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6.01.48	Positional Magnetic Resonance Imaging		
Original Policy Date:	April 5, 2007	Effective Date:	November 1, 2023
Section:	6.0 Radiology	Page:	Page 1 of 10

## Policy Statement

I. Positional (nonrecumbent) magnetic resonance imaging (MRI) (e.g., flexion, extension) is considered **investigational**, including its use in the evaluation of individuals with cervical, thoracic, or lumbosacral back pain.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

## **Policy Guidelines**

FONAR Corporation has 510(k) marketing clearance from the U. S. Food and Drug Administration (FDA) for a magnetic resonance imaging (MRI) system that performs positional MRI scans (i.e., FONAR's Upright<sup>®</sup> MRI, FONAR Corporation, Melville, NY).

#### Coding

Currently, there is no way to signify with coding that a magnetic resonance imaging (MRI) is open or positional. Following are examples of CPT codes that may be used:

MRI, location not specified

• 76498: Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)

MRI of the spine

- **72141**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, cervical; without contrast material
- **72142**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, cervical; with contrast material(s)
- **72146**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, thoracic; without contrast material
- **72147**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, thoracic; with contrast material(s)
- **72148**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, lumbar; without contrast material
- **72149**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, lumbar; with contrast material(s)
- **72156**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical
- **72157**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic
- **72158**: Magnetic resonance (e.g., proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar

MRI of any joint of the upper extremity

- **73221**: Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; without contrast material(s)
- **73222**: Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; with contrast material(s)
- **73223**: Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; without contrast material(s), followed by contrast material(s) and further sequences

#### Description

Positional magnetic resonance imaging (MRI) permits imaging of a patient in various positions, including sitting and standing. This technology is being evaluated as a diagnostic tool for patients with position-dependent back pain.

## **Related Policies**

• Dynamic Spinal Visualization and Vertebral Motion Analysis

### **Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### **Regulatory Status**

Several MRI systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process as open or total body systems for positional imaging. One such system is FONAR's Upright<sup>®</sup> MRI. FDA product code: LNH.

#### Rationale

## Background

#### Back Pain

Determining the cause of back pain is a complex task. In some patients, extensive evaluation with various imaging modalities does not lead to a definitive diagnosis. Some studies have suggested that imaging the body in various positions with "loading" of the spine may lead to more accurate diagnoses. This loading can be accomplished by having the patient sit or stand upright. Also, imaging can be completed with the patient in the position that causes the symptom(s). This theory is being evaluated in suspected nerve root compression and in some cases of spondylolisthesis.

#### Diagnosis

An open magnetic resonance imaging (MRI) system has been developed that allows imaging of a patient in various positions. Imaging can be conducted with partial or full weight-bearing. Dynamic-kinetic imaging (images obtained during movement) can also be obtained with this system. Conventional MRI of the spine is typically completed with a patient in a recumbent position. Weight-bearing can be simulated by imaging in the supine position with a special axial loading device.

One concern with positional MRI is the field strength of the scanners. Today's clinical MRI scanners may operate at a field strength between 0.1 to 3 tesla (T), and are classified as either low-field (<0.5 T), mid-field (0.5 to 1.0 T), or high-field (>1.0 T). Low-field MRI is typically used in open scanners. Open scanners are designed for use during interventional or intraoperative procedures, when a conventional design is contraindicated (e.g., an obese or claustrophobic patient), or for changes in patient positioning.

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In general, higher field strength results in an increase in signal-to-noise ratio, spatial resolution, contrast, and speed. Thus, low-field scanners produce poorer quality images compared with high-field scanners, and longer acquisition times with low-field scanners increases the possibility of image degradation due to patient movement. However, field strength has less of an effect on the contrast-to-noise ratio, which determines the extent to which adjacent structures can be distinguished from one another.

#### **Literature Review**

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations."

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

#### Positional Magnetic Resonance Imaging Clinical Context and Test Purpose

The purpose of positional magnetic resonance imaging (MRI) in patients with position-dependent back or neck pain is to inform a decision whether the pain can be attributed to changes in the spinal canal. For example, pressure on the spinal cord from a herniated disc may be increased with sitting when compared to standing.

The question addressed in this evidence review is: Does the use of positional MRI improve the net health outcome in patients who have position-dependent back or neck pain?

The following PICO was used to select literature relevant to the review.

#### Populations

The relevant population of interest are individuals being evaluated for position-dependent back or neck pain.

#### Interventions

The intervention is positional MRI using seated or standing positions in neutral, extension, and flexion. Positional MRI is administered by referral to a spine specialist in back and neck pain.

#### Comparators

The following test is currently being used to make decisions about managing position-dependent back or neck pain: conventional supine MRI, which is the reference standard. Studies comparing positional MRI with loaded supine MRI are also of interest.

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#### Outcomes

In evaluating this approach to imaging, it is important to determine whether MRI adds actionable diagnostic information. However, it is also important to determine whether treatment of these additional findings results in improved outcomes. This additional step is important given reported concerns about described false-positive findings with MRI of the spine. For example, Jarvik et al (2001) reported that many MRI findings have a high prevalence in subjects without low back pain and that findings such as bulging discs and disc protrusion are of limited diagnostic use.<sup>1</sup>, The authors also reported that the less common findings of moderate or severe central stenosis, root compression, and disc extrusion were more likely to be clinically relevant. The health outcomes of interest include symptoms (e.g., pain), self-reported functional outcomes, and quality of life measures.

The optimum interval to examine health outcomes would be after healing of surgical intervention, typically at 3 to 12 months postprocedure.

#### **Study Selection Criteria**

For the evaluation of the clinical validity of positional MRI, studies that met the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard (describe the reference standard)
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described

#### **Clinically Valid**

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

#### **Review of Evidence**

#### Imaging Under Loading Stress

Dahabreh et al (2011) conducted a systematic review for the Agency for Healthcare Research and Quality that assessed emerging MRI technologies for musculoskeletal imaging under loading stress.<sup>2,</sup> Included were 36 studies that used positional weight-bearing MRI in patients with musculoskeletal conditions. Also included were studies evaluating axial compression devices. Most studies were cross-sectional or had case-control designs. The most commonly imaged body region was the lumbar spine. Four identified studies of lumbar spine imaging compared positional weight-bearing MRI with conventional MRI, myelography, or non-weight-bearing imaging in the same MRI device; however, these studies did not report the effect of the technology on patient outcomes. Two studies of foot imaging that compared weight-bearing MRI with MRI in the supine position with the same MRI device found that the 2 techniques provided similar information. Two studies of knee joint imaging found differences between weight-bearing MRI and non-weight-bearing MRI using the same device; no functional outcomes were reported. The potential effect on image quality of low magnetic field strengths (£0.6 tesla [T]) in weight-bearing MRI scanners was not assessed. Key studies not included in the systematic review are described next.

# Positional Magnetic Resonance Imaging in Neutral, Flexion, and Extension (Kinetic Magnetic Resonance Imaging)

Lao et al (2014) and Lord et al (2014) both published systematic reviews assessing the literature on positional (kinetic) MRI, which consists primarily of examining anatomic changes in neutral, flexion, extension, and axial rotation.<sup>3,4</sup>, Kinetic MRI studies in healthy and symptomatic individuals identified changes in neuroforaminal size, cord compression, cord length, cross-sectional area, ligamentum flavum thickness, and motion at the index and adjacent levels.

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#### Seated Magnetic Resonance Imaging versus Supine Magnetic Resonance Imaging

Ferreiro Perez et al (2007) compared recumbent with upright sitting positions in 89 patients who had disc herniation or spondylolisthesis (cervical or lumbar spine).<sup>5,</sup> Using a 0.6-T Upright MRI system for both positions, pathology (disc herniation or spondylolisthesis) was identified in 68 (76%) patients. Images from 18 (20%) patients were not interpretable due to motion artifact. Pathologic features were better identified (i.e., either only evident or seen to be enlarged) in 52 (76%) of the 68 patients when in the sitting position; 10 of these were only observed in the sitting position. Pathologic features were better identified in the recumbent position in 11 (16%) of the 68 patients. The overall underestimation rate was calculated to be 62% for patients in the recumbent position and 16% for those in the upright-seated position. This research would suggest that there may be advantages when the position during imaging is matched with the positional symptoms of the patient. However, a more appropriate comparison group would be a standard recumbent clinical MRI system (e.g., field strength >0.6 T). In addition, technical problems with motion artifact were due to poor stabilization in an upright sitting position.

#### Standing Magnetic Resonance Imaging versus Supine Magnetic Resonance Imaging

In a study by Tarantino et al (2013), 57 patients with low back pain when standing (50% also had back pain in the supine position) received an MRI in both upright and recumbent positions using a 0.25-T tilting system.<sup>6,</sup> A table tilt of 82° was used to reproduce the orthostatic position without the patient instability associated with standing at 90°. Compared with the supine position, there was a significant decrease in intervertebral disc thickness (11.2 mm vs. 12.9 mm) along with changes in other measures and a qualitative increase in the volume of disc protrusions and/or spondylolisthesis in the upright position.

## Standing Magnetic Resonance Imaging versus Axial Loaded Supine Magnetic Resonance Imaging

In a study by Charoensuk et al (2021), 54 patients suspected of having spinal stenosis underwent both standing MRI and MRI plus axial loading using a compression device.<sup>7,</sup> Primary outcome measures included measures of the intervertebral disc (i.e., cross-sectional area [DA], disc height [DH], and anteroposterior distance [DAP]), dural sac (cross-sectional area [DCSA]), spinal curvature (i.e., lumbar lordosis [LL] and L1-L3-L5 angle [LA]), and total lumbar spine height (LH). Results showed that there was a major difference observed with LL, but minor differences observed in DCSA, DAP, DA, LA, and LH. This suggests that the standing position might be adequately simulated while recumbent by utilizing an axial-loaded MRI using a compression device.

A study by Madsen et al (2008) compared vertical (standing) MRI with recumbent MRI plus axial loading in patients who had lumbar spinal stenosis.<sup>8,</sup> Sixteen patients with neurogenic claudication, experienced mainly during walking or in an erect position, were recruited for this phase of the study. Each patient underwent 4 scans with a 0.6-T Upright MRI system, consisting of vertical, horizontal with compression at a load of 40% of body weight, horizontal with no load, and horizontal with a 50% axial load. All horizontal scans were conducted with a cushion placed below the lower back to induce the extension of the lumbar spine. Results showed a similar DCSA between the 2 positions, suggesting that the standing position might be adequately simulated while recumbent by axial loading and lordosis. Results were not correlated with patient symptoms in this study.

#### **Clinically Useful**

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary testing or therapy.

#### **Direct Evidence**

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

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No evidence from RCTs was identified to support the use of positional MRI for position-dependent back or neck pain. Moreover, the systematic review by Dahabreh et al (2011) concluded that, despite a large number of available studies, considerable uncertainty remained about the utility of this technique for the clinical management of musculoskeletal conditions.<sup>2</sup>

#### **Chain of Evidence**

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of positional MRI for diagnosis of position-dependent back or neck pain has not been established, a chain of evidence cannot be constructed.

#### **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

#### Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

#### 2008 Input

In response to requests, input was received from 1 physician specialty society and 1 academic medical center while the policy was under review in 2008. Both reviewers agreed that positional magnetic resonance imaging is considered investigational.

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

#### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

#### **Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in July 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

### References

 Jarvik JJ, Hollingworth W, Heagerty P, et al. The Longitudinal Assessment of Imaging and Disability of the Back (LAIDBack) Study: baseline data. Spine (Phila Pa 1976). May 15 2001; 26(10): 1158-66. PMID 11413431 Page 7 of 10

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- 3. Lao LF, Zhong GB, Li QY, et al. Kinetic magnetic resonance imaging analysis of spinal degeneration: a systematic review. Orthop Surg. Nov 2014; 6(4): 294-9. PMID 25430713
- 4. Lord EL, Alobaidan R, Takahashi S, et al. Kinetic magnetic resonance imaging of the cervical spine: a review of the literature. Global Spine J. Jun 2014; 4(2): 121-8. PMID 25054099
- Ferreiro Perez A, Garcia Isidro M, Ayerbe E, et al. Evaluation of intervertebral disc herniation and hypermobile intersegmental instability in symptomatic adult patients undergoing recumbent and upright MRI of the cervical or lumbosacral spines. Eur J Radiol. Jun 2007; 62(3): 444-8. PMID 17412542
- 6. Tarantino U, Fanucci E, Iundusi R, et al. Lumbar spine MRI in upright position for diagnosing acute and chronic low back pain: statistical analysis of morphological changes. J Orthop Traumatol. Mar 2013; 14(1): 15-22. PMID 22983676
- Charoensuk J, Laothamatas J, Sungkarat W, et al. Axial loading during supine MRI for improved assessment of lumbar spine: comparison with standing MRI. Acta Radiol. Jan 2023; 64(1): 217-227. PMID 34939453
- Madsen R, Jensen TS, Pope M, et al. The effect of body position and axial load on spinal canal morphology: an MRI study of central spinal stenosis. Spine (Phila Pa 1976). Jan 01 2008; 33(1): 61-7. PMID 18165750

## **Documentation for Clinical Review**

• No records required

## Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Туре	Code	Description
72 72 CPT <sup>•</sup> 72 72 72 72	72141	Magnetic resonance (e.g., proton) imaging, spinal canal and contents,
		cervical; without contrast material
	72142	Magnetic resonance (e.g., proton) imaging, spinal canal and contents,
		cervical; with contrast material(s)
	72146	Magnetic resonance (e.g., proton) imaging, spinal canal and contents,
	72140	thoracic; without contrast material
	72147	Magnetic resonance (e.g., proton) imaging, spinal canal and contents,
		thoracic; with contrast material(s)
	72148	Magnetic resonance (e.g., proton) imaging, spinal canal and contents,
		lumbar; without contrast material
	72149	Magnetic resonance (e.g., proton) imaging, spinal canal and contents,
		lumbar; with contrast material(s)
	72156	Magnetic resonance (e.g., proton) imaging, spinal canal and contents,
		without contrast material, followed by contrast material(s) and further
		sequences; cervical

Туре	Code	Description
	72157	Magnetic resonance (e.g., proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic
	72158	Magnetic resonance (e.g., proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar
	73221	Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; without contrast material(s)
	73222	Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; with contrast material(s)
	73223	Magnetic resonance (e.g., proton) imaging, any joint of upper extremity; without contrast material(s), followed by contrast material(s) and further sequences
	76498	Unlisted magnetic resonance procedure (e.g., diagnostic, interventional)
HCPCS	None	

## **Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/05/2007	BCBSA Medical Policy adoption
10/02/2010	Policy title change from Positional MRI
	Policy revision without position change
09/27/2013	Policy revision without position change. Policy placed on No Further Routine
	Literature Review and Update status.
06/30/2015	Coding Update
08/31/2015	Policy title change from Positional Magnetic Resonance Imaging (MRI)
	Policy revision without position change
03/01/2017	Policy revision without position change
05/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
11/01/2018	Policy revision without position change
11/01/2019	Policy revision without position change
11/01/2020	Annual review. No change to policy statement. Literature review updated.
11/01/2021	Annual review. No change to policy statement. Literature review updated.
11/01/2022	Annual review. Policy statement and literature review updated.
11/01/2023	Annual review. No change to policy statement. Literature review updated.

## **Definitions of Decision Determinations**

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation**: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at <u>www.blueshieldca.com/provider</u>.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: <u>MedPolicy@blueshieldca.com</u>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

## Appendix A

POLICY STATEMENT <mark>(No changes)</mark>				
BEFORE	AFTER			
Positional Magnetic Resonance Imaging 6.01.48	Positional Magnetic Resonance Imaging 6.01.48			
<ul> <li>Policy Statement:         <ol> <li>Positional (nonrecumbent) magnetic resonance imaging (MRI) (e.g., flexion, extension) is considered investigational, including its use in the evaluation of individuals with cervical, thoracic, or lumbosacral back pain.</li> </ol> </li> </ul>	<ul> <li>Policy Statement:         <ol> <li>Positional (nonrecumbent) magnetic resonance imaging (MRI) (e.g., flexion, extension) is considered investigational, including its use in the evaluation of individuals with cervical, thoracic, or lumbosacral back pain.</li> </ol> </li> </ul>			