Policy Statement

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

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® 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 through the 510(k) process as open or total body systems for positional imaging. One such system is FONAR's Upright® MRI. Food and Drug Administration 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 recent 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 (0.5-1.0 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.

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.

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 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 PICOs were used to select literature relevant to the review.

**Patients**

The population of interest are patients 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.

**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. They 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 post procedure.

**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.

**Technically Reliable**
Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

**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).

**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.2 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 two 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 MRI in Neutral, Flexion, and Extension (Kinetic MRI)**
Lao et al (2014) and Lord et al (2014) both published systematic reviews assessing the literature on positional (kinetic) MRI consists primarily of examining anatomic changes in neutral, flexion, extension, and axial rotation.3,4 For example, 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.

**Seated MRI vs Supine MRI**
Ferreiro Perez et al (2007) compared recumbent with upright sitting positions in 89 patients who had disc herniation or spondylolisthesis (cervical or lumbar spine).5 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 MRI vs Supine MRI**

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.6 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 MRI vs Axial Loaded Supine MRI**

A study by Madsen et al (2008) compared vertical (standing) MRI with recumbent MRI plus axial loading in patients who had lumbar spinal stenosis.7 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 similar dural sac cross-sectional area between the two 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, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

**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.

No evidence from randomized controlled trials 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.2

**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.
Summary of Evidence
For individuals who have position-dependent back or neck pain who receive positional MRI, the evidence includes comparative studies. The relevant outcomes are test accuracy, symptoms, functional outcomes, and quality of life. Comparisons of results from positional MRI with results from supine MRI or standing x-ray have indicated that positional MRI provides additional diagnostic data. However, no studies have been identified describing clinical outcomes of patients whose treatments were selected based on these new data. The clinical benefit of basing treatment decisions, including surgery, on these additional findings needs to be established. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
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.

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

Practice Guidelines and Position Statements
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 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

References

**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. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services may be considered investigational.

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<th>Code</th>
<th>Description</th>
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**Policy History**

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

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<tr>
<th>Effective Date</th>
<th>Action</th>
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<tr>
<td>04/05/2007</td>
<td>BCBSA Medical Policy adoption</td>
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<td>10/02/2010</td>
<td>Policy title change from Positional MRI</td>
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<td>09/27/2013</td>
<td>Policy revision without position change. Policy placed on No Further Routine Literature Review and Update status.</td>
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<td>06/30/2015</td>
<td>Coding Update</td>
<td>Administrative Review</td>
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</table>
Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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 (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. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

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.