CDI QUALITY INSTITUTE

Provider Led Entity

CDI Quality Institute PLE
Lumbar Spine/Low Back Pain AUC
2021 Update

Appropriateness of advanced imaging procedures* in patients with lumbar spine/low back pain and the following clinical presentations

*Including MRI, CT, CT myelography, bone scan, PET, PET/CT, SPECT, SPECT/CT

Abbreviation list:

ACOEM	American College of Occupational and Environmental Medicine
ACP	American College of Physicians
ACR	American College of Radiology
APS	American Pain Society
ASNR	American Society of Neuroradiology
AUC	Appropriate Use Criteria
CMS	Centers for Medicare & Medicaid Services
CES	Cauda equina syndrome
CRP	C-reactive protein
CT	Computed tomography
EMTALA	Emergency Medical Treatment and Labor Act
ESR	Erythrocyte sedimentation rate
FDG	Fluorodeoxyglucose
ICSI	Institute for Clinical Systems Improvement
IDSA	Infectious Diseases Society of America
LCD	Local Coverage Determination
MRI	Magnetic resonance imaging
NASS	North American Spine Society
NCCN	National Comprehensive Cancer Network
NCD	National Coverage Determination
NICE	National Institute for Health and Care Excellence
PET	Positron emission tomography
PLE	Provider Led Entity
SCBTMR	Society of Computed Body Tomography & Magnetic Resonance
SPECT	Single-photon emission computed tomography
SSR	Society for Skeletal Radiology
STIR	Short tau inversion recovery sequence
U of MI	University of Michigan
VA/DoD	Veterans Affairs/Department of Defense
VCF	Vertebral compression fracture
WBC	White blood cell

Appropriate Use Criteria: How to Use this Document

The CDI Quality Institute follows the recommendation framework defined by the Appraisal of Guidelines for Research & Evaluation (AGREE II), AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews) and a modified version of the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies) to evaluate the strength of recommendations concerning advanced imaging. Considerations used to determine a recommendation are listed below.

Primary recommendation (green): A strong recommendation for imaging; there is confidence that the desirable effects of imaging outweigh its undesirable effects.

Alternative recommendation (yellow): A conditional recommendation for imaging; the desirable effects of imaging likely outweigh its undesirable effects, although some uncertainty may exist. The individual patient's circumstances, preferences, and values should be considered on a case-by-case basis. This may include: contraindication to the primary recommendation, specific clinical circumstances that require use of the alternative recommendation, or the primary recommendation has results that are inconclusive or incongruent with the patient's clinical diagnosis. Case-by-case indications to consider have been noted in brackets.

Recommendation against imaging (red): The undesirable effects of imaging outweigh any desirable effects. Additionally, the recommendation may be impractical or not feasible in the targeted population and/or practice setting(s).

Low back pain AUC summary:

- In patients with low back pain, urgent or emergent advanced imaging is recommended for patients with red flags, such as suspicion of cancer, infection, fracture, cauda equina/conus medullaris syndrome and major/progressive neurological deficits.
- Advanced imaging is not routinely recommended for patients with uncomplicated low back pain, an absence of red flags, and no prior conservative management (generally defined as ≥ 4 weeks).
- Patients without red flags may present with radiculopathy, spinal stenosis (neurogenic claudication) or nonspecific back pain. In general, advanced imaging of the lumbar spine is indicated in these patients if they have uncontrolled or progressively severe pain, marked debility, or have failed to improve following an appropriate course of conservative therapy. Imaging is also indicated to plan for injection therapy or surgery.
- The majority of guidelines recommend **MRI** (**without contrast** or **without and with contrast**) as the preferred imaging modality for low back pain. MRI does not use ionizing radiation, and provides better visualization of neurologic structures, better soft tissue contrast and better detection of vertebral marrow abnormalities. The use of contrast may be useful for cases of suspected cancer or infection, unexplained neurologic deficits, known or suspected neurologic disorders, in patients with a history of lumbar surgery, or for further evaluation of abnormalities previously noted on noncontrast imaging.
- **CT** is indicated for patients unable to undergo MRI, with equivocal findings on MRI, with discordant MRI findings and clinical symptoms, for surgical planning, for fusion evaluation and to characterize bony abnormalities such as fractures and osseous neoplasms.
- **CT myelography** may be useful to evaluate cauda equina syndrome, neurologic deficits, or suspected intradural pathology in patients who cannot undergo MRI. CT myelography may also be needed in patients with radiculopathy or stenosis if metal artifact arising from instrumentation limits visualization of neurologic structures on MRI.
- **Bone scan** with **SPECT** or **SPECT/CT** is indicated to evaluate for metastatic disease in patients with indeterminate bone lesions detected on MRI or CT. Bone scan can also be useful to evaluate infection or detect and characterize fractures in patients who cannot undergo MRI.
- The indications for **PET or PET/CT** in the evaluation of low back pain are limited, however it may be useful to evaluate indeterminate bone lesions in patients with known PET-sensitive cancer.
- High velocity/major trauma likely meets the *EMTALA* definition of a suspected or confirmed emergency medical condition. It is therefore excluded from these imaging recommendations.

Low back pain and/or radiculopathy with suspicion of cancer:

- Green – **MRI lumbar spine without IV contrast** or **MRI lumbar spine without and with IV contrast**
- Yellow – **MRI lumbar spine with IV contrast**
  [further evaluate abnormalities previously noted on noncontrast imaging]
- Yellow – **CT lumbar spine** or **CT myelography lumbar spine**
  [*MRI contraindicated or findings indeterminate; intervention planning; further evaluate or characterize bone lesion(s)*]
- Yellow – **Bone scan, SPECT**, **SPECT/CT**
  [*further evaluate or characterize bone lesion(s)*]
- Yellow – **PET** or **PET/CT**
  [*further evaluate or characterize bone lesion(s)*]
- Red – **Gallium scan whole body; WBC scan**

Level of Evidence: Moderate

Notes concerning use of contrast: MRI IV contrast may be indicated for cases of suspected or known cancer, particularly to evaluate unexplained neurologic deficits, to evaluate for intradural or paraspinal metastases, or to characterize intramedullary/intradural lesions. Follow-up imaging with contrast may also be indicated for further evaluation of abnormalities previously seen on noncontrast imaging.

Notes concerning applicability and/or patient preferences: None

Guideline, article, and PLE expert panel consensus opinion summary:
Overview:
Low back pain with suspicion of cancer is a red flag and urgent diagnostic imaging is advised (*VA/DOD* 2017; Thorson et al [*ICSI*] 2018; Chou et al [*ACP & APS*] 2007; Nabors et al [*NCCN*] 2021; Chiodo et al [*U of M*I] 2020). In patients with new onset pain, cancer may be suspected in those with a previous history of cancer, clinical signs such as unexplained weight loss, osteolytic or sclerotic changes on plain radiographs, or unexplained laboratory abnormalities (e.g. elevated ESR) (Chiodo et al [*U of MI*] 2020; PLE expert panel consensus opinion). MRI is generally preferred over CT as the initial advanced imaging modality for this scenario (Chou et al [*ACP & APS*] 2007; Nabors et al [*NCCN*] 2021; Hutchins et al [*ACR*] 2021; PLE expert panel consensus opinion).

MRI lumbar spine:
MRI is the preferred imaging modality for low back pain and cancer-related concerns, as it does not use ionizing radiation and provides better visualization of neurologic structures, better soft tissue contrast and better detection of vertebral marrow abnormalities (Chou et al [*ACP & APS*] 2007; Hutchins et al [*ACR*] 2021; Bussieres et al 2008; Nabors et al [*NCCN*] 2021; Hegmann et al [*ACOEM*] 2019; Chiodo et al [*U of MI*] 2020). It can be useful for evaluation of marrow-based lesions, particularly those with an indeterminate or aggressive appearance for malignancy (PLE expert panel consensus opinion; Bussières et al 2008; Bestic et al [*ACR*] 2019; He et al 2018; Liu et al 2019). The use of MRI without and with IV contrast is considered the gold standard of imaging central nervous system cancers (Nabors et al [*NCCN*] 2021; Hutchins et al [*ACR*] 2021). The use of IV contrast with MRI improves the sensitivity and specificity for intradural lesions and can be helpful in patients with a clinical suspicion for intradural metastases, intradural/perineural neoplasm, and/or cord abnormalities noted on previous noncontrast MRI (PLE

expert panel consensus opinion; Hutchins et al [*ACR*] 2021; Nabors et al [*NCCN*] 2021).

CT lumbar spine:
CT is indicated for patients with low back pain and a suspicion of cancer who cannot undergo MRI (Hutchins et al [*ACR*] 2021; Nabors et al [*NCCN*] 2021; Chiodo et al [*U of MI*] 2020). It can also be used when there are equivocal or indeterminate findings on MRI, to facilitate detection of bony abnormalities (such as occult bone tumors), or to evaluate an increased area of uptake on bone scan (Hutchins et al [*ACR*] 2021; PLE expert panel consensus opinion; Bestic et al [*ACR*] 2020).

CT myelography lumbar spine:
CT myelography is indicated to evaluate for intradural neoplasm or metastases, or suspicion of cancer with cord impingement or radiculopathy in patients who cannot undergo MRI (PLE expert panel consensus opinion; Hutchins et al [*ACR*] 2021). Myelography is invasive, with some risk of injection and post-myelography headache (Hutchins et al [*ACR*] 2021; PLE expert panel consensus opinion).

Bone scan, SPECT, SPECT/CT:
While not typically used as an initial imaging study, bone scan, SPECT and SPECT/CT may be useful to evaluate for widespread osseous metastatic disease, or for further characterization of indeterminate lesions previously detected on MRI or CT (Hutchins et al [*ACR*] 2021; Hegmann et al [*ACOEM*] 2019; Bestic et al [*ACR*] 2020; PLE expert panel consensus opinion). For marrow-based lesions, radionuclide scanning has a sensitivity of 0.75-0.98 (Bussieres et al 2008).

PET or PET/CT:
FDG-PET scanning can be useful in evaluating widespread metastatic disease and distinguishing between benign versus malignant compression fractures (Hutchins et al [*ACR*] 2021; He et al 2018). It can also be a valuable adjunct to conventional imaging in the diagnosis of primary bone tumors (Bestic et al [*ACR*] 2020), particularly in patients with known PET-sensitive cancers (PLE expert panel consensus opinion).

Clinical/Imaging Notes:

- Neoplastic abnormalities of the spine in adult patients may include intramedullary masses, intradural extramedullary masses, diffuse leptomeningeal disease, bone tumors, extradural soft-tissue neoplasms, soft-tissue masses, and tumors of nerves, muscle or connective tissue (*ACR–ASNR–SCBT-MR–SSR* 2018).
- A history of cancer is the strongest risk factor for spinal neoplasm (Chou et al [*ACP*] 2011; Henscke et al 2013).
    - Other risk factors such as age ≥ 50 years, unexplained weight loss, failure of pain to improve after one month, and insidious onset have a lower positive predictive value (Chou et al [*ACP*] 2011; Chiodo et al [*U of MI*] 2020). The risk of cancer is increased when a combination of red flags is present (Henschke et al 2013).
- Abnormalities on conventional radiographs and an elevated ESR have a 78% sensitivity and 67% specificity for neoplasm on MRI. With this strategy, immediate MRI would be reserved for patients with abnormal radiographs and/or ESR (Chou et al [*ACP & APS*] 2007).

Technical Notes:

- STIR, T2 fat saturation and/or diffusion-weight images may increase the conspicuity and sensitivity for vertebral neoplasm (PLE expert panel consensus opinion).

Evidence update (2010-present):

High Level of Evidence:
None

Moderate Level of Evidence:
None

Low Level of Evidence:
Liu et al (2020) analyzed CT, MR, and [FDG PET] emission computed tomography ([ECT]) in diagnosing [bone] spinal tumors of 121 patients. Each patient underwent $\geq$ 2 imaging exams, with all diagnosed by pathology after core needle or surgical biopsy. The kappa coefficient of MR, CT, and [FDG PET] ECT was 46.1%, 36.0%, and 55.9%, respectively. The area under the curve of [FDG PET] ECT, MR, and CT scans was 0.809, 0.705, and 0.704, respectively; and the differences among them were significant ($P < .05$). Post hoc multiple comparisons showed no significant differences among imaging examinations in terms of sensitivity, specificity, misdiagnosis rate, and coincidence rate ($P > .05$). Although [FDG PET] ECT was the most accurate imaging method, its large radiation dosage limits its widespread application. Furthermore, MR verified spinal tumors more effectively; however, CT excluded them more efficiently. In summary, when all factors are considered, MR is still the optimal modality for the diagnosis of [bone] spinal tumors, especially during the initial screening.

Wnuk et al (2018) conducted a retrospective cohort study to determine the proportion of MRI examinations with a detectable impact on patient care (actionable outcomes - including findings leading to an intervention such as surgery, new diagnosis of cancer, infection, or fracture, or following known lumbar spine pathology). A total of 5,365 outpatient lumbar MRI exams were conducted; patient notes were examined to verify outcomes. The proportion of actionable lumbar spine MRI was 13%. Of 36 suspected cases of cancer or infection, 81% were false positives. Further investigations were ordered on 59% of suspicious examinations, 86% of which were false positives. The authors conclude that the percentage of lumbar spine MRI that has a detectable impact on patient management is surprisingly low and unrelated to the appropriateness of the examination. Additionally, detection of significant disease other than spinal degeneration is rare, even in the presence of red flags, and true-positive findings are outnumbered by false-positive findings with potential to result in patient harm.

He et al (2018) retrospectively evaluated the differential diagnostic value of 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (^{18}F-FDG) PET/CT for benign and malignant vertebral compression fractures (VCFs), compared to MRI, among 87 patients (n = 116 VCFs). MRI was performed in all patients, with FDG PET/CT also performed in 51 patients. Three malignant features (convex posterior cortex, epidural mass formation, and pedicle enhancement) from MRI and the maximum standardized uptake value (SUVmax) from ^{18}F-FDG PET/CT were evaluated in benign and malignant VCFs, respectively. Results showed that the sensitivity and specificity for predicting malignant VCFs were 75.6% and 77.3% for convex posterior cortex, 82.9% and 81.3% for epidural mass formation, and 85.7% and 70.8% for pedicle enhancement. ^{18}F-FDG PET/CT demonstrated higher sensitivity (100%) but lower specificity (38.9%) as compared to MRI with regard to differentiation between benign and malignant VCFs. The authors conclude that, in a situation where MRI findings are not diagnostic, ^{18}F-FDG PET/CT provides additional information as it has high sensitivity.

Low back pain and/or radiculopathy with suspicion of infection:

- Green – **MRI lumbar spine without IV contrast** or **MRI lumbar spine without and with IV contrast**
- Yellow – **MRI lumbar spine with IV contrast**
  [further evaluate abnormalities previously noted on noncontrast imaging]
- Yellow – **CT lumbar spine** or **CT myelography lumbar spine**
  [*MRI contraindicated or findings indeterminate; intervention planning*]
- Yellow – **Bone scan, SPECT, SPECT/CT**
  [MRI contraindicated or findings indeterminate]
- Yellow **– Gallium scan whole body** [with or without **SPECT** or **SPECT/CT**]
  [MRI contraindicated or findings indeterminate]
- Red –**WBC scan; PET**; **PET/CT**

Level of Evidence: Moderate

Notes concerning use of contrast: MRI IV contrast may be indicated for cases of suspected infection. It can be useful to characterize disc, epidural, paraspinous, or osseous abnormalities noted on noncontrast MRI, and is useful to differentiate phlegmon from abscess.

Notes concerning applicability and/or patient preferences: None

Guideline, article, and PLE expert panel consensus opinion summary:
Overview:
Low back pain with suspected infection is a red flag and urgent diagnostic imaging is recommended (*VA/DOD* 2017; Thorson et al [*ICSI*] 2018; Chou et al [*ACP & APS*] 2007; Chiodo et al [*U of MI*] 2020). There is agreement among multiple high quality guidelines (Bussieres et al 2008; Chou et al [*ACP & APS*] 2007; *VA/DoD* 2017; Thorson et al [*ICSI*] 2018; Chiodo et al [*U of MI*] 2020; Hegmann et al [*ACOEM*] 2019) that imaging, preferably with MRI, is indicated when spine infection is suspected.

MRI lumbar spine:
MRI is the preferred imaging modality for low back pain and infection-related concerns, including new pain following an invasive spine procedure (Hutchins et al [*ACR*] 2021; Ortiz et al [*ACR*] 2021; Hegmann et al [*ACOEM*] 2019; Berbari et al [*IDSA*] 2015: strong recommendation, low quality evidence; Chou et al [*ACP & APS*] 2007; Bussieres et al 2008; Chiodo et al [*U of MI*] 2020; PLE expert panel consensus opinion). Its use is generally preferred over CT, as it does not use ionizing radiation and provides better visualization of neurologic structures, better soft tissue contrast, and better detection of vertebral marrow abnormalities (Chou et al [*ACP & APS*] 2007; Hutchins et al [*ACR*] 2021). MRI has high sensitivity and specificity, and allows for the diagnosis of infection prior to the appearance of bone destruction on CT or conventional radiographs (Hutchins et al [*ACR*] 2021; Berbari et al [*IDSA*] 2015; Ortiz et al [*ACR*] 2021). MRI has also been shown to be more accurate than radiography and bone scan (sensitivity of 96%, specificity of 92%, accuracy of 94%) for suspected osteomyelitis, spondylodiscitis, paraspinous abscess, and epidural abscess (Bussières et al 2008; Berbari et al [*IDSA*] 2015). MRI without and with IV contrast is often utilized for the evaluation of patients with suspected spine infection, due to excellent tissue characterization and anatomic delineation (Ortiz et al [*ACR*] 2021). It can show findings suggestive of possible spine infection, including marrow or paraspinal muscle edema, abnormal fluid collections, and signal or erosive changes within the intervertebral disc and/or end plate (Ortiz et al [*ACR*] 2021; PLE

expert panel consensus opinion). MRI with IV contrast is useful to differentiate between phlegmon and abscess, and can be helpful for additional information in a patient who has had a recent corresponding MRI without IV contrast (PLE expert panel consensus opinion).

CT lumbar spine:
CT is indicated in patients with back and/or radicular pain and a suspicion of infection who cannot undergo MRI (Berbari et al [*IDSA*] 2015: weak recommendation, low quality evidence; Chiodo et al [*U of MI*] 2020; Chou et al [*ACP & APS*] 2007), and can be used to evaluate for endplate destruction or poorly demarcated endplate erosions when MRI is indeterminate or equivocal (Ortiz et al [*ACR*] 2021; PLE expert panel consensus opinion). It is also of value for presurgical planning of suspected infection-related spine instability or cord compression (Ortiz et al [*ACR*] 2021; PLE expert panel consensus opinion).

CT myelography lumbar spine:
CT myelography is indicated to evaluate for osteomyelitis or spondylodiscitis in radiculopathy patients who cannot undergo MRI or who have substantial metal artifact arising from implants and/or instrumentation (PLE expert panel consensus opinion). Myelography is invasive, however with some risk of infection and post-myelography headache (Hutchins et al [*ACR*] 2021; PLE expert panel consensus opinion).

3-Phase Bone Scan
With a high sensitivity but low specificity, 3-phase bone scan can be utilized in select situations for patients with suspected spine infection (Hegmann et al [*ACOEM*] 2019; Ortiz et al [*ACR*] 2021).

Gallium Scan whole body [with or without **SPECT** or **SPECT/CT**]
Ga-67 scintigraphy combined with SPECT can be useful when MRI cannot be obtained (Ortiz et al [*ACR*] 2021; Berbari et al [*IDSA*] 2015: weak recommendation, low quality evidence). Gallium scan is less sensitive but more specific than skeletal scintigraphy to evaluate for suspected spine infection (Ortiz et al [*ACR*] 2021).

WBC Scan
Indium-tagged WBC scanning lacks sensitivity in the diagnosis of native vertebral osteomyelitis and should not be primarily used in establishing the diagnosis (Berbari et al [*IDSA*] 2015).

PET or PET/CT
Recent findings note that PET may be considered as a complementary imaging modality in select patients with suspected infection (Ortiz et al [*ACR*] 2021; Berbari et al [*IDSA*] 2015: weak recommendation, low level of evidence; He et al 2018). However, at this time, there is a CMS national non-coverage determination for use of FDG PET among patients with infection (*NCD 220.6.16*). CMS has determined that the evidence is inadequate to conclude that FDG PET improves health outcomes in the Medicare populations.

<u>Clinical Notes:</u>

- Infectious conditions may include spinal infection, such as disc space infection, vertebral osteomyelitis, epidural abscess, and surrounding soft-tissue infection, including postoperative infections. It may also include spinal cord infection, including abscess (*ACR–ASNR–SCBT-MR–SSR* 2018).

- Infection may be suspected in patients with back pain following the clinical exam, on plain radiography, or with elevated inflammatory markers (ESR or CRP) (PLE expert panel consensus opinion).
- Clinical features predicting the presence of vertebral infection may include new or worsening back pain with a fever (Thorson et al [*ICSI*] 2018; Berbari et al [*IDSA*] 2015), new or worsening back pain and elevated ESR or CRP (Berbari et al [*IDSA*] 2015), new moderate or severe pain following an invasive spine procedure (Chou et al [*ACP* & *APS*] 2007), new onset back pain in a high risk patient, and disproportionate back pain (PLE expert panel consensus opinion).
- Risk factors for spinal infection include intravenous drug use, immunosuppression, recent infection, and history of tuberculosis or active tuberculosis (Chou et al [*ACP* & *APS*] 2007).
- While imaging has a role in the diagnostic evaluation of suspected spine infection, a high index of clinical suspicion for an infectious etiology is required, and laboratory parameters should include serum erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), white blood cell (WBC) count with differential, and blood cultures (Ortiz et al [*ACR*] 2021).
- Urgent imaging is recommended in patients when features suggest vertebral infection. Timely diagnosis may prevent serious sequelae (Chou et al [*ACP*] 2011; Thorson et al [*ICSI*] 2018).
- An ESR and/or CRP can be useful to direct care in patients with equivocal findings on MRI and/or CT. An elevated ESR or CRP result in patients with back pain, though not specific, has a sensitivity that can range from 94% to 100% (Berbari et al [*IDSA*] 2015).

Technical notes:

- STIR or T2 fat saturation images are useful to identify marrow edema and paraspinous/epidural edema, phlegmon or abscess (PLE expert panel consensus opinion).
- Diffusion-weight imaging (the "claw sign") may help differentiate inflammatory disc degeneration from vertebral spondylodiscitis (Patel et al 2014).
- Imaging with IV contrast is useful to differential phlegmon from abscess (Patel et al 2014).

Evidence update (2010-present):

High Level of Evidence:

None

Moderate Level of Evidence:

None

Low Level of Evidence:

Wnuk et al (2018) conducted a retrospective cohort study to determine the proportion of MRI examinations with a detectable impact on patient care (actionable outcomes - including findings leading to an intervention such as surgery, new diagnosis of cancer, infection, or fracture, or following known lumbar spine pathology). A total of 5,365 outpatient lumbar MRI exams were conducted; patient notes were examined to verify outcomes. The proportion of actionable lumbar spine MRI was 13%. Of 36 suspected cases of cancer or infection, 81% were false positives. Further investigations were ordered on 59% of suspicious examinations, 86% of which were false positives. The authors conclude that the percentage of lumbar spine MRI that has a detectable impact on patient management is surprisingly low and unrelated to the appropriateness of the examination. Additionally, detection of significant disease other than spinal degeneration is rare, even in the presence of red flags, and true-positive findings are outnumbered by false-positive findings with potential to result in patient harm.

Lumbar spine symptoms with progressive neurologic deficit, new onset of incontinence, and/or clinical suspicion of cauda equina syndrome:

- Green – **MRI lumbar spine without IV contrast** or **MRI lumbar spine without and with IV contrast**
- Yellow – **MRI lumbar spine with IV contrast**
  [further evaluate abnormalities previously noted on noncontrast imaging]
- Yellow – **CT lumbar spine** or **CT myelography lumbar spine**
  [*MRI contraindicated or findings indeterminate; intervention planning*]
- Red – **Bone scan**; **PET**; **PET/CT**; **SPECT**; **SPECT/CT; Gallium scan whole body; WBC scan**

Level of Evidence: Moderate

Notes concerning use of contrast: MRI IV contrast is often indicated for cases with new, progressive, or unexplained neurologic deficits, and is useful to characterize abnormalities within the conus medullarais or intradural extramedullary space seen on previous MRI without IV contrast. It can also be useful in patients with a history of previous surgery, particularly in the evaluation of recurrent radiculopathy.

Notes concerning applicability and/or patient preferences: Consulting and reporting requirements are not required for orders for applicable imaging services made by ordering professionals under the following circumstances (*42 C.F.R. § 414.94. 2015*):

- Emergency services when provided to individuals with emergency medical conditions; or
- For an inpatient and for which payment is made under Medicare Part A.

Guideline, article, and PLE expert panel consensus opinion summary:

Overview:

Low back pain with serious or progressive neurologic deficits (including suspected cauda equina or conus medullaris syndrome) is a red flag for which urgent, and possibly emergent, diagnostic imaging is recommended (*VA/DOD* 2017; Thorson et al [*ICSI*] 2018; Chou et al [*ACP & APS*] 2007; Chiodo et al [*U of MI*] 2020). There is agreement among multiple high quality guidelines (Bussieres et al 2008; Chou et al [*ACP/APS*] 2007; *VA/DoD* 2017; Thorson et al [*ICSI*] 2018; Hutchins et al [*ACR*] 2021) that imaging, preferably with MRI, is indicated when neurologic deficit or weakness is suspected.

MRI lumbar spine:

MRI is recommended as the imaging procedure of choice when patients have clinical signs or symptoms consistent with cauda equina syndrome or when severe or progressive neurologic deficits are present (Chou et al [*ACP & APS*] 2007, strong recommendation, moderate quality evidence; Hutchins et al [*ACR*] 2021; Hegmann et al [*ACOEM*] 2019; Bussieres et al 2008; Chiodo et al [*U of MI*] 2020). MRI is generally preferred over CT as it does not use ionizing radiation and provides better visualization of neurologic structures, better soft tissue contrast, and better detection of vertebral marrow abnormalities (Chou et al [*ACP & APS*] 2007; Hutchins et al [*ACR*] 2021). While MRI without IV contrast is the preferred initial study, MRI without and with IV contrast may be helpful to delineate etiology of cauda equina syndrome when there is underlying clinical suspicion of malignancy, infection, or inflammation (Hutchins et al [*ACR*] 2021). MRI with IV contrast can be useful for additional information in a patient who has had a recent corresponding MRI without IV contrast (PLE expert panel consensus opinion).

CT lumbar spine:
Although MRI is superior for soft-tissue contrast and characterizing the etiology of cauda equina syndrome, CT without IV contrast can identify compression of the cauda equina or conus medullaris (Hutchins et al [*ACR*] 2021; Chou et al [*ACP & APS*] 2007). However, CT uses ionizing radiation, and therefore should be used as an alternative in patients with contraindications to MRI, in patients with equivocal findings on MRI, or if needed for surgical planning (PLE expert panel consensus opinion).

CT myelography lumbar spine:
CT myelography may be indicated in patients with cauda equina syndrome or major neurologic deficits if the patient is unable to undergo MRI, can be useful in patients with equivocal findings on MRI or noncontrast CT, and may be useful for surgical planning (Hutchins et al [*ACR*] 2021; PLE expert panel consensus opinion). Myelography is invasive, however, with some risk of injection and post-myelography headache (PLE expert panel consensus opinion).

Clinical notes:

- Cauda equina syndrome may be secondary to compression of the conus medullaris or lumbosacral nerve roots that form the cauda equina (Hutchins et al [*ACR*] 2021; PLE expert panel consensus opinion).
- Signs or symptoms of cauda equina syndrome include (Thorson et al [*ICSI*] 2018; Chiodo et al [*U of MI*] 2020; Hutchins et al [*ACR*] 2021):
    - Back pain
    - Lower extremity radiculopathy
    - Progressive neurologic deficit (e.g., progressive weakness in the lower limbs)
    - Recent bowel or bladder dysfunction
    - Sexual dysfunction
    - Saddle anesthesia
- Urinary retention alone or with bilateral sciatica and rectal incontinence are accurate predictors of CES. Pre- and post-void bladder ultrasound could help with the clinical assessment for cauda equina syndrome (Balasubramanian et al 2010).
- Urgent imaging is recommended in patients when features suggest cauda equina syndrome (CES), or for severe or progressive neurologic deficits at one or multiple levels. Timely diagnosis may prevent serious sequelae with these entities (Chou et al [*ACP*] 2011; Thorson et al [*ICSI*] 2018).

Evidence update (2010-present):
High Level of Evidence:
None

Moderate Level of Evidence:
None

Low Level of Evidence:
Dionne et al (2019) conducted a systematic review on the diagnostic accuracy of red flags to clinically identify MRI-confirmed Cauda Equina Syndrome (CES). Seven studies were included (n = 569), with studies on CES caused by disease process excluded (infection, malignancy, trauma, autoimmune, congenital disorders). Potential signs or symptoms of CES were compared to MRI findings. Diagnostic data was pooled for reduced anal tone, leg pain, back pain, saddle anesthesia, urinary retention, urinary incontinence and bowel incontinence from six of the studies. Pooled sensitivity for signs and symptoms

ranged from 0.19 (95% CI 0.09 to 0.33) to 0.43 (95% CI 0.30 to 0.56) while pooled specificity ranged from 0.62 (95% CI 0.59 to 0.73) to 0.88 (95% CI 0.85 to 0.92). The authors conclude key clinical signs and symptoms commonly used as red flags to screen for CES are not robust enough on their own, as their diagnostic accuracy is poor. Red flags used to identify potential CES appear to be more specific than sensitive. Saddle anesthesia had a pooled specificity of 0.85, bowel incontinence 0.83, reduced anal tone 0.83, urinary retention 0.72 and urinary incontinence 0.7. As such, when these symptoms or signs are present, they should be considered justification for prompt diagnostic workup. MRI remains the investigation of choice to confirm the presence of CES. *While the study reports that low back pain and leg pain are specific for CES, with a specificity of 0.62 and 0.66 respectively, this data applies only to a group of patients being evaluated for suspected CES. In the larger population, back pain and leg pain are not specific for CES* (PLE expert panel consensus opinion).

Low back pain with suspected fragility or insufficiency fracture*:

- Green – **MRI lumbar spine without IV contrast**
- Yellow - **MRI lumbar spine without and with IV contrast**
- Yellow – **MRI lumbar spine with IV contrast**
  [further evaluate abnormalities previously noted on noncontrast imaging]
- Yellow – **CT lumbar spine**
- Yellow – **Bone scan**, **SPECT**, **SPECT/CT**
  [*MRI contraindicated or findings indeterminate; further evaluate or characterize bone lesion(s)*]
- Yellow – **PET** or **PET/CT**
  [*further evaluate or characterize bone lesion(s)*]
- Red – **CT myelography; Gallium scan whole body; WBC scan**

*Fractures secondary to normal forces on deficient underlying bone. Fractures caused by high-energy injuries (traffic trauma, fall from greater than standing height, crushing injury, penetrating trauma) are excluded from this scenario (e.g., Zhu et al 2020).

Level of Evidence: Moderate

Notes concerning use of contrast: MRI IV contrast may be useful to evaluate indeterminate fractures, or to evaluate fractures with suspected cancer or infection. It is also useful for the further evaluation of abnormalities previously noted on noncontrast imaging.

Notes concerning applicability and/or patient preferences: Patients with emergency medical conditions (likely including major trauma) are excluded from the consulting and reporting requirements (*42 C.F.R. § 414.94. 2015*).

Guideline, article, and PLE expert panel consensus opinion summary:

Overview:

Conventional radiographs are recommended for the initial evaluation of low velocity trauma cases with risk factors for fracture, or in patients with suspected vertebral compression fractures (Chou et al [*ACP & APS*] 2007; Chiodo et al [*U of MI*] 2020; Hutchins et al [*ACR*] 2021). A number of guidelines recommend advanced imaging to exclude fracture in patients with osteoporosis and/or chronic steroid use, after initial evaluation with radiography (Bussieres et al 2008; Chou et al [*ACP/APS*] 2007; Thorson et al [*ICSI*] 2018; Hutchins et al [*ACR*] 2021; *VA/DOD* 2017: strong recommendation; Chiodo et al [*U of MI*] 2020). Multiple CMS *Local Coverage Determinations* (LCDs) cover percutaneous vertebroplasty or kyphoplasty only when there is acute (< 6 weeks) osteoporotic vertebral compression fracture (T5- L5) confirmed by recent (within 30 days) advanced imaging.

MRI lumbar spine:

MRI is an appropriate initial imaging modality following radiographs, as the detection of marrow edema is paramount to determining the chronicity of fracture deformities (PLE expert panel consensus opinion; Bussières et al 2008; Shah et al [*ACR*] 2018). MRI may provide valuable information to help determine the need for intervention and for procedural guidance (Shah et al [*ACR*] 2018). It is also recommended to evaluate for ligamentous injury or worsening neurologic deficit associated with fracture, or to distinguish between malignant and benign compression fractures (Hutchins et al [*ACR*] 2021; PLE expert panel consensus opinion). MRI without and with IV contrast may be helpful to delineate etiology of

fracture when underlying malignancy, infection, or inflammation are suspected (Hutchins et al [*ACR*] 2021). MRI with IV contrast can be useful for additional information in a patient who has had a recent corresponding MRI without IV contrast (PLE expert panel consensus opinion).

CT lumbar spine:
CT without IV contrast is useful to define fractures not visible on plain radiographs (Hegmann et al [*ACOEM*] 2019), and can provide a detailed analysis of fractures that extend to the posterior column of the vertebra or for evaluating the integrity of pedicles and the posterior cortex (Hutchins et al [*ACR*] 2021; Shah et al [*ACR*] 2018). It may also be appropriate for vertebroplasty/kyphoplasty planning, or to differentiate benign from pathologic fractures (PLE expert panel consensus opinion; Bussières et al 2008).

Bone scan, SPECT, SPECT/CT:
Tc-99m bone scan with SPECT/CT can be useful for radiographically occult fractures (Hutchins et al [*ACR*] 2021; Hegmann et al [*ACOEM*] 2019). Bone scintigraphy can also be useful to evaluate indeterminate findings on plain radiography, CT, or MRI, or to evaluate for multiple lesions in patients with indeterminate findings on CT or MRI (PLE expert panel consensus opinion). SPECT/CT has been shown to precisely localize abnormalities in the vertebra, particularly in complicated cases (Shah et al [*ACR*] 2018). The significance of uptake on bone scan needs to be interpreted with caution, however, as increased plate-like uptake can occur with disc degeneration and inflammatory discopathy as well (PLE expert panel consensus opinion). Of note, increased uptake on bone scan does not allow differentiation between benign and pathologic fractures (PLE expert panel consensus opinion).

PET or PET/CT:
FDG-PET may on occasion be useful to evaluate for pathologic fractures in patients with known PET-sensitive cancers who have indeterminate findings on MRI and/or CT (PLE expert panel consensus opinion; Hutchins et al [*ACR*] 2021).

<u>Clinical notes:</u>

- Risk factors that increase the likelihood of spinal fracture in a patient with low back pain include older age, known osteoporosis, prolonged corticosteroid use, trauma, disproportionate pain, and pain following heavy lifting (Thorson et al [*ICSI*] 2018; Chiodo et al [*U of MI*] 2020; Shah et al [*ACR*] 2018; PLE expert panel consensus opinion).
- Patients with severe uncontrolled, incapacitating or unrelenting pain and a suspicion of fracture warrant consideration for urgent workup and/or referral (Thorson et al [*ICSI*] 2018; PLE expert panel consensus opinion).
- Imaging is recommended after a trial of conservative therapy in patients with risk factors for vertebral compression fracture (Chou et al [*ACP*] 2011).
- In patients with negative radiographs, repeat radiograph should be considered if moderate or severe pain persists at follow-up at 2-4 weeks (PLE expert panel consensus opinion).

<u>Technical notes:</u>

- MRI examinations should include sagittal STIR or T2 fat saturations images to evaluate for marrow edema (PLE expert panel consensus opinion).
- Fluid-sensitive MRI sequences (short tau inversion recovery or fat-saturated T2-weighted imaging), are helpful for detecting acute fractures, identifying fracture clefts, and differentiating synchronous fractures (Shah et al [*ACR*] 2018).

- Consider inclusion of T1 and/or STIR coronal MRI images through the sacrum to evaluate for sacral insufficiency fractures, which also occur frequently in this patient group (PLE expert panel consensus opinion).

Evidence update (2010-present):
High Level of Evidence:
None

Moderate Level of Evidence:
None

Low Level of Evidence:
Chang et al (2020) retrospectively evaluated whether CT features can predict bone marrow edema (BME) on MRI and fracture age in a total of 189 thoracolumbar compression fractures (total n = 103). Patients were imaged with both spine CT and MRI (analyzed by two musculoskeletal radiologists), and presence and extent of BME were assessed on MRI. On CT, five features were analyzed (presence of cortical or endplate fracture line, presence of trabecular fracture line, presence of condensation band, change in trabecular attenuation, and width of paravertebral soft-tissue change). All five CT findings were predominantly seen in fractures with BME ($p < 0.001$). Elevated trabecular attenuation, presence of a cortical or endplate fracture line, and paravertebral soft-tissue width showed excellent diagnostic indication for fractures with BME (ROC AUCs: 0.990, 0.976, and 0.950, respectively). Interobserver agreement was good for the trabecular fracture line factor and excellent for all other factors. The authors conclude that CT is a good modality for evaluating vertebral compression fracture. It shows excellent diagnostic performance compared with MRI for distinguishing symptomatic compression fracture with BME from those without BME and for differentiating extent of BME.

He et al (2018) retrospectively evaluated the differential diagnostic value of 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (^{18}F-FDG) PET/CT for benign and malignant vertebral compression fractures (VCFs), compared to MRI, among 87 patients (n = 116 VCFs). MRI was performed in all patients, with FDG PET/CT executed in 51 patients. Three malignant features (convex posterior cortex, epidural mass formation, and pedicle enhancement) from MRI and the maximum standardized uptake value (SUVmax) from ^{18}F-FDG PET/CT were evaluated in benign and malignant VCFs, respectively. Results showed that the sensitivity and specificity for predicting malignant VCFs were 75.6% and 77.3% for convex posterior cortex, 82.9% and 81.3% for epidural mass formation, and 85.7% and 70.8% for pedicle enhancement. ^{18}F-FDG PET/CT demonstrated higher sensitivity (100%) but lower specificity (38.9%) as compared to MRI with regard to differentiation between benign and malignant VCFs. The authors conclude that, in a situation where MRI findings are not diagnostic, ^{18}F-FDG PET/CT provides additional information as it has high sensitivity.

Wnuk et al (2018) conducted a retrospective cohort study to determine the proportion of MRI examinations with a detectable impact on patient care (actionable outcomes - including findings leading to an intervention such as surgery, new diagnosis of cancer, infection, or fracture, or following known lumbar spine pathology). A total of 5,365 outpatient lumbar MRI exams were conducted; patient notes were examined to verify outcomes. The proportion of actionable lumbar spine MRI was 13%. Of 36 suspected cases of cancer or infection, 81% were false positives. Further investigations were ordered on 59% of suspicious examinations, 86% of which were false positives. The authors conclude that the percentage of lumbar spine MRI that has a detectable impact on patient management is surprisingly low and unrelated to the appropriateness of the examination. Additionally, detection of significant disease

other than spinal degeneration is rare, even in the presence of red flags, and true-positive findings are outnumbered by false-positive findings with potential to result in patient harm.

Low back pain and/or radiculopathy with no red flags or complicating features; patient has not completed an appropriate period (≥ 4 weeks) of conservative therapy:

- **Red – MRI**
- **Red - CT or CT myelography**
- **Red – Bone scan, SPECT, SPECT/CT**
- **Red – PET or PET/CT**
- **Red – Gallium scan whole body**
- **Red – WBC scan**

Level of Evidence: High

Notes concerning applicability and/or patient preferences: Patient education is essential to patient acceptance (Thorson et al [*ICSI*] 2018; *VA/DOD* 2017; Chou et al [*ACP* & *APS*] 2007).

Guideline, article, and PLE expert panel consensus opinion summary:

Overview:

A number of high quality guidelines agree that clinicians should not routinely recommend imaging for patients with uncomplicated low back pain, an absence of red flags, and no prior management (Chou et al. [*ACP & APS*] 2007, strong recommendation/moderate quality evidence; Thorson et al [*ICSI*] 2018: moderate quality of evidence, strong recommendation; Hutchins et al [*ACR*] 2021; *VA/DOD* 2017, strong recommendation; Stochkendahl et al 2018; Chiodo et al [*U of MI*] 2020). The *North American Spine Society* states that there is insufficient evidence to make a recommendation for or against obtaining imaging of low back pain in the absence of red flags (Kreiner et al [*NASS*] 2020: Grade I Recommendation).

Uncomplicated acute low back pain and/or radiculopathy is a benign, self-limited condition that does not warrant any imaging studies (Hutchins et al [*ACR*] 2021), as the natural course of acute sciatica caused by lumbar disc herniation is favorable (Hegmann et al [*ACOEM*] 2019; Bussieres et al 2008; PLE expert panel consensus opinion). Within 6 weeks, approximately 90% of episodes will resolve satisfactorily regardless of treatment (Chiodo et al [*U of MI*] 2020). MRI within the first 4-6 weeks of suspected lumbar disc herniation is generally necessary only when there is progressive neurologic deficit, intolerable pain levels despite conservative care, and/or if the result is likely to change management (surgical referral or injection is planned) (Hegmann et al [*ACOEM*] 2019; Chiodo et al [*U of MI*] 2020; Bussières et al 2008; *NICE* 2016).

Clinical Notes:

- High quality studies have shown that early imaging does not improve outcome and does not result in psychological benefits (Chou et al [*ACP*] 2011).
- Most of the reported series in the literature exclude patients who are candidates for urgent or emergent surgery; as a result, these recommendations do not apply to this group of patients. Imaging is indicated in patients who are being considered for urgent or immediate injection therapy or surgical intervention (PLE expert panel consensus opinion).

- Conservative therapy may include manipulation, exercise, physical therapy, pharmacological therapy or time (if the patient is unable or unwilling to undergo other available noninvasive treatments) (PLE expert panel consensus opinion).

Evidence update (2010-present):

High Level of Evidence:

Jarvik et al (2015) conducted a prospective cohort of 5239 patients with low back pain over 65 compared early imaging with radiography and/or MRI/CT to delayed imaging (4-6 weeks) using propensity score matching. There were not clinically significant differences in primary RMDQ pain questionnaire, numerical pain rating, brief pain inventory at 3, 6 or 12 months. Only 1 case (0.06%) of cancer (lymphoma) was diagnosed on the early imaging study. Patients who underwent imaging diagnostics early had more fractures detected (2% in the early radiograph group vs. 0.6% in the no early or no radiograph group; 0.9% in the early MRI/CT group vs 0% in the no early or no MRI/CT group). Early imaging was not associated with better one-year outcomes.

Moderate Level of Evidence:

Graves et al (2012) conducted a prospective study 1226 workers with disability claims found that early (before 6 weeks) MRI did not improve patient centered outcomes (as assessed by RDQ and SF-36) and is in fact associated with an increased likelihood and duration of disability.

Low Level of Evidence:

Jacobs et al (2020) conducted a retrospective matched cohort study of new episodes of uncomplicated non-specific low back pain, using data from the U.S. Department of Veterans Affairs (VA) Corporate Data Warehouse. A total of 405,965 unique episodes were included, including a total of 9,977 individuals (2.46%) who received a lumbar spine MRI within 6 weeks of their index visit. Results found that these early MRIs were associated with more back surgeries (1.48% vs. 0.12% in episodes without early MRI), greater use of prescription opioids (35.1% vs. 28.6%), and a higher final pain score (3.99 vs. 3.87). The authors conclude that the association between early imaging and increased utilization was apparent, even in a setting largely unaffected by the incentives of fee-for-service care.

Konstantinou et al (2018) conducted a prospective cohort study to describe the prognosis and prognostic factors in primary care patients with low back-related leg pain and sciatica. A total of 609 patients visiting their family doctor were included. Information about pain, function, psychological, and clinical variables was collected, and all patients received an MRI scan. Good outcome was defined as $\geq$ 30% reduction in disability (measured by the Roland-Morris Disability Questionnaire). Response rates were 402 (66%) at 4 months and 450 (73.9%) at 12 months. A total of 74.2% patients were clinically diagnosed with sciatica. At 12-month follow-up, 55% of patients improved in both the total sample and the sciatica group. Longer leg pain duration (OR 0.41; CI: 0.19-0.90), higher identity score/sum of symptoms (OR 0.70; CI 0.53-0.93), and patient's belief that the problem will last a long time (OR 0.27; CI 0.13-0.57) were strongest independent prognostic factors negatively associated with improvement. Lack of nerve root compression on MRI was not a strong independent prognostic factor related to improvement in both the total sample and sciatica groups.

Moderate to severe leg pain/lumbar radiculopathy, with or without low back pain, and any of the following:

- **Failure of conservative therapy*,**
- **Major or progressive neurologic deficits, and/or**
- **Planning and evaluation for injection therapy and/or surgery:**

  - **Green** – **MRI lumbar spine without IV contrast** or **MRI lumbar spine without and with IV contrast**
  - **Yellow** – **MRI lumbar spine with IV contrast**
    [further evaluate abnormalities previously noted on noncontrast imaging]
  - **Yellow** – **CT lumbar spine** or **CT myelography lumbar spine**
    [*MRI contraindicated or findings indeterminate; intervention planning*]
  - **Red** – **Bone scan**, **SPECT**, **SPECT/CT; PET** or **PET/CT; Gallium scan whole body; WBC scan**

*Failure of conservative care can be defined as moderate to severe persistent symptoms following conservative care for 4 weeks, increasing pain during a trial of conservative care, uncontrolled pain, significant limitation of function, inability to perform the activities of daily living, or inability to participate in noninvasive care for an appropriate period of time (PLE expert panel consensus opinion).

Level of Evidence: High

Notes concerning use of contrast: The use of MRI IV contrast may be indicated in patients with radiculopathy or stenosis if they have unexplained neurologic deficits, a suspected or possible neurologic disorder, or if they have a history of prior surgery. Follow-up imaging with contrast may also be indicated for further evaluation of abnormalities previously seen on noncontrast imaging.

Notes concerning applicability and/or patient preferences: Patient education is essential to patient acceptance (Thorson et al [*ICSI*] 2018; *VA/DOD* 2017; Chou et al [*ACP* & *APS*] 2007).

Guideline, article, and PLE expert panel consensus opinion summary:

Overview:

Absent red flags, first-line treatment for low back pain is conservative therapy (Hutchins et al [*ACR*] 2021). Diagnostic imaging, preferably MRI, is recommended when neurologic deficits are serious or progressive, or when there is severe or intractable pain persisting after an appropriate course of conservative therapy (Kreiner et al [*NASS*] 2014: grade A recommendation; Kreiner et al [*NASS*] 2020: work group consensus statement; PLE expert panel consensus opinion; *VA/DoD* 2017: strong recommendation; Chou et al [*ACP & APS*] 2007: strong recommendation, moderate evidence; Chiodo et al [*U of MI*] 2020). This includes a patient whose limitations due to consistent symptoms have persisted for 1 month or more to further evaluate the possibility of potentially serious pathology (Hegmann et al [*ACOEM*] 2019). Imaging may also be appropriate for a patient who is a candidate for surgery or epidural steroid injection (*VA/DoD* 2017: strong recommendation; PLE expert panel consensus opinion).

MRI lumbar spine:

MRI, generally without contrast, is recommended for low back pain and/or radiculopathy with persistent or progressive symptoms after conservative therapy (lasting at least 4-6 weeks), or if the patient is a

candidate for surgery or epidural steroid injection (Hegmann et al [*ACOEM*] 2019; Chiodo et al [*U of MI*] 2020; Chou et al [*ACP & APS*] 2007: strong recommendation, moderate evidence). MRI provides superior delineation of soft tissue anatomy and pathology, and superior definition of neurologic structures (Chiodo et al [*U of MI*] 2020; PLE expert panel consensus opinion). It can also confirm the presence of anatomic narrowing of the spinal canal or presence of nerve root impingement (Kreiner et al [*NASS*] 2013). In cases where an epidural glucocorticosteroid injection is being considered for temporary relief of acute or subacute radiculopathy, MRI at 3-4 weeks (before the injection) may be reasonable (Hegmann et al [*ACOEM*] 2019: moderate (B) recommendation, moderate confidence). MRI with IV contrast can be useful in patients with a history of previous surgery to evaluate abnormalities seen on a previous MRI without IV contrast (PLE expert panel consensus opinion).

CT lumbar spine:
CT can be useful to confirm the presence of a disc herniation in patients with history and physical examination consistent with radiculopathy (Kreiner et al [*NASS*] 2014: grade A recommendation), particularly if MRI is contraindicated or unavailable, to evaluate findings on MRI, or for surgical planning following MRI (Hegmann et al [*ACOEM*] 2019; Chiodo et al [*U of MI*] 2020; PLE expert panel consensus opinion). CT may also be useful to evaluate for injection therapy or for surgical planning (Hegmann et al [*ACOEM*] 2019; PLE expert panel consensus opinion), as it can delineate osseous margins and aid in trajectory planning for hardware fixation (Hutchins et al [*ACR*] 2021).

CT myelography lumbar spine:
CT myelography may be necessary to evaluate for lumbar radiculopathy in patients who cannot undergo MRI, or with indeterminate findings on routine MRI or CT (Hegmann et al [*ACOEM*] 2019; Chiodo et al [*U of MI*] 2020; Hutchins et al [*ACR*] 2021; Kreiner et al [*NASS*] 2012: grade A recommendation). CT myelography may also be useful to evaluate for injection therapy or for surgical planning (PLE expert panel consensus opinion). If there is strong consideration for surgery, then CT myelography should be considered instead of CT alone (Hegmann et al [*ACOEM*] 2019: level C recommendation, moderate confidence). Myelography is invasive, however with some risk of injection and post-myelography headache (PLE expert panel consensus opinion).

<u>Clinical/Imaging notes:</u>

- The natural history of lumbar disc herniation with radiculopathy is for improvement in the first 4 weeks for most patients with noninvasive therapy (*VA/DOD* 2017).
- Early treatment of low back pain with radiculopathy is noninvasive and may consist of spinal manipulative therapy, exercise therapy, physical therapy, use of external stimulators and/or pharmacologic treatment (PLE expert panel consensus opinion).
- Failure of conservative care can be defined as moderate to severe persistent symptoms following conservative care for 4 weeks, increasing pain during a trial of conservative care, uncontrolled pain, significant limitation of function, inability to perform the activities of daily living, or inability to participate in noninvasive care for an appropriate period of time (PLE expert panel consensus opinion).
- Imaging is recommended after a trial of conservative therapy in patients with signs or symptoms of radiculopathy or spinal stenosis (Chou et al [*ACP*] 2011).
- Findings on MRI and CT are nonspecific and require strict correlation of symptoms and findings on physical exam to determine the significance (Kreiner et al [*NASS*] 2020; PLE expert panel consensus opinion).

<u>Evidence update (2010-present):</u>

High Level of Evidence:
el Barzouhi et al (2013) reported an observational study to assess the MRI observer variation in patients with sciatica who are potential candidates for lumbar disc surgery. Excellent agreement was found on the affected disc level (kappa range 0.81-0.86) and the nerve root that most likely caused the sciatic symptoms (kappa range 0.86-0.89). Interobserver agreement was moderate to substantial for the probability of disc herniation (kappa range 0.57-0.77) and the probability of nerve root compression (kappa range 0.42-0.69).

Moderate Level of Evidence:
None

Low Level of Evidence:
Kim et al (2019) retrospectively analyzed causes of pain, MRI imaging characteristics, and therapeutic effect of spinal injection in 381 consecutive patients with extreme low back pain or sciatica. Treatment response (numerical pain rating scale decrease of $\geq$ 30%) was measured. The most frequent cause of pain was spinal stenosis (largely in patients $\geq$ 50 years of age), followed by herniated intervertebral disc, facet osteoarthritis, and osteoporotic compression fracture. Spinal injection was effective in 44.2% of cases. Those responding to injection showed significantly lower rate of lumbar surgery within 6 months (P = 0.004). The authors conclude that patients with extreme low back pain or sciatica had similar clinical and imaging characteristics as those with typical low back pain referred for spinal injection. Spinal injection could be an effective method of pain control for patients with extreme low back pain or sciatica.

Kim et al (2018) conducted a systematic review summarizing the available evidence on the diagnostic accuracy of imaging (index test) compared to surgery (reference test) for identifying lumbar disc herniation (LDH) in adult patients. A total of 14 studies were included (total n = 940). Nine studies investigated CT, eight myelography, and six MRI. All patients (age 14-82) had clinical findings consistent with LDH. Summary estimates of sensitivity and specificity of the different imaging techniques varied between 76 and 81%, with moderate to very low quality evidence. CT, myelography, and MRI showed comparable accuracy.

Konstantinou et al (2018) conducted a prospective cohort study to describe the prognosis and prognostic factors in primary care patients with low back-related leg pain and sciatica. A total of 609 patients visiting their family doctor were included. Information about pain, function, psychological, and clinical variables was collected, and all patients received an MRI scan. Good outcome was defined as $\geq$ 30% reduction in disability (measured by the Roland-Morris Disability Questionnaire). Response rates were 402 (66%) at 4 months and 450 (73.9%) at 12 months. A total of 74.2% patients were clinically diagnosed with sciatica. At 12-month follow-up, 55% of patients improved in both the total sample and the sciatica group. Longer leg pain duration (OR 0.41; CI: 0.19-0.90), higher identity score/sum of symptoms (OR 0.70; CI 0.53-0.93), and patient's belief that the problem will last a long time (OR 0.27; CI 0.13-0.57) were strongest independent prognostic factors negatively associated with improvement. Lack of nerve root compression on MRI was not a strong independent prognostic factor related to improvement in both the total sample and sciatica groups.

Ekedahl et al (2017) retrospectively evaluated subgroup differences in 1-year response to transforaminal epidural steroid injection (TESI) by relating MRI findings and clinical test results, baseline characteristics, the number of TESIs performed, and conservative treatment to reduction in leg pain and self-reported disability among patients with chronic radicular pain. In a cohort of 100 subjects, 170 TESIs were

performed for 1 year. The sample was stratified by type and location of disc herniation, grade of nerve root compression, and positive Slump test. Treatment response was evaluated by visual analogue scale leg pain and self-reported disability. Clinical findings failed to predict the 1-year treatment response. Low age, short duration of leg pain, central/subarticular disc herniation, and high-grade subarticular nerve compression predicted a favorable 1-year response to TESI.

Lumbar spinal stenosis with either of the following:

- **Moderate or severe pain, marked debility or limitation of function persisting after a course of conservative therapy*, and/or**
- **Planning or evaluation for injection therapy or surgery**

  - **Green – MRI lumbar spine without IV contrast** or **MRI lumbar spine without and with IV contrast**
  - **Yellow – MRI lumbar spine with IV contrast**
    [further evaluate abnormalities previously noted on noncontrast imaging]
  - **Yellow – CT lumbar spine** or **CT myelography lumbar spine**
    [MRI contraindicated or findings indeterminate; intervention planning]
  - **Red – Bone scan; PET; PET/CT; SPECT; SPECT/CT; Gallium scan whole body; WBC scan**

*Failure of conservative care can be defined as moderate to severe persistent symptoms following conservative care for 4 weeks, increasing pain during a trial of conservative care, uncontrolled pain, significant limitation of function, inability to perform the activities of daily living, or inability to participate in noninvasive care for an appropriate period of time (PLE expert panel consensus opinion).

Level of Evidence: High

Notes concerning use of contrast: MRI IV contrast may be indicated in patients with stenosis if they have unexplained neurologic deficits, a suspected or possible neurologic disorder, or if they have a history of prior surgery. Follow-up imaging with contrast may also be indicated for further evaluation of abnormalities seen on previous noncontrast imaging.

Notes concerning applicability and/or patient preferences: Patient education is essential to patient acceptance (Thorson et al [*ICSI*] 2018; *VA/DOD* 2017; Chou et al [*ACP* & *APS*] 2007).

Guideline, article, and PLE expert panel consensus opinion summary:
Overview:
For patients with low back pain, diagnostic imaging is recommended in patients with low back pain and clinical signs of lumbar spinal stenosis if they are candidates for surgery or epidural steroid injection, when neurologic deficits are serious or progressive, or when there is pain persisting after an appropriate course of conservative therapy (*VA/DoD* 2017: strong recommendation; Chou et al [*ACP & APS*] 2007: strong recommendation, moderate evidence; PLE expert panel consensus opinion). MRI is the procedure of choice to evaluate for lumbar spinal stenosis, as it provides superior delineation of soft tissue anatomy and pathology, and superior definition of neurologic structures (Kreiner et al [*NASS*] 2013: Grade B; PLE expert panel consensus opinion). CT is recommended in patients with history and physical examination consistent with lumbar spinal stenosis for whom MRI and CT myelography are contraindicated, inappropriate, or inconclusive (Kreiner et al [*NASS*] 2013: Grade B). CT may also be useful to evaluate for injection therapy or for surgical planning (PLE expert panel consensus opinion). CT myelography is recommended in patients with history and physical examination consistent with lumbar spinal stenosis who cannot undergo MRI or for whom MRI is inconclusive (Kreiner et al [*NASS*] 2013: Grade B). CT myelography may also be useful to evaluate for injection therapy or for surgical planning (PLE expert panel consensus opinion). Myelography is invasive, with some risk of injection and post-

myelography headache (PLE expert panel consensus opinion).

Clinical notes:

- Lumbar spinal stenosis presents with variable symptoms which may include low back pain, buttock and/or leg pain, weakness and neurogenic claudication, and is secondary to narrowing of the spinal canal (Kreiner et al [*NASS*] 2013).
- Early treatment of lumbar spinal stenosis is noninvasive and may consist of spinal manipulative therapy, exercise therapy, physical therapy or pharmacologic therapy or time (for patients unable to undergo available noninvasive treatments) (PLE expert panel consensus opinion).
- Failure of conservative care can be defined as moderate to severe pain which persists following an appropriate period of conservative care (typically 4-6 weeks), pain increasing during a course of conservative therapy, moderate or marked resting pain and/or persistent limitation of function (PLE expert panel consensus opinion).
- Imaging is recommended after a trial of conservative therapy in patients with signs or symptoms of symptomatic spinal stenosis (Chou et al [*ACP*] 2011).

Technical notes:

- Findings on MRI and CT are nonspecific and require strict correlation of symptoms and findings on physical exam to determine the significance (PLE expert panel consensus opinion).
- The use of well-defined, articulated and validated criteria for assessing dural sac narrowing on MRI, CT or CT myelography is recommended to improve interobserver and intraobserver reliability (Kreiner et al [*NASS*] 2013).

Evidence update (2010-present):

High Level of Evidence:

None

Moderate Level of Evidence:

Alsaleh et al (2017) conducted a prospective study to determine the reliability and dependability of MRI and CT in the assessment of lumbar spinal stenosis. CT and MRI scans (performed within one year of each other) of 54 patients (mean age 65 years; range 23-85) referred for surgical consultation were reviewed. Intra-observer and inter-observer reliability was determined between three reviewers using Kappa coefficient. Results found almost perfect intra-observer reliability for MRI by the two expert reviewers ($k = 0.91$ for surgeon and $k = 0.92$ for neuro-radiologist). For CT, intra-observer agreement for the surgeon was $k = 0.77$, while the neuro-radiologist was higher ($k = 0.96$). For both CT and MRI, the standardized qualitative assessment used by the two expert reviewers had a better inter-observer reliability than that between the expert reviewers and the general reporting radiologist, who did not utilize a standardized assessment system. When the qualitative assessment was compared directly, CT overestimated the degree of stenosis 20-35 % of the time ($p < 0.05$) while MRI overestimated the degree of stenosis 2-11 % of the time ($p < 0.05$). No correlation was found between qualitative and quantitative analysis with functional status. The authors conclude that MRI is a more reliable tool than CT, but neither correlates with functional status.

Low Level of Evidence:

Kim et al (2019) retrospectively analyzed causes of pain, MRI imaging characteristics, and therapeutic effect of spinal injection in 381 consecutive patients with extreme low back pain or sciatica. Treatment response (numerical pain rating scale decrease of $\geq$ 30%) was measured. The most frequent cause of

pain was spinal stenosis (largely in patients ≥ 50 years of age), followed by herniated intervertebral disc, facet osteoarthritis, and osteoporotic compression fracture. Spinal injection was effective in 44.2% of cases. Those responding to injection showed significantly lower rate of lumbar surgery within 6 months (P = 0.004). The authors conclude that patients with extreme low back pain or sciatica had similar clinical and imaging characteristics as those with typical low back pain referred for spinal injection. Spinal injection could be an effective method of pain control for patients with extreme low back pain or sciatica.

Moderate to severe low back pain with either of the following:

- **Failure of an appropriate course of noninvasive conservative therapy*, and/or**
- **Planning or evaluation for injection therapy or surgery**

  - Green – **MRI lumbar spine without IV contrast** or **MRI lumbar spine without and with IV contrast**
  - Yellow – **MRI lumbar spine with IV contrast**
    [further evaluate abnormalities previously noted on noncontrast imaging]
  - Yellow – **CT lumbar spine** or **CT myelography lumbar spine**
    [MRI contraindicated or findings indeterminate; intervention planning; further evaluate or characterize bone lesion(s)]
  - Yellow – **Bone scan**, **SPECT**, **SPECT/CT**
    [further evaluate or characterize bone lesion(s)]
  - Red **– PET**; **PET/CT; Gallium scan whole body; WBC scan**

*Failure of conservative care can be defined as moderate to severe persistent symptoms following conservative care for 4 weeks, increasing pain during a trial of conservative care, uncontrolled pain, significant limitation of function, inability to perform the activities of daily living, or inability to participate in noninvasive care for an appropriate period of time (PLE expert panel consensus opinion).

Level of Evidence: Low

Notes concerning use of contrast: MRI IV contrast may be indicated to evaluate abnormalities noted on prior noncontrast imaging.

Notes concerning applicability and/or patient preferences: Patient education is essential to patient acceptance (Thorson et al [*ICSI*] 2018; *VA/DOD* 2017; Chou et al [*ACP* & *APS*] 2007).

Guideline, article, and PLE expert panel consensus opinion summary:
Overview:
Absent red flags, first-line treatment for low back pain is conservative therapy (Hutchins et al [*ACR*] 2021). There is agreement among multiple high quality guidelines that imaging should not be performed in patients with low back pain without red flags/high risk features without a period of conservative care (Chou et al [*ACP/APS*] 2007: strong recommendation, moderate quality evidence; Thorson et al [*ICSI*] 2018: moderate quality of evidence, strong recommendation; *VA/DOD* 2017, strong recommendation; Stochkendahl et al 2018). The decisions by the spine subspecialist to image the patient are largely predicated on the need to exclude underlying pathologies, to assess for injection therapy, and to assess for surgery (PLE expert panel consensus opinion). MRI is the advanced imaging procedure of choice to evaluate patients with low back pain unresponsive to conservative therapy or requiring surgery or injection, as it provides superior delineation of soft tissue anatomy and pathology, and superior definition of neurologic structures (Hegmann et al [*ACOEM*] 2019; Chiodo et al [*U of MI*] 2020; PLE expert panel consensus opinion). CT is indicated for patients who cannot undergo MRI and in patients with indeterminate findings on MRI, to evaluate for injection therapy, or for surgical planning (Hegmann et al [*ACOEM*] 2019; Chiodo et al [*U of MI*] 2020; PLE expert panel consensus opinion). CT myelography can be useful if MRI is contraindicated or unavailable, to evaluate indeterminate findings on MRI, to

evaluate for injection therapy or for surgical planning (PLE expert panel consensus opinion; Hegmann et al [*ACOEM*] 2019; Chiodo et al [*U of MI*] 2020; Hutchins et al [*ACR*] 2021). CT myelography may also be useful to evaluate for injection therapy or for surgical planning (PLE expert panel consensus opinion). If there is strong consideration for surgery, then CT myelography should be considered instead of CT alone (Hegmann et al [*ACOEM*] 2019: level C recommendation, moderate confidence). Myelography is invasive, however with some risk of injection and post-myelography headache (PLE expert panel consensus opinion).

Clinical/Imaging notes:

- Clinicians should consider using validated tools to assess and follow pain and disability (PLE expert panel consensus opinion).
- Practitioners should emphasize that acute low back pain is nearly always benign and generally resolves within 1 to 6 weeks, and the first line treatment for low back pain is conservative care (Patel et al [*ACR*] 2016).
- Conservative care may consist of spinal manipulation, exercise therapy, physical therapy, cognitive behavioral therapy, intensive interdisciplinary rehabilitation, massage therapy, acupuncture, yoga, pharmacologic therapy, progressive relaxation or time (for patients unable or unwilling to undergo available noninvasive treatments) (Chou et al [*ACP* & *APS*] 2007).
- Failure of conservative care can be defined as moderate to severe persistent symptoms following conservative care for 4 weeks, increasing pain during a trial of conservative care, uncontrolled pain, significant limitation of function, inability to perform the activities of daily living, or inability to participate in noninvasive care for an appropriate period of time (PLE expert panel consensus opinion).
- In referring patients with nonspecific low back pain who have failed noninvasive therapies, other published guidelines suggest referring patients to a spine specialist after a period of 3 months or longer (Chou et al [*ACP* & *APS*] 2007).

Evidence update (2010-present):

High Level of Evidence:

None

Moderate Level of Evidence:

None

Low Level of Evidence:

Brusko et al (2019) conducted a retrospective study to evaluate the outcome of 23 patients who underwent SPECT or CT/SPECT studies with hypermetabolic foci used to plan cervical or lumbar spine fusion surgery. At 3 months, 18 patients (78.3%) reported improvement in pain. At 6 months, 11 patients (47.8%) reported complete relief of symptoms, and at 12 months, 19 patients (82.6%) reported significant relief of symptoms. The authors concluded that SPECT imaging may be a useful adjunct to guide surgical planning and may result in substantial clinical improvement following surgery.

Tender et al (2019) conducted a retrospective study of 315 patients who underwent diagnostic CT-SPECT. 48 patients underwent either cervical (n = 25) or lumbar (n = 23) fusion. The overall axial spinal pain, as assessed through self-reporting of visual analog scale scores at 6 months postoperatively, improved from 9.04 ± 1.4 to 4.34 ± 2.3 (p = 0.026), with cervical fusion patients improving from 8.8 ± 1.8 to 3.92 ± 2.2 (p = 0.019) and lumbar fusion patients improving from 9.35 ± 0.7 to 4.87 ± 2.3 (p = 0.008). The authors concluded that CT-SPECT may offer a diagnostic advantage over current imaging modalities

in identifying the primary pain generator in patients with axial spinal pain.

Berg et al (2019) conducted a retrospective study of 114 patients to assess reliability of lumbar facet arthropathy evaluation with CT or MRI in patients with (n = 66) and without (n = 48) lumbar disc prosthesis and to estimate the reliability for individual CT and MRI findings indicating facet arthropathy. Three radiologists independently rated facet joint space narrowing, osteophyte / hypertrophy, erosions, subchondral cysts, and total grade facet arthropathy at each of the three lower lumbar levels on both CT and MRI. Results found interobserver agreement on total grade facet arthropathy to be moderate at all levels with CT (kappa 0.47–0.48) and poor to fair with MRI (kappa 0.20–0.32). The presence of a disc prosthesis did not influence the levels of agreement.

Kim et al (2019) retrospectively analyzed causes of pain, MRI imaging characteristics, and therapeutic effect of spinal injection in 381 consecutive patients with extreme low back pain or sciatica. Treatment response (numerical pain rating scale decrease of $\geq$ 30%) was measured. The most frequent cause of pain was spinal stenosis (largely in patients $\geq$ 50 years of age), followed by herniated intervertebral disc, facet osteoarthritis, and osteoporotic compression fracture. Spinal injection was effective in 44.2% of cases. Those responding to injection showed significantly lower rate of lumbar surgery within 6 months (P = 0.004). The authors conclude that patients with extreme low back pain or sciatica had similar clinical and imaging characteristics as those with typical low back pain referred for spinal injection. Spinal injection could be an effective method of pain control for patients with extreme low back pain or sciatica.

History of lumbar spine surgery and any of the following:

- **New or progressive symptoms*,**
- **Suspicion of device or hardware failure, and/or**
- **Preoperative planning**

- **Green** – **MRI lumbar spine without IV contrast** or **MRI lumbar spine without and with IV contrast**
- **Green** – **CT lumbar spine**
- **Yellow** – **MRI lumbar spine with IV contrast**
  [further evaluate abnormalities previously noted on noncontrast imaging]
- **Yellow** – **CT myelography lumbar spine**
  [*MRI contraindicated or findings indeterminate; intervention planning*]
- **Yellow** - **Bone scan, SPECT**, **SPECT/CT**
  [*further evaluate or characterize bone lesion(s)*]
- **Red** – **PET** or **PET/CT; Gallium scan whole body; WBC scan**

*For infection-related concerns, see scenario 2 of this document (suspected infection).

Level of Evidence: Low

Notes concerning use of contrast: MRI IV contrast is often indicated in patients with a history of prior surgery, or to evaluate abnormalities noted on prior noncontrast imaging.

Notes concerning applicability and/or patient preferences: Patient education is essential to patient acceptance (Thorson et al [*ICSI*] 2018; *VA/DOD* 2017; Chou et al [*ACP* & *APS*] 2007).

Guideline, article, and PLE expert panel consensus opinion summary:
Overview:
There can be many causes of back pain following surgery (Hutchins et al [*ACR*] 2021). In patients with new symptoms (e.g., pain, radiculopathy) and a previous history of lumbar fusion surgery, interspinous device placement, or arthroplasty surgery, advanced imaging is indicated, particularly with CT or MRI (Hutchins et al [*ACR*] 2021; Chiodo et al [*U of MI*] 2020; Choudhri et al 2014).

MRI lumbar spine:
MRI, either without contrast, or without and with contrast, is appropriate for new or progressive symptoms or findings after prior lumbar surgery, and is usually the imaging test of choice to distinguish disc herniation from scar tissue associated with prior surgery (Chiodo et al [*U of MI*] 2020; Hutchins et al [*ACR*] 2021). MRI with IV contrast can be useful for additional information in a patient who has had a recent corresponding MRI without IV contrast, such as nerve root compression or arachnoiditis (PLE expert panel consensus opinion; Hutchins et al [*ACR*] 2021).

CT lumbar spine or CT myelography lumbar spine:
CT lumbar spine without IV contrast can be useful in detecting painful hardware failure, such as prosthetic loosening, malalignment, or metallic fracture (Hutchins et al [*ACR*] 2021). Following instrumented posterolateral lumbar fusions or anterior lumbar interbody fusion (ALIF) with cage

instrumentation, CT imaging with fine-cut axial and multi-planar reconstruction views is recommended as a method to assess fusion status (Choudhri et al 2014: grade B recommendation; Hutchins et al [*ACR*] 2021). The addition of IV contrast is not necessary to evaluate bony fusion and hardware but may be useful in assessment of epidural abscess for patients in this scenario (Hutchins et al [*ACR*] 2021). CT myelography can also be useful in specific postsurgical situations (Hegmann et al [*ACOEM*] 2019). Compared to MRI, it has safety advantages for patients with implanted devices and is also useful for imaging those with significant artifact from surgical hardware (Hutchins et al [*ACR*] 2021). Thin section CT or CT myelography with multiplanar reconstructions are recommended to evaluate the integrity of disc replacement devices and/or interspinous devices in symptomatic patients (PLE expert panel consensus opinion).

Bone scan, SPECT, SPECT/CT:
Bone scintigraphy and SPECT can on occasion be useful to evaluate for the source of low back pain, such as further evaluation of a bone lesion (PLE expert panel consensus opinion). However, technetium-99 bone scanning is not recommended as a reliable method to assess fusion status following lumbar fusion surgery (Choudhri et al 2014: grade C recommendation).

Clinical notes:

- Following lumbar fusion surgery, static lumbar radiographs are not recommended as a stand-alone method to assess fusion status (Choudhri et al 2014).
- When bilateral posterolateral intertransverse bridging bone is observed on CT scans, the presence of solid fusion is strongly suggested (Choudhri et al 2014).
- In the setting of anterior lumbar interbody fusion (ALIF), the demonstration of bridging bone posterior to the cage (posterior sentinel sign) on CT scans correlates with the presence of solid fusion with a consensus of reviewers, but intraobserver variability limits the generalizability of a single rater assessment (Choudhri et al 2014).
- Following uninstrumented lumbar fusion surgery, when noninvasive assessment of fusion status is desired, lateral flexion and extension lumbar radiographs are recommended (Choudhri et al 2014).

Technical notes:

- CT examinations obtained to evaluate the integrity of spine fusions should utilize thin sections with reformatted sections in the sagittal and coronal or coronal oblique planes (PLE expert panel consensus opinion).
- CT and MRI spine examinations obtained in patients with instrumentation, interbody implants with metallic beads, metallic interbody implants or total disc replacement implants should utilize metal artifact reduction techniques (PLE expert panel consensus opinion).

Evidence update (1980-present):
High Level of Evidence:
None

Moderate Level of Evidence:
Carreon et al (2007) conducted a cross-sectional blinded study of 86 patients to determine intraobserver and interobserver agreement of plain radiographs and fine-cut (1-mm) CT scans with sagittal and coronal reconstructions in evaluating fusion status after instrumented posterolateral fusions. Three spine surgeons graded the fusions using 1-year postoperative flexion/extension lateral and

anteroposterior radiographs, and fine-cut CT. Two separate readings, two weeks apart, were done on each patient by each surgeon. Results found intraobserver agreement to assess fusion status was moderate for CT with both classification systems (Molinari = 0.48, Glassman 0.47), and fair-to-moderate for x-ray (Molinari: 0.37, Glassman: 0.43). Interobserver agreement was moderate for both classification systems using CT (Molinari = 0.48, Glassman 0.48), and fair for both systems using x-ray (Molinari = 0.24, Glassman 0.26). The authors conclude that fine-cut CT scans with reconstructions have a considerably greater degree of interobserver/intraobserver agreement compared with flexion/extension and anteroposterior radiographs. Observers agreed most often when fusion was assessed as solid. Fusion evaluation based on radiographs agreed with CT scans only half the time.

Low Level of Evidence:
Berg et al (2019) conducted a retrospective study of 114 patients to assess reliability of lumbar facet arthropathy evaluation with CT or MRI in patients with (n = 66) and without (n = 48) lumbar disc prosthesis and to estimate the reliability for individual CT and MRI findings indicating facet arthropathy. Three radiologists independently rated facet joint space narrowing, osteophyte / hypertrophy, erosions, subchondral cysts, and total grade facet arthropathy at each of the three lower lumbar levels on both CT and MRI. Results found interobserver agreement on total grade facet arthropathy to be moderate at all levels with CT (kappa 0.47–0.48) and poor to fair with MRI (kappa 0.20–0.32). Disc prosthesis at the rated level did not influence agreement.

Lee et al (2013) conducted a prospective study of 108 patients (mean age 64.3 years, range 37–86) to evaluate the usefulness of dynamic flexion-extension radiographs as a method for evaluating fusion, by comparing it with 3D thin-section CT. All patients were diagnosed with severe spinal stenosis and Grade I and Grade II spondylolisthesis, underwent posterior lumbar interbody fusion (PLIF) surgery, and followed-up by dynamic plain radiographs, functional rating scale, and 3D thin-section CT for 1 year after surgery. There was a poor agreement on average (59.0%) and a statistical nonagreement (Kappa=0.151), indicating diagnostic agreement using plain radiographs has a low level of significance. 3D-CT had > 91% interobserver and interobserver agreement, with mean kappa values of $\geq$ 0.5, indicating a significantly high level of objective diagnostic agreement. There was no statistically significant difference between the radiography-assessed fusion and nonfusion groups in clinical assessment values, and CT fusion and nonfusion groups did not show significant differences. Authors conclude that for an objective and accurate assessment of fusion after PLIF surgery, it would be more appropriate to look for interbody bridging bone formation at 12 months by 3D thin-section CT rather than dynamic flexion-extension radiographs.

Guideline exclusions:

- Cases meeting the definition of a suspected or confirmed emergency medical condition (e.g., major or high velocity trauma)
- Staging, follow-up, or surveillance of cancer
- Inflammatory spondyloarthropathy
- Use of MR discography or CT discography
- Pregnant patients, and
- Pediatric patients

AUC Revision History:

Revision Date:	New AUC Clinical Scenario(s):	Posting Date:	Approved By:
07/13/2021	n/a	07/20/2021	CDI Quality Institute's Multidisciplinary Committee

Information on our evidence development process, including our conflicts of interest policy is available on our website at **https://www.mycdi.com/ple**

Provider Led Entity

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