Proposed Changes to Existing Measure for HEDIS®[1] MY 2022: Use of Imaging Studies for Low Back Pain (LBP)

NCQA seeks comments on proposed modifications to the HEDIS Health Plan *Use of Imaging Studies for Low Back Pain (LBP)* measure. NCQA proposes to modify the denominator criteria by expanding the upper age limit from 50 to 74 years of age, applying four additional guidelines-based clinical exclusions and applying existing cross-cutting exclusions for members with advanced illness/frailty and in palliative care.

The intent of this measure is to assess the percentage of eligible members 18–50 years of age with a principal diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis. Clinical guidelines generally do not recommend imaging for acute low back pain in the absence of serious underlying conditions, or "red flags."

Low back pain is one of the major disabling health conditions among adults 60 and older, although most cases are self-limiting. Given the incidence of low back pain in the aging population, NCQA received guidance to consider expanding the age range. NCQA proposes 74 as the upper age limit. Individuals with advanced age (75 and older) often require individualized care that may rely more heavily on shared decision making rather than on strict adherence to guidelines. However, due to the varied feedback we received on an appropriate upper age limit, or whether there should be *any* upper limit, we seek additional input through public comment.

Expanding the upper age limit requires further consideration of appropriate red-flag exclusions. Clinical guidelines state that osteoporosis, which increases in prevalence with age, and fragility fractures, a potential indicator of undiagnosed osteoporosis, are red flag conditions that may warrant further imaging. Ankylosing spondylitis (an inflammatory condition) and spinal surgery are also considered red flags. Although they are not necessarily related to older age, our expert panels agreed that excluding members with these conditions improves measure validity. Panels also agreed with applying the existing cross-cutting exclusions of palliative care and advanced illness/frailty.

Based on clinical guidelines and support from expert panels, NCQA recommends the following changes to the measure:

- Expand the upper age limit from 50 to 74 years.
- Apply four additional clinical exclusions: any history of osteoporosis; any history of spinal surgery; any history of ankylosing spondylitis; and fragility fracture within 90 days prior to index date.
- Apply two cross-cutting exclusions: palliative care and advanced Illness/frailty.

NCQA seeks feedback on the following questions:

1. Is an upper age limit of 74 appropriate for the measure?
2. Should there be any upper age limit?

Supporting documents include the draft measure specifications, evidence workup and performance data.

NCQA acknowledges the contributions of the Geriatric and Bone and Joint Measurement Advisory Panels.

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Use of Imaging Studies for Low Back Pain (LBP)

SUMMARY OF CHANGES TO HEDIS MY 2022

- Expanded the age range, increasing upper age limit to 74 years.
- Added Medicare product line.
- Added new required exclusions to (step 4).
- Added advanced illness/frailty as an exclusion (step 5).
- Clarified members receiving hospice care are a required exclusion.

Description

The percentage of members 18-~~50~~ 74 years of age with a ~~primary~~ principal diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.

Calculation

The measure is reported as an inverted rate [1–(numerator/eligible population)]. A higher score indicates appropriate treatment of low back pain (i.e., the proportion for whom imaging studies did not occur).

Definitions

Intake Period	January 1–December 3 of the measurement year. The Intake Period is used to identify the first eligible encounter with a ~~primary~~ principal diagnosis of low back pain.
IESD	Index Episode Start Date. The earliest date of service for an eligible encounter during the Intake Period with a principal diagnosis of low back pain.
Negative Diagnosis History	A period of 180 days (6 months) prior to the IESD when the member had no claims/encounters with any diagnosis of low back pain.

Eligible Population

~~***Note:** Members in hospice are excluded from the eligible population. Refer to General Guideline 17: Members in Hospice.*~~

Product line	Commercial, Medicaid, Medicare (report each product line separately).
Ages	18 years as of January 1 of the measurement year to 74~~50~~ years as of December 31 of the measurement year.
Continuous enrollment	180 days (6 months) prior to the IESD through 28 days after the IESD.
Allowable gap	~~No gaps in enrollment during the continuous enrollment period.~~None.
Anchor date	IESD.
Benefit	Medical.

Event/diagnosis Follow the steps below to identify the eligible population.

Step 1 Identify all members in the specified age range who had any of the following during the Intake Period:

- An outpatient visit (Outpatient Value Set), observation visit (Observation Value Set) or an ED visit (ED Value Set) with a principal diagnosis of uncomplicated low back pain (Uncomplicated Low Back Pain Value Set).
  - Do not include visits that result in an inpatient stay (Inpatient Stay Value Set).
- Osteopathic or chiropractic manipulative treatment (Osteopathic and Chiropractic Manipulative Treatment Value Set) with a principal diagnosis of uncomplicated low back pain (Uncomplicated Low Back Pain Value Set).
- Physical therapy visit (Physical Therapy Value Set) with a principal diagnosis of uncomplicated low back pain (Uncomplicated Low Back Pain Value Set).
- Telephone visit (Telephone Visits Value Set) with a principal diagnosis of uncomplicated low back pain (Uncomplicated Low Back Pain Value Set).
- E-visit or virtual check-in (Online Assessments Value Set) with a principal diagnosis of uncomplicated low back pain (Uncomplicated Low Back Pain Value Set).

Step 2 Determine the IESD. For each member identified in step 1, determine the earliest episode of low back pain. If the member had more than one encounter, include only the first encounter.

Step 3 Test for Negative Diagnosis History. Exclude members with a diagnosis of uncomplicated low back pain (Uncomplicated Low Back Pain Value Set) during the 180 days (6 months) prior to the IESD.

Step 4: Required exclusions Exclude ~~any member who had a diagnosis for which imaging is clinically appropriate. Any~~members who meet any of the following ~~meet~~ criteria:

- *Cancer.* Cancer any time during the member's history through 28 days after the IESD. Any of the following meet criteria:
  - Malignant Neoplasms Value Set.
  - Other Neoplasms Value Set.
  - History of Malignant Neoplasm Value Set.
  - Other Malignant Neoplasm of Skin Value Set.
- *Recent trauma.* Trauma (Trauma Value Set) any time during the 3 months (90 days) prior to the IESD through 28 days after the IESD.
- *Intravenous drug abuse.* IV drug abuse (IV Drug Abuse Value Set) any time during the 12 months (1 year) prior to the IESD through 28 days after the IESD.
- *Neurologic impairment*. Neurologic impairment (Neurologic Impairment Value Set) any time during the 12 months (1 year) prior to the IESD through 28 days after the IESD.
- *HIV.* HIV (HIV Value Set) any time during the member's history through 28 days after the IESD.

- *Spinal infection.* Spinal infection (Spinal Infection Value Set) any time during the 12 months (1 year) prior to the IESD through 28 days after the IESD.
- *Major organ transplant.* Major organ transplant (Organ Transplant Other Than Kidney Value Set; Kidney Transplant Value Set; History of Kidney Transplant Value Set) any time in the member's history through 28 days after the IESD.
- *Prolonged use of corticosteroids.* 90 consecutive days of corticosteroid treatment any time during the 366-day period that begins 365 days prior to the IESD and ends on the IESD.

To identify consecutive treatment days, identify calendar days covered by at least one dispensed corticosteroid (Corticosteroid Medications List). For overlapping prescriptions and multiple prescriptions on the same day assume the member started taking the second prescription after exhausting the first prescription. For example, if a member had a 30-day prescription dispensed on June 1 and a 30-day prescription dispensed on June 26, there are 60 covered calendar days (June 1–July 30).

Count only medications dispensed during the 12 months (1 year) prior to and including the IESD. When identifying consecutive treatment days, do not count days supply that extend beyond the IESD. For example, if a member had a 90-day prescription dispensed on the IESD, there is one covered calendar day (the IESD).

No gaps are allowed.

Corticosteroid Medications

Description	Prescription	
Corticosteroid	• Hydrocortisone • Cortisone • Prednisone • Prednisolone	• Methylprednisolone • Triamcinolone • Dexamethasone • Betamethasone

- *Osteoporosis*. Osteoporosis therapy (Osteoporosis Medication Therapy Value Set, Long-Acting Osteoporosis Medications Value Set) or dispensed prescription to treat osteoporosis (Osteoporosis Medication List) any time during the member's history through 28 days after the IESD.

Osteoporosis Medications

Description	Prescription	
Bisphosphonates	• Alendronate • Alendronate-cholecalciferol —Ibandronate	• Risedronate —Zoledronic acid
Other agents	• Abaloparatide • Denosumab • Raloxifene	• Romosozumab • Teriparatide

- *Fragility fractures.* Fracture of the spine and, hip ~~or distal radius~~ (Fragility Fractures Value Set) any time during the 3 months (90 days) prior to the IESD through 28 days after the IESD.
- *History of spinal surgery.* History of spinal surgery ~~of lumbar and sacral regions~~ (Lumbar Surgery Value Set) any time during the member's history through 28 days after the IESD.
- *Ankylosing spondylitis.* Ankylosing spondylitis (Ankylosing Spondylitis Value Set) any time during the member's history through 28 days after the IESD.
- *Palliative care*. Exclude members receiving palliative care (Palliative Care Assessment Value Set; Palliative Care Encounter Value Set; Palliative Care Intervention Value Set) during the intake period through the end of the measurement year.
- Members receiving hospice care. (Refer to *General Guideline 17: Members in Hospice*.)

Step 5: Exclusions

Exclude members who meet any of the following criteria:

***Note**: Supplemental and medical record data may not be used for these exclusions.*

- Members 66 years of age and older as of December 31 of the measurement year (all product lines) with frailty **and** advanced illness. Members must meet **BOTH** of the following frailty and advanced illness criteria to be excluded:

1. At least one claim/encounter for frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set) during the measurement year.
2. Any of the following during the measurement year or the year prior to the measurement year (count services that occur over both years):
   - At least two outpatient visits (Outpatient Value Set), observation visits (Observation Value Set), ED visits (ED Value Set), telephone visits (Telephone Visits Value Set), e-visits or virtual check-ins (Online Assessments Value Set), nonacute inpatient encounters (Nonacute Inpatient Value Set) or nonacute inpatient discharges (instructions below; the diagnosis must be on the discharge claim) on different dates of service, with an advanced illness diagnosis (Advanced Illness Value Set). Visit type need not be the same for the two visits. To identify a nonacute inpatient discharge:
     1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
     2. Confirm the stay was for nonacute care based on the presence of a nonacute code (Nonacute Inpatient Stay Value Set) on the claim.
     3. Identify the discharge date for the stay.
   - At least one acute inpatient encounter (Acute Inpatient Value Set) with an advanced illness diagnosis (Advanced Illness Value Set).
   - At least one acute inpatient discharge with an advanced illness diagnosis (Advanced Illness Value Set) on the discharge claim. To identify an acute inpatient discharge:

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
2. Exclude nonacute inpatient stays (Nonacute Inpatient Stay Value Set).
3. Identify the discharge date for the stay.

– A dispensed dementia medication (Dementia Medication List).

Dementia Medications

Description	Prescription
Cholinesterase inhibitors	• Donepezil • Galantamine • Rivastigmine
Miscellaneous central nervous system agents	• Memantine
Dementia combinations	• Donepezil-memantine

Step 6 Calculate continuous enrollment. Members must be continuously enrolled for 180 days (6 months) prior to the IESD through 28 days after the IESD.

Administrative Specification

Denominator The eligible population.

Numerator An imaging study (Imaging Study Value Set) with a diagnosis of uncomplicated low back pain (Uncomplicated Low Back Pain Value Set) on the IESD or in the 28 days following the IESD.

Note

- *Although denied claims are not included when assessing the numerator, all claims (paid, suspended, pending and denied) must be included when identifying the eligible population.*
- *Do not include supplemental data when identifying the eligible population or assessing the numerator. Supplemental data can be used for only required exclusions for this measure.*

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table LBP-1/2: Data Elements for Use of Imaging Studies for Low Back Pain

	Administrative
Measurement year	✓
Eligible population	✓
Number of required exclusions	✓
Numerator events by administrative data	✓

~~Number of events by supplemental data~~	~~✓~~
Reported rate	✓

Use of Imaging Studies for Low Back Pain (LBP)
Measure Workup

Topic Overview

Importance and Prevalence

Health importance

Clinical guidelines for treating patients with acute low back pain strongly recommend against the use of imaging in the absence of "red flags" (i.e., indications of a serious underlying pathology such as a fracture or tumor) (Downie et al., 2013).

While it is important to avoid imaging in patients with nonspecific low back pain, it is also important to use imaging to quickly detect certain serious underlying pathologies, such as malignancy, fracture or infection. For example, early detection of infection can facilitate directed treatment and prevent further spread of infectious disease, but these serious pathologies have low prevalence rates in patients with low back pain; therefore, routine imaging in the absence of "red flags" is not recommended by clinical guidelines (Downie et al., 2013).

Choosing Wisely, an initiative of the American Board of Internal Medicine Foundation in collaboration with more than 70 specialty society partners, promotes a "national dialogue on avoiding wasteful or unnecessary medical tests, treatments and procedures" by publishing recommendations from the specialty societies to "facilitate wise decisions about the most appropriate care based on a patient's individual situation." Nine specialty societies have published recommendations regarding the use of imaging for patients with low back pain (Choosing Wisely, 2020), indicating the topic's importance to health care providers.

Society	*Choosing Wisely* Recommendation Regarding the Use of Imaging for Patients With Low Back Pain
American Academy of Physical Medicine and Rehabilitation	Don't order an imaging study for back pain without performing a thorough physical examination.
American Association of Neurological Surgeons and Congress of Neurological Surgeons	Don't obtain imaging (plain radiographs, magnetic resonance imaging, computed tomography [CT] or other advanced imaging) of the spine in patients with non-specific acute low back pain and without red flags.
American College of Occupational and Environmental Medicine	Don't initially obtain X-rays for injured workers with acute non-specific low back pain.
American Society of Anesthesiologists—Pain Medicine	Avoid imaging studies (MRI, CT or X-rays) for acute low back pain without specific indications.
American Academy of Family Physicians	Don't do imaging for low back pain within the first 6 weeks, unless red flags are present.
American Chiropractic Association	Avoid routine spinal imaging in the absence of clear clinical indicators for patients with acute low back pain of less than 6 weeks duration.
American College of Emergency Physicians	Avoid lumbar spine imaging in the emergency department for adults with non-traumatic back pain unless the patient has severe or progressive neurologic deficits or is suspected of having a serious underlying condition (such as vertebral infection, cauda equina syndrome, or cancer with bony metastasis).
American College of Physicians	Don't obtain imaging studies in patients with non-specific low back pain.
North American Spine Society	Don't recommend imaging of the spine within the first 6 weeks of an acute episode of low back pain in the absence of red flags.

Prevalence

Approximately 2.63 million ED visits in the U.S. each year are due to a low back pain-related disorder (Friedman, et al., 2011). An estimated 75%–85% of all Americans will experience back pain at some point in their lives (American Association of Neurological Surgeons, 2020), and approximately 25% of Americans will experience at least one day of back pain during any 3-month period (Deyo, 2006).

Financial importance and cost-effectiveness

In addition to the negative health outcomes associated with routine imaging, there are also financial costs. A 2008–2015 cohort study of nearly 2.5 million U.S. patients diagnosed with low back pain or lower extremity pain found that total costs of care among those who did not receive surgery amounted to $1.8 billion (within 12 months after initial diagnosis). This amount accounts for 70.8% of the total 12-month costs for the entire study cohort. Additionally, 32.3% of these nonsurgical patients received imaging within 30 days of diagnosis and 35.3% received imaging without a trial of physical therapy. These findings suggest that early imaging is a driver of health care expenditures among non-surgical patients with a diagnosis of low back or extremity pain. Of note, exclusion criteria for the study included red-flag diagnoses and opiate use prior to diagnosis (Kim, et al., 2019).

The inappropriate use of imaging is a large contributing factor to the high costs associated with low back pain. The combined total costs of direct medical expenditures and loss of work productivity due to low back pain have been as high as $635 billion a year in the U.S. (Yang, et al., 2016). Reducing inappropriate imaging is critical in order to reduce the number of ineffective treatments and unnecessary costs (Owens et al., 2011). For example, a 2015 study demonstrated that imaging, when compared to physical therapy as a first-line management strategy for new episodes of low back pain, is more expensive and leads to higher utilization outcomes. The study found that among patients receiving imaging, average charges were $1,306, while among patients receiving physical therapy, average charges were $504. Additionally, in a 1-year follow-up of study participants, patients who received advanced imaging had higher utilization outcomes. Utilization outcomes included surgery, injections, spine specialist visits and ED visits (Fritz et al., 2015).

Supporting Evidence for Diagnostic Testing

The evidence presented in Table 1 outlines the clinical guidelines for managing patients with low back pain (Enix et al., 2020, Thorson et al., 2018; VA/DoD, 2017; Chou et al., 2007; van Tudler et al., 2006) and a systematic evidence review of the diagnostic accuracy of red flag signs and symptoms for fracture and malignancy in patients with low back pain (Downie et al., 2013).

Guidelines consistently recommend that diagnostic procedures focus on identification of red flags and exclusion of specific diseases when diagnosing a patient with nonspecific low back pain. Guidelines recommend taking the patient's history and a clinical examination before ordering an imaging study, with the primary purpose of identifying any red flags. Guidelines strongly recommend against performing imaging in the absence of red flags for patients whose back pain has persisted for 4–6 weeks or less. In patients with acute low back pain and/or radiculopathy and whose symptoms worsen or persist overtime, guidelines recommend imaging only for patients who have previously undergone a recommended treatment plan and who are also suitable candidates for surgery (Enix et al., 2020, Thorson et al., 2018; VA/DoD, 2017; Goertz et al., 2012; Chou et al., 2007; van Tudler et al., 2006).

Although guidelines agree about the importance of avoiding imaging in patients with nonspecific low back pain, they differ as to how they define "nonspecific" low back pain and "red flags." This variation has led to confusion among clinicians regarding which patients are appropriate for imaging. In addition, there are varying levels of evidence supporting the use of different red flags to identify potential fractures, spinal infection or malignancy. Guidelines generally do not contain information on the diagnostic accuracy of their

endorsed red flags. A 2013 systematic review evaluated the use of 53 red flags for fracture or malignancy in patients with low back pain and found virtually no change in the probability of detecting an underlying pathology using them.

Studies in the review analyzed a combined 26 red flags to screen for fracture. Four had a meaningful probability of detecting a fracture: older age (age >50, >54, >64, >70, >74), prolonged use of corticosteroid drugs, severe trauma and the presence of a contusion or abrasion, with an average post-test probability for the detection of fracture of 9%, 33%, 11% and 62%, respectively. For malignancy, only history of cancer provided informative results, with an average post-test probability of 33% for detection of malignancy. Red flags are also recommended to screen for infection and neurological impairments such as cauda equina syndrome; however, the incidence of these conditions in patients with low back pain is too low to derive meaningful results from published studies (Downie et al., 2013).

Health care disparities

More generally, evidence has shown a greater prevalence of pain and greater severity of symptoms among racial minorities, who receive poorer pain assessment and treatment than Whites, across a variety of settings and all types of pain (Anderson et al., 2009; Meghani et al., 2012). This general evidence on pain assessment disparities may explain another study that found White patients tended to receive more rapid and advanced imaging for uncomplicated low back pain than non-White patients. The study also found that low-income patients and those treated in smaller practices or practices reliant on Medicaid revenue were less likely to receive rapid imaging for uncomplicated low back pain. This evidence suggests that patients with higher socioeconomic status may more often receive imaging (Pham et al., 2009).

Gaps in care

A study published in the *Journal of the American College of Radiology* found that 26% of medical images ordered for patients with acute low back pain were inappropriate, with a 53% and 35% inappropriate referral rate for CT and MRI, respectively (Lehnert & Bree, 2010). Overall, evidence suggests that between 10% and 20% of all imaging studies are unnecessary (Picano, 2004). For example, lumbar spine MRIs are commonly performed for uncomplicated low back pain. Approximately 11% of older adults with acute, uncomplicated low back pain receive unnecessary advanced imaging. Additionally, between 30% and 66% of lumbar spine MRIs ordered by Veterans Affairs providers are deemed unnecessary (Nevedal et al., 2019). Another study of uncomplicated low back pain in fee-for-service Medicare beneficiaries demonstrated that 28.8% of the study cohort received imaging for low back pain within 28 days of diagnosis, which is deemed inappropriate by guidelines (Pham et al., 2009).

Specific Guideline Recommendations

Table 1. Recommendations for Imaging Patients with Acute Low Back Pain

Organization (Year)	Area of Focus	Recommendation	Rating
North American Spine Society (2020)	Imaging	Q. In the absence of red flags, what are the imaging (X-ray, CT or MRI) recommendations for patients with acute or chronic low back pain? A. There is insufficient evidence to make a recommendation for or against obtaining imaging in the absence of red flags.	Grade of Recommendation: I
Institute for Clinical Systems Improvement (2018)	Imaging	Clinicians should not routinely recommend imaging (x-ray, computed tomography [CT], magnetic resonance imaging [MRI]) for patients with nonspecific or radicular low back pain and an absence of red flags on clinical presentation.	Strong Recommendation, Moderate Quality of Evidence
Veterans Affairs/ Department of Defense (2017)	Diagnostic Approach	For patients with low back pain, we recommend that clinicians conduct a history and physical examination, that should include identifying and evaluating neurologic deficits (e.g., radiculopathy, neurogenic claudication), red flag symptoms associated with serious underlying pathology (e.g., malignancy, fracture, infection), and psychosocial factors.	Strong for
Veterans Affairs/ Department of Defense (2017)	Diagnostic Approach	For patients with acute axial low back pain (i.e., localized, non-radiating), we recommend against routinely obtaining imaging studies or invasive diagnostic tests	Strong against
Veterans Affairs/ Department of Defense (2017)	Diagnostic Approach	For patients with low back pain, we recommend diagnostic imaging and appropriate laboratory testing when neurologic deficits are serious or progressive or when red flag symptoms are present.	Strong for
Organization (Year)	**Area of Focus**	**Recommendation**	**Rating**
American College of Radiology (2015)	Imaging	Imaging is recommended for patients with acute, subacute or chronic uncomplicated low back pain or radiculopathy with one or more of the following: low velocity trauma, osteoporosis, elderly individual, or chronic steroid use. X-ray lumbar spine and CT lumbar spine w/o IV contrast recommended as the initial imaging study in patients with osteoporosis or history of steroid use. MRI lumbar spine w/o IV contrast can be useful to evaluate for ligamentous injury or worsening neurologic deficit. MRI can depict marrow edema in these scenarios.	Usually appropriate
American College of Radiology (2015)	Imaging	Imaging is recommended for patients with acute, subacute or chronic low back pain or radiculopathy with one or more of the following: suspicion of cancer, infection or immunosuppression. In these patients, MRI lumbar spine with IV contrast is useful for neoplasia patients suspected of epidural or intraspinal disease. Noncontrast MRI can be sufficient if there is low risk of epidural and/or intraspinal disease. Contrast CT lumbar spine can be useful if MRI is contraindicated or unavailable.	Usually appropriate

American College of Radiology (2015)	Imaging	Imaging is recommended for patients with low back pain or radiculopathy who have new or progressing symptoms or clinical findings with history of prior lumbar surgery. MRI lumbar spine with and w/o IV contract can differentiate disc from scar. CT lumbar spine can be useful in post-fusion patients or when MRI is contraindicated or indeterminate.	Usually appropriate
American College of Radiology (2015)	Imaging	Imaging is recommended for patients with low back pain with suspected cauda equina syndrome or rapidly progressive neurologic deficit. MRI lumbar spine with and w/o IV contrast is usually appropriate depending on clinical circumstances. CT myelography lumbar spine may be useful if MRI is nondiagnostic or contraindicated.	Usually appropriate
Organization (Year)	**Area of Focus**	**Recommendation**	**Rating**
American College of Physicians and American Pain Society (2007)	Evaluation	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
American College of Physicians and American Pain Society (2007)	Diagnostic Imaging	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
American College of Physicians and American Pain Society (2007)	Reassessment	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
Organization (Year)	**Recommendation**	**Area of Focus**	**Rating**
European Cooperation in Science and Technology (2006)	Evaluation	Undertake diagnostic triage consisting of appropriate history taking and physical examination at the first assessment to exclude serious pathology and nerve root pain. If serious spinal pathology and nerve root pain are excluded, manage the low back pain as nonspecific.	Level of Evidence: D
European Cooperation in Science and Technology (2006)	Diagnostic Imaging	Diagnostic imaging tests (including X-rays, CT and MRI) are not routinely indicated for acute nonspecific low back pain.	Level of Evidence: A
European Cooperation in Science and Technology (2006)	Reassessment	Reassess those patients who are not resolving within a few weeks after the first visit or those who are following a worsening course. Exclude serious pathology and nerve root pain. If identified, consider further appropriate management. Identify psychosocial factors and manage appropriately.	Level of Evidence: D

Grading System Key

North American Spine Society (2020)

Levels of Evidence for Primary Research Question	
Diagnostic Studies	
Level I	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review of Level I studies
Level II	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review of Level II studies
Level III	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review of Level III studies
Level IV	• Case-control study • Poor reference standard
Level V	• Expert opinion

Grade of Recommendations for Summaries or Reviews of Studies	
A	Good evidence (Level I studies with consistent findings) for or against recommending intervention
B	Fair evidence (Level II or III with consistent findings) for or against recommending intervention
C	Poor quality evidence (Level IV or V studies) for or against recommending intervention
I	There is insufficient or conflicting evidence not allowing a recommendation for or against intervention

Grade of Recommendation	Standard Language	Levels of Evidence	
A	Recommended	Two or more consistent Level I studies	
B	Suggested	One Level I study with additional supporting Level II or III studies	Two or more consistent Level II or III studies
C	May be considered; is an option	One Level I, II, III or IV study with supporting Level IV studies	Two or more consistent Level IV studies
I	Insufficient evidence to make recommendation for or against	A single level I, II, III or IV study without other supporting evidence	More than one study with inconsistent findings

Institute for Clinical Systems Improvement (2018)

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change our confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
Low Quality Evidence	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

American College of Radiology (2015)

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.

Usually Note Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

Veterans Affairs/Department of Defense (2017)
See the system described in the table below.

American College of Physicians and American Pain Society (2007)

Clinical Practice Guidelines Grading System*		
	Strength of Recommendation	
Quality of Evidence	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

*Adapted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) work group.

Interpretation of Grading System		
Grade of Recommendation	**Benefit Versus Risks and Burdens**	**Methodological Quality of Supporting Evidence**
Strong Recommendation; High Quality Evidence	Benefits clearly outweigh risks and burden or vice versa	RCTs without important limitations or overwhelming evidence from observational studies
Strong Recommendation; Moderate Quality Evidence	Benefits clearly outweigh risks and burden or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies
Strong Recommendation; Low Quality Evidence	Benefits clearly outweigh risks and burden or vice versa	Observational studies or case series
Weak Recommendation; High Quality Evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies
Weak Recommendation; Moderate Quality Evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptional strong evidence from observational studies
Weak Recommendation; Low Quality Evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risks and burden may be closely balanced	Observational studies or case series
Insufficient	Balance of benefits and risks cannot be determined	Evidence is conflicting, poor quality or lacking

Methods for Grading the Strength of Overall Evidence for an Intervention*	
Grade	**Definition**
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 methodologic flaws).
Poor	Evidence is insufficient 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.

*Adapted from methods developed by the U.S. Preventive Services Task Force.

European Cooperation in Science and Technology (2006)

Strength of Recommendations	
Therapy and Prevention	
Level A	Generally consistent findings provided by (a systematic review of) multiple high quality randomised controlled trials (RCT).
Level B	Generally consistent findings provided by (a systematic review of) multiple low quality RCTs or non-randomised controlled trials (CCT).
Level C	One RCT (either high or low quality) or inconsistent findings from (a systematic review of) multiple RCTs or CCTs.
Level D	No RCTs or CCTs.
Prognosis	
Level A	Generally consistent findings provided by (a systematic review of) multiple high quality prospective cohort studies.
Level B	Generally consistent findings provided by (a systematic review of) multiple low quality prospective cohort studies or other low quality prognostic studies.
Level C	One prognostic study (either high or low quality) or inconsistent findings from (a systematic review of) multiple prognostic studies.
Level D	No prognostic studies.
Diagnosis	
Level A	Generally consistent findings provided by (a systematic review of) multiple high quality diagnostic studies.
Level B	Generally consistent findings provided by (a systematic review of) multiple low quality diagnostic studies.
Level C	One diagnostic study (either high or low quality) or inconsistent findings from (a systematic review of) multiple diagnostic studies.
Level D	No diagnostic studies.

Table 2. Common Red Flags in Recent Clinical Guidelines (LBP Current and Potential)

Red Flag	North American Spine Society (2020)	Institute for Clinical Systems Improvement (2018)	Veterans Affairs/Dept of Defense (2017)	American College of Radiology (2015)
Cancer, or cancer risk	➲	➲	➲	➲
Unexplained weight loss	➲		➲	
Immunosuppression	➲		➲	➲
Intravenous drug use	➲		➲	
Fever	➲		➲	
Trauma, or significant trauma relative to age	➲	➲	➲	
Cauda equina syndrome		➲	➲	➲
Spinal infection risk		➲		➲
Fragility fracture risk		➲		
Unrelenting pain/Incapacitating pain, including night pain		➲		
Progressive neurologic deficit/weakness		➲	➲	➲
Bilateral radiculopathy		➲	➲	➲
History of osteoporosis			➲	➲
Chronic corticosteroid use			➲	➲
History of prior lumbar surgery				➲

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HEDIS Health Plan Performance Rates: Use of Imaging Studies for Low Back Pain (LBP)

Table 1. HEDIS LBP Measure Performance—Commercial Plans

Measurement Year	Total Number of Plans (N)	Performance Rates (%)						
		Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2019	392	76.0	6.1	67.8	71.2	76.0	80.3	83.8
2018	399	75.9	6.1	67.2	72.2	76.1	80.3	83.6
2017	410	74.0	6.6	64.9	69.6	74.3	79.0	82.4
2016	414	75.2	6.2	67.0	70.8	75.3	79.5	82.8
2015	404	75.2	6.3	65.0	70.9	75.3	79.6	83.2

Table 2. HEDIS LBP Measure Performance—Medicaid Plans

Measurement Year	Total Number of Plans (N)	Performance Rates (%)						
		Mean	Standard Deviation	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
2019	221	71.7	6.1	63.9	67.0	71.6	75.7	80.2
2018	232	71.7	6.1	63.3	67.2	71.8	75.0	79.9
2017	244	70.5	6.9	62.1	66.2	70.5	74.4	78.3
2016	242	73.6	6.0	66.1	69.9	73.7	77.1	81.4
2015	221	75.1	5.9	67.9	71.8	75.0	78.1	82.8