Clinical Review Criteria
Weight-Bearing MRI

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Criteria

For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Magnetic Resonance Imaging (MRI) (220.2)</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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For Non-Medicare Members
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Background

Magnetic resonance imaging (MRI) uses magnetic fields and radiofrequency waves to provide images of internal organs and tissues. Among other applications, MRI is widely used to diagnose joint and musculoskeletal disorders especially injuries affecting the knee, shoulder, hip, elbow and wrist.

Conventional MRI may have limits for diagnosing certain conditions such as degenerative cervical spinal disorders in which symptoms are aggravated when patients are standing and relieved when patients are lying down. The closed cylindrical design of standard MRI systems requires patients to be imaged in a supine position. Thus, with conventional non-weight-bearing MRI, the conditions under which symptoms arise are often not reproduced. Biomechanical studies have found a decrease in spinal canal cross-sectional area (or dural sac) and spinal foraminal dimensions with weight-bearing (axial loading) and with flexion and extension. In some cases, MRI findings correlate with patient symptoms. Disk extrusion, disk sequestration and nerve root compression are infrequently seen in asymptomatic patients, leading to the common belief that nerve root compression seen on MRI is clinically relevant. MRI of patients in the supine position may not identify clinically relevant spinal canal and foraminal stenosis, or the degree of nerve root compression (Kumura et al., 2005; Weishaupt & Boxheimer, 2003).

Weight-bearing MRI is proposed as an alternative to conventional MRI imaging. There are two ways to image the weight-bearing spine. One approach is to simulate weight bearing using a special device with conventional MRI machines. A study of patients with symptoms of spinal stenosis (Hiwatashi et al., 2004) found that imaging with axially loaded MR imaging can yield information that results in different treatment decisions than standard MRI. The Hiwatashi study used a device, consisting of a harness/jacket with straps connected to a footplate that applies an axial load to the patient’s spine during imaging in the supine position.

The other approach is to use a vertically open-configuration MRI that allows the patient to be imaged in a weight-bearing position. There are two FDA-approved devices:

- The Indomitable MRI scanner (Fonar) was approved by the FDA in October 2000 for imaging multiple planes of the head and body. It has an open design and the patient-scanning table can be moved to a variety of

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positions with the patient on it. Scanning positions include a vertical (upright) position, a horizontal (supine) position and an angled position (angles between -20o and 90o). Fonar, the manufacturer, claims that this is the only MRI system that can scan patients in flexion, extension, rotation and lateral bending (Fonar website; FDA website).

- The G-scan (Esaote) was approved by the FDA in August, 2004; its use is limited to imaging the ankle, knee, hip, shoulder joint and spine. The scanning table can also be moved to a variety of positions with the patient on it. The table can be rotated to angles between supine (0o) to fully upright (90o). The system also includes specialized knee, hand/wrist, ankle/foot and shoulder coils (Esaote website; FDA website).

Weight-bearing MRI has not been previously reviewed by MTAC.

Assessment questions:

- Diagnostic accuracy: What is the evidence on the ability of upright MRI to accurately detect problems/pathology compared to conventional MRI?
- Diagnostic impact: What is evidence on whether findings from weight-bearing MRI contribute substantially to improved diagnosis compared to conventional MRI?
- Therapeutic impact: What is the evidence that more appropriate therapy is used after weight-bearing MRI compared to conventional MRI?

Medical Technology Assessment Committee (MTAC)

Weight-Bearing MRI

06/04/2007: MTAC REVIEW

Evidence Conclusion: There are no published studies on the diagnostic accuracy (sensitivity/specificity), diagnostic impact or therapeutic impact of upright MRI compared to conventional MRI. One study with the Fonar Upright MRI system (Perez et al., 2007 in press) compared the diagnostic yield of the new device compared to conventional MRI. There was no gold standard comparison; rather, weight-bearing MRI was compared to conventional MRI. 68 pathologies were identified in 89 symptomatic patients by one or both methods. The authors considered a technology to be “superior” if it identified a pathology not detected by the other method, or indicated a herniation or spondylolisthesis that was larger in size. Upright MRI was found to be superior to recumbent MRI in 52 out of 68 pathologies identified, and recumbent MRI was found to be superior to upright MRI in 11 cases. The reports by the Washington State Labor and Industries Department and the Washington State Department of Health both also concluded that there was insufficient evidence on the diagnostic accuracy or utility of weight-bearing MRI.

Articles: Diagnostic accuracy: No studies were identified evaluated the sensitivity and specificity of weight-bearing MRI compared to conventional MRI, using an objective comparison. The empirical articles identified in the search generally involved obtaining spinal measurements with patients in various positions. For example, Hirasawa et al. (2007) examined 20 asymptomatic volunteers with the Fonar Indomitable MRI scanner in supine, sitting and standing positions. The primary outcome measures were differences in spinal measurements, specifically mean dural sac cross-sectional area and diameter. One study was identified that compared clinical diagnoses of patients imaged with weight-bearing MRI versus conventional MRI. This study (Ferreiro Perez et al., in press 2007) was critically appraised. See Evidence Table. Diagnostic accuracy: No studies were identified evaluated the sensitivity and specificity of weight-bearing MRI compared to conventional MRI, using an objective comparison. The empirical articles identified in the search generally involved obtaining spinal measurements with patients in various positions. For example, Hirasawa et al. (2007) examined 20 asymptomatic volunteers with the Fonar Indomitable MRI scanner in supine, sitting and standing positions. The primary outcome measures were differences in spinal measurements, specifically mean dural sac cross-sectional area and diameter. One study was identified that compared clinical diagnoses of patients imaged with weight-bearing MRI versus conventional MRI. This study (Ferreiro Perez et al., in press 2007) was critically appraised. See Evidence Table. Diagnostic impact: No studies were identified that evaluated whether findings from weight-bearing MRI contribute substantially to improved diagnosis compared to conventional MRI. Therapeutic impact: No studies were identified that reported quantitative data on whether more appropriate therapy was used after weight-bearing MRI than conventional MRI.

The use of weight-bearing MRI does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
### Codes

No specific codes for this service