radiology (ACR). 2009. Guideline available at <http://www.guideline.gov/content.aspx?id=15739>.  10 - Practice Guideline for the Performance of MRI of the Adult Spine. Reston (VA): American College of Radiology (ACR). 2012. Guideline available at <http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/MRI_Adult_Spine.pdf>.  11 - Roberts CC, Daffner RH, Weissman BN, et al. Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® metastatic bone disease. [online publication]. Reston (VA): American College of Radiology (ACR). 2012. Guideline available at <http://www.guideline.gov/content.aspx?id=37930>.  12 - Seidenwurm DJ, Wippold FJ II, Cornelius RS, et al. Expert Panel on Neurologic Imaging. ACR Appropriateness Criteria® myelopathy. Reston (VA): American College of Radiology (ACR). 2011. Guideline available at <http://www.guideline.gov/content.aspx?id=35146>.  13 - University of Michigan Health System. Acute low back pain. Ann Arbor (MI): University of Michigan Health System. 2010 Jan. Guideline available at <http://www.guideline.gov/content.aspx?id=23939>.  14 - Wippold FJ II, Cornelius RS, Broderick DF, et al. Expert Panel on Neurologic Imaging. ACR Appropriateness Criteria® dementia and movement disorders. [online publication]. Reston (VA): American College of Radiology (ACR). 2010. Guideline available at <http://www.guideline.gov/content.aspx?id=32612>.  15 - Work Loss Data Institute. Low back - lumbar & thoracic (acute & chronic). Corpus Christi (TX): Work Loss Data Institute. 2011. Guideline available at <http://www.guideline.gov/content.aspx?id=33184>.  **2016 Submission:**   * ACR Appropriateness Criteria® low back pain. * Patel ND, Broderick DF, Burns J, et al. Expert Panel on Neurologic Imaging. * 2015 * Patel ND, Broderick DF, Burns J, et al. Expert Panel on Neurologic Imaging. ACR Appropriateness Criteria® low back pain. [online publication]. Reston (VA): American College of Radiology (ACR). 2015. 12 p. * <https://acsearch.acr.org/docs/69483/Narrative>. | | | |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | **2014 Submission:**  Guideline # 1 –  *Adult patient with acute uncomplicated\* LBP (<4 weeks' duration.)  \*Uncomplicated definition: non-traumatic LBP without neurologic deficits or indicators of potentially serious pathologies)—(see red flag list for details in the original guideline document).  For most young or middle-aged adults, early diagnostic evaluation of low back complaints may focus on 3 basic questions (diagnostic imaging is infrequently required) (Jarvik, 2002).*  *Is there underlying systemic disease?*  *Is there neurologic impairment that might require surgical intervention?*  *Is social or psychological distress amplifying or prolonging the pain?*  Radiographs not initially indicated [B]  Special investigations not indicated [B]  *Adult patient with uncomplicated subacute (4-12 wks.' duration) or persistent low back pain (LBP) (>12 wks.' duration) AND no previous treatment trial.  A trial of up to 4-6 wk. of conservative care is appropriate before radiographs.* Radiographs not initially indicated [B]  *Adult patient with non-traumatic acute LBP AND sciatica (no red flags).  The first clinical clue to neurologic impairment usually is a history of sciatica: sharp pain radiating down the posterior or lateral aspect of the leg, often associated with numbness or paresthesia.*  Radiographs not initially indicated [B]  Guideline # 2 –  Clinicians should conduct a focused history and physical examination to help place patients with low back pain into 1 of 3 broad categories: nonspecific low back pain, back pain potentially associated with radiculopathy or spinal stenosis, or back pain potentially associated with another specific spinal cause. The history should include assessment of psychosocial risk factors, which predict risk for chronic disabling back pain (strong recommendation, moderate-quality evidence).  Clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain (strong recommendation, moderate-quality evidence).  Clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination (strong recommendation, moderate-quality evidence).  Clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (preferred) or computed tomography only if they are potential candidates for surgery or epidural steroid injection (for suspected radiculopathy) (strong recommendation, moderate-quality evidence).  Clinicians should provide patients with evidence-based information on low back pain with regard to their expected course, advise patients to remain active, and provide information about effective self-care options (strong recommendation, moderate-quality evidence).  For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy (strong recommendation, moderate-quality evidence). For most patients, first-line medication options are acetaminophen or non-steroidal anti-inflammatory drugs.  For patients who do not improve with self-care options, clinicians should consider the addition of non-pharmacologic therapy with proven benefits-for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence).  Guideline # 3 –  Clinical Condition: Suspected Spine Trauma  **Variant 9:** Blunt trauma meeting criteria for thoracic or lumbar imaging. With or without localizing signs.  MRI thoracic or lumbar spine without contrast: 5  MRI thoracic and lumbar spine without and with contrast: 1  **Variant 10:** Blunt trauma meeting criteria for thoracic or lumbar imaging. Neurologic abnormalities.  MRI thoracic or lumbar spine without contrast: 9  MRI thoracic and lumbar spine without and with contrast: 1  Guideline # 4 –  Clinical Condition: Stress (Fatigue/Insufficiency) Fracture, Including Sacrum, Excluding Other Vertebrae  **Variant 1:** Suspect stress fracture. First imaging modality.  MRI area of interest without contrast: 1  MRI area of interest without and with contrast: 1  **Variant 2:** Suspect stress fracture in patient with "need-to-know diagnosis", not hip or sacrum, Radiographs normal.  MRI area of interest without contrast: 9  MRI area of interest without and with contrast: 1  **Variant 3:** Suspect stress fracture, not hip or sacrum. Radiographs normal. Bone scan positive and nonspecific.  MRI area of interest without contrast: 9  MRI area of interest without and with contrast: 1  **Variant 4**: Suspect stress fracture in otherwise normal patient. Radiographs normal.  MRI area of interest without contrast: 2  MRI area of interest without and with contrast: 1  **Variant 5:** Clinical differential fracture versus metastasis in long bone. Radiographs normal, bone scan hot but nonspecific.  MRI area of interest without contrast: 9  MRI area of interest without and with contrast: 5  **Variant 6:** Clinical differential insufficiency fracture versus metastasis in sacrum. Radiographs normal, bone scan hot but nonspecific.  MRI sacrum without contrast: 6  MRI sacrum without and with contrast: 1  **Variant 7**: Suspect insufficiency fracture in sacrum/pelvis; elderly patient. Radiographs normal. Bone scan hot in linear pattern typical for fracture.  MRI pelvis without contrast: 6  MRI pelvis without and with contrast: 1  **Variant 8**: Suspect insufficiency fracture (any location) in osteoporotic patient or patient on long-term corticosteroid therapy. Radiographs normal.  MRI area of interest without contrast: 9  MRI area of interest without and with contrast: 1  **Variant 9:** Suspect insufficiency fracture in osteoporotic patient or patient on long-term corticosteroid therapy. Radiographs and bone scan obtained within the preceding 48 hours are normal.  MRI area of interest without contrast: 9  MRI area of interest without and with contrast: 1  Guideline # 5 –  Clinical Condition: Low Back Pain  **Variant 1:** Uncomplicated acute low back pain and/or radiculopathy, nonsurgical presentation. No red flags. (Red flags defined in the [original guideline])  MRI lumbar spine without contrast: 2  MRI lumbar spine without and with contrast: 2  **Variant 2:** Patient with one or more of the following: low velocity trauma, osteoporosis, focal and/or progressive deficit, prolonged symptom duration, age >70 years.  MRI lumbar spine without contrast: 8  MRI lumbar spine with and without contrast: 3  **Variant 3:** Patient with one or more of the following: suspicion of cancer, infection, and/or immunosuppression.  MRI lumbar spine without contrast: 7  MRI lumbar spine without and with contrast: 8  **Variant 4:** Low back pain and/or radiculopathy. Surgery or intervention candidate.  MRI lumbar spine without contrast: 8  MRI lumbar spine without and with contrast: 5  **Variant 5:** Prior lumbar surgery.  MRI lumbar spine without contrast: 6  MRI lumbar spine without and with contrast: 8  **Variant 6:** Cauda equina syndrome, multifocal deficits or progressive deficit.  MRI lumbar spine without contrast: 9  MRI lumbar spine without and with contrast: 8  Guideline # 6 –  Initial Evaluation and Data Set   * Clinicians should not recommend imaging (including computed tomography [CT], magnetic resonance imaging [MRI] and x-ray) for patients with non-specific low back pain [Strong Recommendation, Moderate Quality Evidence]   Core Treatment Plan   * Clinicians should not recommend imaging (including computed tomography [CT], magnetic resonance imaging [MRI], and x-ray) for patients with non-specific low back pain [Strong Recommendation, Moderate Quality Evidence].   No Imaging First Six Weeks with Radicular Pain; Use Core Treatment Plan   * Clinicians should not recommend imaging (including CT, MRI or x-ray) for patients in the first six weeks of radicular pain [Strong Recommendation, Moderate Quality Evidence].   Guideline # 7 –  MRI for patients with acute LBP during the first 6 weeks if they have demonstrated progressive neurologic deficit, cauda equina syndrome, significant trauma with no improvement in atypical symptoms, a history of neoplasia (cancer), or atypical presentation (e.g., clinical picture suggests multiple nerve root involvement) – Recommended, Insufficient Evidence (I)  MRI is not recommended for acute radicular pain syndromes in the first 6 weeks unless they are severe and not trending towards improvement and both the patient and the surgeon are willing to consider prompt surgical treatment, assuming the MRI confirms ongoing nerve root compression. Repeat MRI without significant clinical deterioration in symptoms and/or signs is also not recommended. – Not Recommended, Evidence (C)  MRI is recommended for patients with subacute or chronic radicular pain syndromes lasting at least 4 to 6 weeks in whom the symptoms are not trending towards improvement if both the patient and surgeon are considering prompt surgical treatment, assuming the MRI confirms ongoing nerve root compression. In cases where an epidural glucocorticosteroid injection is being considered for temporary relief of acute or subacute radiculopathy, MRI at 3 to 4 weeks (before the epidural steroid injection) may be reasonable. – Moderately Recommended, Evidence (B)  MRI is recommended as an option for the evaluation of select chronic LBP patients in order to rule out concurrent pathology unrelated to injury. This option should not be considered before 3 months and only after other treatment modalities (including NSAIDs, aerobic exercise, other exercise, and considerations for manipulation and acupuncture) have failed. – Recommended, Insufficient Evidence (I)  Standing or weight-bearing MRI for any back or radicular pain syndrome or condition – Not Recommended, Insufficient Evidence (I)  Guideline # 8 –  Patients with High Risk of Serious Pathology (Red Flags and High Index of Suspicion)  Spinal fracture or compressions—plain lumbosacral (LS) spine X-ray [B]. After 10 days, if fracture still suspected or multiple sites of pain, consider either bone scan [C] or referral [D] before considering computed tomography (CT) or magnetic resonance imaging (MRI).  Guideline # 9 –  Clinical Condition: Primary Bone Tumors  *Variant 1* Screening, first study: MRI area of interest without or with contrast: 1  *Variant 2* Persistent symptoms, but radiograph negative: MRI area of interest without or with contrast: 9  *Variant 3* Definitively benign on radiographs (excluding osteoid osteoma): MRI area of interest without or with contrast: 1  *Variant 4* Clinically suspected osteoid osteoma: MRI area of interest without or with contrast: 6  *Variant 5* Suspicious for malignant characteristics on radiograph: MRI area of interest without or with contrast: 9  Guideline # 10 –  Indications for spine MRI include, but are not limited to, the evaluation of: congenital spine and spinal cord malformations; inflammatory/autoimmune disorders; demyelinating disease; multiple sclerosis (MS); acute disseminated encephalomyelitis (ADEM); acute inflammatory demyelinating polyradiculopathy (Guillian-Barre syndrome); connective tissue disorders (e.g., systemic lupus erythematosus); infectious conditions; spinal infection, including disk space infection, vertebral osteomyelitis, and epidural abscess; spinal cord infection including abscess; vascular disorders; spinal vascular malformations and/or the cause of occult subarachnoid hemorrhage; spinal cord infarction degenerative conditions; degenerative disk disease and its sequelae in the lumbar, thoracic, and cervical spine; neurodegenerative disorders such as subacute combined degeneration, spinal muscular atrophy, amyotrophic lateral sclerosis; trauma; nature and extent of injury to spinal cord, vertebral column, ligaments, thecal sac, and paraspinal soft tissues following trauma; neoplastic abnormalities intramedullary tumors; intradural extramedullary masses; intradural leptomeningeal disease; extradural soft tissue and bony neoplasms; treatment fields for radiation therapy; miscellaneous spinal abnormalities associated with scoliosis; syringohydromyelia (multiple etiologies, including Chiari malformations, trauma, etc); postoperative fluid collections and soft tissue changes (extradural and intradural); and pre-procedure assessment for vertebroplasty and kyphoplasty.  Guideline # 11 –  Clinical Condition: Metastatic Bone Disease  *Variant 3* Breast Carcinoma. Follow-up bone scan reveals single "hot" lesion in spine: MRI spine without contrast: 9 | MRI spine without and with contrast: 1  *Variant 4* Breast carcinoma. Three "hot" areas in spine revealed by bone scan. No back pain: MRI spine without contrast: 9 | MRI spine without and with contrast: 1  *Variant 9* Patient with known malignancy, with back pain and partially collapsed vertebra on radiography. Otherwise healthy : MRI spine without contrast: 9 | MRI spine without and with contrast: 1  *Variant 11* Patient with multiple myeloma presenting with acute low back pain: MRI lumbar spine without contrast: 8 | MRI lumbar spine without and with contrast: 1  Guideline # 12 –  Clinical Condition: Myelopathy  *Variant 1* Traumatic: MRI spine without contrast: 8 | MRI spine without and with contrast: 2 | MRI spine flow without contrast: 2  *Variant 2* Painful: MRI spine without contrast: 8 | MRI spine without and with contrast: 7 | MRI spine flow without contrast: 2  *Variant 3* Sudden Onset: MRI spine without contrast: 9 | MRI spine without and with contrast: 8 | MRI spine flow without contrast: 2  *Variant 4* Stepwise Progressive: MRI spine without contrast: 9 | MRI spine without and with contrast: 9 | MRI spine flow without contrast: 2  *Variant 5* Slowly Progressive: MRI spine without contrast: 9 | MRI spine without and with contrast: 9 | MRI spine flow without contrast: 2  *Variant 6* Infectious Disease Patient: MRI spine without contrast: 8 | MRI spine without and with contrast: 9 | MRI spine flow without contrast: 2  *Variant 7* Oncology Patient: MRI spine without contrast: 9 | MRI spine without and with contrast: 8 | MRI spine flow without contrast: 2  Guideline # 13 –  Initial Visit:   * Assess for "red flags" of serious disease (see Table 1 in the original guideline document), as well as psychological and social risks for chronic disability (see Table 2 in original guideline document). Diagnostic tests are usually unnecessary [IC]. If a patient has a red flag, obtain magnetic resonance imaging (MRI) and refer to specialist as appropriate. * X-rays, MRI, or computed tomography (CT) scan are not recommended for routine evaluation of patients with acute low back problems within the first 4-6 weeks of symptoms unless a red flag and high index of suspicion is noted on clinical evaluation. * For radicular pain without weakness, by ≥3 weeks: If no improvement, obtain MRI [IIB]. If not diagnostic, obtain electromyography (EMG). If pathology proven, consider evaluation by specialist in back pain or surgical evaluation [IA]. If pathology not proven, consider referral to specialist in back pain [ID]. Although opioid pain medications are effective [IIA], they are generally not indicated as first-line treatment and early opioid use may be associated with longer disability controlling for case severity [IIC].   Guideline # 14 –  Clinical Condition: Dementia and Movement Disorders  *Variant 12* Motor neuron disease: MRI spine without contrast: 8 | MRI spine without and with contrast: 7  Guideline #15 –  Identify Radicular Signs   * First visit: may be with Primary Care Physician MD/DO (50%), Orthopedist (33%), or Chiropractor (17%) (or rarely other specialists, including pain specialists) * Determine presence or absence of radiculopathy:   + Medical history   + Sensation: Feeling pain radiating below the knee (calf or lower), not just referred pain (pain radiating to buttocks or thighs), and dermatological sensory loss   + Straight leg raising test (sitting and supine), productive of leg pain   + Motor strength and deep tendon reflexes   + Document flexibility/range of motion (ROM) (fingertip test), muscle atrophy (calf measurement), local areas of tenderness, visual pain analog, sensation alternation * Rule out "red flag" diagnoses, including diagnostic studies, for specialist referral:   + Cauda Equina Syndrome (Schedule emergency procedure) (Refer to the original guideline document for International Classification of Diseases, Ninth Revision [ICD-9] codes for this and other diagnoses)   + Fracture, Compression fracture, Dislocation, Wound   + Cancer, Infection   + Dissecting/Ruptured Aortic Aneurysm   + Others (prostate problems, endometriosis/gynecological disorders, urinary tract infections, and renal pathology)   Without Radiculopathy (90% of cases)   * Also first visit (day 1):   + Prescribe activity modification, if necessary, based on severity and difficulty of job, while encouraging return to activity as much as possible; limited passive therapy with heat/ice (3 to 4 times/day); stretching/exercise (training by physical therapist OK); appropriate analgesia (i.e., acetaminophen) and/or anti-inflammatory (i.e., ibuprofen) [Benchmark cost: $14]; back to work except for severe cases in 72 hours, possibly modified duty; AVOID bed rest.   + REASSURE PATIENT: Patient education - common problem (90% of patients recover spontaneously in 4 weeks)   + No x-rays unless significant trauma (e.g., a fall)   + If muscle spasms, then consider muscle relaxant with limited sedative side effects [Benchmark cost: $44] * Second visit (day 3 to 10 - about 1 week after first visit, or sooner, because delayed treatment is not recommended)   + Document progress (flexibility, areas of tenderness, motor strength, straight leg raise--sitting and supine)   + If still 50% disabled (i.e., cannot return to work) then consider referral for exercise/instruction/manual therapy [Benchmark cost: $250]: Options are physical therapist, chiropractor, massage therapist, or occupational therapist (3 visits in first week), or by treating DO/MD (Choose providers supporting active therapy and not just passive modalities. The focus of treatment should not be symptom reduction, but improving function with a goal to return to work.) Consider screening for psychosocial symptoms in cases with expectations of delayed recovery.   + Discontinue muscle relaxant * Third visit (day 10 to 17 - about 1 week after second visit)   + Document progress   + Prescribe muscle-conditioning exercises   + At this point 66% to 75% should be back to regular work   + While not indicated in the absence of red flags, if still disabled, then consider imaging study (anterior-posterior [AP]/lateral 2-view x-ray of lumbar) [Benchmark cost: $150] to rule out tumor, fracture, osteoporosis, myelopathy   + Maintain therapy, continue focus on active therapy and not passive modalities, 2 visits in next week, teach home exercises   + End manual therapy at 4 weeks (1 visit in last week)   With Radiculopathy (10% of cases)   * Also first visit (day 1)   + Same as non-radicular * Second visit (day 3 to 10 - about 1 week after first visit)   + Same as non-radicular, but   + Reassure, but if increased numbness or weakness of either leg, get back to provider in one day   + Consider referral to nonsurgical musculoskeletal physician (Orthopedist/Physical Medicine/Sports Medicine) * Third visit (day 10 to 17 - about 1 week after second visit)   + Same as non-radicular, but   + About 50% can be back at modified duty   + If improvement, then add strengthening exercises, increased activity * Fourth visit (day 21 to 28 - about 1 to 2 weeks after third visit)   + Document objective findings, if no improvement then:   + First magnetic resonance imaging (MRI) (about 3% of total cases, or 30% of radicular cases) to confirm extruded disk with nerve root displacement (≥1 month conservative therapy) [Benchmark cost: $1,600]   + MRI or computed tomography (CT) not indicated without obvious clinical level of nerve root dysfunction, clear radicular findings, or before 3 to 4 weeks   + EMGs (electromyography) may be useful to obtain unequivocal evidence of radiculopathy, after 4 to 8 weeks conservative therapy, but EMGs are not necessary if radiculopathy is already clinically obvious   + Consider an epidural steroid injection (ESI) for severe cases hoping to avoid surgery [Benchmark cost: $676]   + If psychological factors retarding recovery are suspected, possibly refer to psychologist for testing [Benchmark cost: $540].   + Education: Consider back school as an option, if available.   + If no improvement 7 to 14 days after the first ESI, consider prescribing 2nd ESI [Benchmark cost: $615]; there should be a maximum of two ESIs, and the second ESI can be 7 to 14 days after the first, depending upon the patient's response and functional gain * Surgery (three months or more -- after appropriate work-up and consultation, concordance between radicular findings on radiologic evaluation and physical exam findings) (about 2% of total cases, or 20% of radicular cases) (See also ODG Indications for Surgery™ -- Discectomy in Procedure Summary of the original guideline document). Unequivocal objective findings are required based on neurological examination and testing.   + Refer to fellowship trained Spine Surgeon: Neurosurgeon (50%), Orthopedist (50%)   + Before surgery, screen for psychological symptoms that could affect surgical outcome (e.g., substance abuse, child abuse, work conflicts, somatization, verbalizations, attorney involvement, smoking)   + Review options/outcomes with patient, let patient be part of decision making   + Simple discectomy/laminectomy, minimally invasive [Benchmark cost: $17,400]   + Post-operative pain, walking exercises, physical therapy * Failure to recover: See the Procedure Summary (in the original guideline document) for options that may be available, along with links to the medical evidence. Also, see the NGC summary of the Work Loss Data Institute's guideline Pain (chronic).   **2016 Submission:** | | | |
| **Variant Number** | **Variant of Clinical Condition** | **MRI lumbar spine without contrast** | **MRI lumbar spine without and with contrast** |
| 1 | Acute, subacute, or chronic uncomplicated low back pain or radiculopathy. No red flags. No prior management. | 2 | 2 |
| 2 | Acute, subacute, or chronic uncomplicated low back pain or radiculopathy. One or more of the following: low velocity trauma, osteoporosis, elderly individual, or chronic steroid use.[[1]](#footnote-1) | 7 | Not Rated |
| 3 | Acute, subacute, or chronic low back pain or radiculopathy. One or more of the following: suspicion of cancer, infection, or immunosuppression. | 7 | 8 |
| 4 | Acute, subacute, or chronic low back pain or radiculopathy. Surgery or intervention candidate with persistent or progressive symptoms during or following 6 weeks of conservative management. | 8 | 5 |
| 5 | Low back pain or radiculopathy. New or progressing symptoms or clinical findings with history of prior lumbar surgery. | 6 | 8 |
| 6 | Low back pain with suspected cauda equina syndrome or rapidly progressive neurologic  deficit. | 9 | 8 |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | **2014 Submission:**  The following grading scale applies to recommendations from guideline #1:  Grades of Recommendation: This tool has been developed to grade recommendations according to the strength of available scientific evidence (level A to D)  *A:* At least one meta-analysis, systematic review or RCT rated as 1++, and directly applicable to the target population; or a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+,directly applicable to the target population and demonstrating overall consistency of results  *B:* A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+  *C:* A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++\*\*  *D:* Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+; or evidences from trials classified as (minus) regardless of the level /  The following grading scale applies to recommendations from guideline #2:   |  |  |  | | --- | --- | --- | | Quality of Evidence | Strength of Recommendation | | | Benefits Do or Do Not Clearly Outweigh Risks | Benefits and Risks and Burdens are Finely Balanced | | High | Strong | Weak | | Moderate | Strong | Weak | | Low | Strong | Weak | | Insufficient evidence to determine net benefits or harms | I Recommendation | |   Method for grading the strength of the overall evidence for an intervention:  *Good:* Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality trials)  *Fair:* Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least 1 higher-quality trial of sufficient sample size; 2 or more higher-quality trials with some inconsistency; at least 2 consistent, lower-quality trials, or multiple consistent observational studies with no significant methodological flaws).  *Poor:* Evidence is sufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.  The following grading scale applies to recommendations from guideline #’s 3, 4, 5, 9, 11, 12, and 14:  Rating Scale:  1,2,3 Usually not appropriate  4,5,6 May be appropriate  7,8,9 Usually appropriate  The following grading scale applies to recommendations from guideline #’s 6 and 7:  Strength of Evidence Ratings  *A:* Strong evidence-base: Two or more high-quality studies.\*  *B:* Moderate evidence-base: At least one high-quality study or multiple moderate-quality studies\*\* relevant to the topic and the working population.  *C:* Limited evidence-base: At least one study of moderate quality.  *I:* Insufficient evidence: Evidence is insufficient or irreconcilable.  \*For therapy and prevention, randomized controlled trials (RCTs) or crossover trials with narrow confidence intervals and minimal heterogeneity. For diagnosis and screening, cross sectional studies using independent gold standards. For prognosis, etiology or harms, prospective cohort studies with minimal heterogeneity.  \*\*For therapy and prevention, well-conducted cohort studies. For prognosis, etiology or harms, well-conducted retrospective cohort studies or untreated control arms of RCTs.  The following grading scale applies to recommendations from guideline #8:  Levels of Evidence for the Most Significant Recommendations  *A:* Randomized controlled trials  *B:* Controlled trials, no randomization  *C:* Observational studies  *D:* Opinion of expert panel  The following grading scale applies to recommendations from guideline #10:  The guideline does not report a grading scale.  The following grading scale applies to recommendations from guideline #13:   |  |  | | --- | --- | | Levels of Evidence for the Most Significant Recommendations | Strength of Recommendation | | *A:* Randomized controlled trials | *I:* Generally should be performed | | *B:* Controlled trials, no randomization | *II:* May be reasonable to perform | | *C:* Observational trials  *D:* Opinion of expert panel | *III:* Generally should not be performed |   The following grading scale applies to recommendations from guideline #15:  *Ranking by Type of Evidence*   1. Systematic Review/Meta-Analysis 2. Controlled Trial - Randomized (RCT) or Controlled 3. Cohort Study-Prospective or Retrospective 4. Case Control Series 5. Unstructured Review 6. Nationally Recognized Treatment Guideline (from www.guideline.gov ) 7. State Treatment Guideline 8. Other Treatment Guideline 9. Textbook 10. Conference Proceedings/Presentation Slides   *Ranking by Quality within Type of Evidence*   1. High Quality 2. Medium Quality 3. Low Quality   **2016 Submission:**  Patel et al. referenced 30 articles within the Appropriateness Criteria®. Three of the studies were assigned to category 1 (defined as *the study is well-designed and accounts for common biases*).Two of the studies were assigned to category 2 (defined as *the study is moderately well-designed and accounts for most common biases*). Seven of the studies were assigned to category 3 (defined as *there are important study design limitations*). The final 18 studies were assigned to category 4 (defined as t*he study is not useful as primary evidence; the article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus*).  The guideline notes that “while there are references that report on studies with design limitations, 5 well designed or good quality studies provide good evidence." | | | |
| Provide all other grades and definitions from the evidence grading system | **2014 Submission:**  The full rating systems are provided in Section 1.a4.3.  **2016 Submission:**  Category 1 - The study is well-designed and accounts for common biases.  Category 2 - The study is moderately well-designed and accounts for most common biases.  Category 3 - There are important study design limitations. Category 4 - The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. | | | |
| Grade assigned to the **recommendation** with definition of the grade | **2014 Submission:**  The systematic review that served as the basis for guideline development identified 48 relevant studies. Each study was rated based on the following quality scale:  *Category 1* The study is well-designed and accounts for common biases.  *Category 2* The study is moderately well-designed and accounts for most  common biases.  *Category 3* There are important study design limitations.  *Category 4* The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:  a) the study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);  b) the study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;  c) the study is an expert opinion or consensus document.  Eight of the studies were assigned to category 2. Nine of the studies were assigned to category 3. The final 31 studies were assigned to category 4.  **2016 Submission:**  Recommendations made within theACR guideline ranged from a value of 2 (defined as *Usually Not Appropriate)* through 9 (defined as *Usually Appropriate*).  The evidence supporting these recommendations demonstrates consensus within the clinical community that MRI of the lumbar spine is not appropriate for patients presenting with uncomplicated low back pain and that imaging should only be used when the low back pain is in conjunction with a red-flag condition or scenario (as defined by recommendations graded with values of 7 through 9, considered *usually appropriate)*. | | | |
| Provide all other grades and definitions from the recommendation grading system | **2014 Submission:**  All grades are described in Section 1a.7.2.  **2016 Submission:**  1, 2, 3 Usually not appropriate  4, 5, 6 May be appropriate  7, 8, 9 Usually appropriate | | | |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | **2014 Submission:**  The body of evidence evaluated for clinical guideline #5 includes three experimental studies, fifteen observational studies, and thirty reviews or other study designs. Experimental studies ranged in size from 47 to 380 cases. Observational studies ranged in size from 20 to 736 cases. For reviews and other study designs, the sample size ranged from 1 to 474 patients. The quantity and quality of the body of evidence is further bolstered by the literature used for guideline development for the other guidelines that support this measure.  Results cited in this body of evidence are consistent across studies and guidelines.  **2016 Submission:**  The body of evidence evaluated for the ACR guideline includes 2 experimental studies, 10 observational studies, and 18 reviews or other study designs. Experimental studies ranged in size from 246 to 380 cases. Observational studies ranged in size from 23 to 5,239 cases.  The quantity and quality of the body of evidence is further bolstered by the literature used for guideline development for the other guidelines that support this measure. | | | |
| Estimates of benefit and consistency across studies | **2014 Submission:**  Given the high costs associated with performing unnecessary MRI lumbar spine studies and the fact that MRI lumbar spine studies are inappropriate prior to conservative therapy, the overall net benefit in reducing overuse of MRI lumbar spine studies is a reduction in cost and a reduction in the number of procedures performed, per beneficiary.  **2016 Submission:**  Given the high costs associated with performing unnecessary MRI lumbar spine studies and the fact that MRI lumbar spine studies are generally inappropriate prior to attempting conservative therapy, the net benefit in reducing overuse of MRI lumbar spine studies is a reduction in cost and a reduction in the number of downstream procedures performed, per beneficiary. | | | |
| What harms were identified? | **2014 Submission:**  No harms in measure implementation were identified to counter the net benefit of the measure.  **2016 Submission:**  No harms in measure implementation were identified to counter the net benefit of the measure. | | | |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | **2014 Submission:**  In addition to the fifteen guidelines cited above, a review of the clinical literature was conducted during the measure contractor’s annual review of the literature for additional evidence and/or new studies that substantiate the measure’s intent. Citations and summaries for the 28 items included in this review can be found in Section 1a.8.2. Some of these 28 studies have been published since the period of guideline development. Results cited in these studies are consistent across studies and with the guidelines cited above.  **2016 Submission:**  During the measure contractors annual review of the literature, there were no newly identified articles that changed the conclusions presented in the systematic review used to create the ACR Appropriateness Criteria® for low back pain.  A review of the clinical literature was conducted during the measure contractor’s annual review of the literature for additional evidence and/or new studies that support the measure’s intent. The measure contractor identified relevant peer-reviewed publications by searching the PubMed MEDLINE database from January 1, 2014 to January 15, 2016, limiting included results to those published in the English language and that had abstracts available in PubMed.  This search initially identified 781 articles; a further review by the contractor’s clinical and measure-development team resulted in the inclusion of 26 articles. All newly identified articles supported the current measure specifications.  In addition to the red-flag conditions supported by the ACR guideline, the current measure specifications further exclude 10 red-flag conditions (i.e., lumbar spine surgery 90 days prior to MRI, congenital spine and spinal cord malformations, spinal vascular malformations and/or the cause of occult subarachnoid hemorrhage, spinal cord infarction, treatment fields for radiation therapy, spinal abnormalities associated with scoliosis, syringohydromyelia, post-operative fluid and soft tissue changes, IV drug abuse, and intraspinal abscess), which were added in previous years in response to prior reviews of the literature, feedback from the contractor’s technical expert panel, and comments provided by other stakeholders. | | | |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

**1a.4.2 What process was used to identify the evidence?**

**1a.4.3.** **Provide the citation(s) for the evidence.**

1. While ACR lists elderly individuals as patients for whom an MRI lumbar spine is appropriate, the accompanying literature review developed by ACR notes, “[a] recent study found no statistically significant difference in primary outcomes after 1 year for older adults who had spine imaging within 6 weeks after an initial visit for care for low back pain versus similar patients who did not undergo early imaging; thus this panel does not include age older than 50 as an independent red flag.” As NQF #0514 excludes patients with red-flag conditions, elderly patients are not removed from the measure, aligning with findings from the ACR literature review to support guideline development. [↑](#footnote-ref-1)