MP 6.01.46
Dynamic Spinal Visualization and Vertebral Motion Analysis

BCBSA Ref. Policy: 6.01.46
Last Review: 09/19/2018
Effective Date: 12/15/2018
Section: Radiology

Related Policies
6.01.48 Positional Magnetic Resonance Imaging
9.01.502 Experimental / Investigational Services

DISCLAIMER
Our medical policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

POLICY
The use of dynamic spinal visualization is considered investigational.
Vertebral motion analysis is considered investigational.

POLICY GUIDELINES
Cineradiography/videofluoroscopy can be used once per anatomic area with modifier -59 (distinct procedural service) appended to the code when it is used for additional anatomic regions.

These procedures have both a technical and a professional component.

There is no specific code for vertebral motion analysis and some dynamic spinal visualization techniques. In such circumstances, refer to the unlisted codes in the Codes table.

BENEFIT APPLICATION

BLUECARD/NATIONAL ACCOUNT ISSUES
State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

BACKGROUND

PATIENT POPULATION
Dynamic spinal visualization and vertebral motion analysis are proposed for individuals who are being evaluated for back or neck pain and are being considered for standard flexion/extension radiographs. Flexion/extension radiographs may be performed with passive external force or by the patient’s own movement. Typically, radiographs are taken at the end ranges of flexion and extension and the intervertebral movements (rotation and translation) are measured to assess spinal instability. Flexion/extension radiographs may be used to assess radiographic instability in order to diagnose and determine the most effective treatment (eg, physical therapy, decompression, or spinal fusion) or to assess the efficacy of spinal fusion.
DYNAMIC SPINAL VISUALIZATION

Digital Motion X-Ray
Most spinal visualization technologies use x-rays to create images either on film, video monitor, or computer screen. Digital motion x-ray involves the use of film x-ray or computer-based x-ray “snapshots” taken in sequence as a patient moves. Film x-rays are digitized into a computer for manipulation, while computer-based x-rays are automatically created in a digital format. Using a computer program, the digitized snapshots are then sequenced and played on a video monitor, creating a moving image of the inside of the body. This moving image can then be evaluated by a physician alone or by using computer software that evaluates several aspects of the body’s structure, such as intervertebral flexion and extension, to determine the presence or absence of abnormalities.

Videofluoroscopy and Cineradiography
Videofluoroscopy and cineradiography are different names for the same procedure, which uses fluoroscopy to create real-time video images of internal structures of the body. Unlike standard x-rays, which take a single picture at 1 point in time, fluoroscopy provides motion pictures of the body. The results of these techniques can be displayed on a video monitor as the procedure is being conducted, as well as recorded, to allow computer analysis or evaluation at a later time. Like digital motion x-ray, the results can be evaluated by a physician alone or with the assistance of computer software.

Dynamic Magnetic Resonance Imaging
Dynamic magnetic resonance imaging (MRI) is also being developed to image the cervical spine. This technique uses an MRI-compatible stepless motorized positioning device and a real-time true fast imaging with steady-state precession sequence to provide passive kinematic imaging of the cervical spine. The quality of the images is lower than a typical MRI sequence but is proposed to be adequate to observe changes in the alignment of vertebral bodies, the width of the spinal canal, and the spinal cord. Higher resolution imaging can be performed at the end positions of flexion and extension.

Vertebral Motion Analysis
Vertebral motion analysis systems like the KineGraph VMA (Vertebral Motion Analyzer) provide assisted bending with fluoroscopic imaging and computerized analysis. The device uses facial recognition software to track vertebral bodies across the images. Proposed benefits of the vertebral motion analysis are a reduction in patient-driven variability in bending and assessment of vertebral movement across the entire series of imaging rather than at the end range of flexion and extension.

REGULATORY STATUS
In 2012, the KineGraph VMA™ (Vertebral Motion Analyzer; Ortho Kinematics) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process (k133875). The system includes a Motion Normalizer™ for patient positioning, standard fluoroscopic imaging, and automated image recognition software. Processing of scans by Ortho Kinematics is charged separately. Food and Drug Administration product code: LLZ.

RATIONALE
This evidence review was created in December 2006 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through July 9, 2018.

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.

**DYNAMIC SPINAL VISUALIZATION**

**Clinical Context and Test Purpose**
The purpose of dynamic spinal visualization is to determine whether the abnormal movement of the spine contributes to neck or back pain. This would inform clinical decision making about the appropriate intervention, either physical therapy or surgery.

The question addressed in this evidence review is: Does the use of dynamic spinal visualization provide additional information beyond that obtained with conventional imaging technology and does this additional information improve health outcomes?

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

**Patients**
The relevant population of interest is individuals being evaluated for back or neck pain.

**Interventions**
The test being considered is dynamic spinal visualization.

**Comparators**
The following tests are currently being used to make decisions about managing abnormal movement contributing to back and neck pain: conventional radiography and magnetic resonance imaging (MRI).

**Outcomes**
The outcomes of interest are whether dynamic spinal visualization leads to new findings and whether these findings improve health outcomes, including pain and function.

**Timing**
Short-term outcomes after physical therapy or surgery.

**Setting**
Dynamic spinal visualization is administered in an outpatient setting.

**Technically Reliable**
Assessment of technical reliability focuses on specific tests and operators and requires 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).
As of the most recent literature update, the evidence on dynamic spinal visualization remains predominantly comparisons of spine kinetics in patients with neck or back pain to healthy controls.

**Systematic Reviews**
A systematic by Xu et al (2017) reviewed 13 studies on dynamic supine MRI for patients with cervical spondylotic myelopathy, although it appears that the studies evaluated flexion/extension images rather than continuous motion.1

**Case-Control Studies**
Teyhen et al (2007) compared 20 patients with lower back pain to 20 healthy controls to provide construct validity for a clinical prediction rule that would identify patients likely to benefit from stabilization exercises,2 while Ahmadi et al (2009) used digital videofluoroscopy to compare 15 patients who had lower back pain with 15 controls to refine criteria for diagnosing lumbar segmental instability.3

**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 (RCTs).

No RCTs were identified that support the clinical utility of dynamic spinal visualization for this population.

The literature evaluating the clinical utility of dynamic spinal visualization techniques, including digital motion x-ray and cineradiography (videofluoroscopy) for the evaluation and assessment of the spine, is limited to a few studies involving small numbers of participants.4-6 No evidence was identified to indicate that clinical use improves health outcomes.

**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 dynamic spinal visualization has not been established, a chain of evidence cannot be constructed.

**Section Summary: Dynamic Spinal Visualization**
The literature evaluating the clinical utility of dynamic spinal visualization techniques, including digital motion x-ray and cineradiography (videofluoroscopy) and dynamic MRI, for the evaluation and assessment of the spine, is limited to a few studies involving small numbers of participants. The available studies have compared spine kinetics in patients who had neck or back pain with that in healthy controls. No literature was identified on the diagnostic accuracy of dynamic visualization in a relevant patient population. No evidence was identified to indicate that clinical use improves health outcomes such as symptoms or function.
VERTEBRAL MOTION ANALYSIS

Clinical Context and Test Purpose
The purpose of vertebral motion analysis (VMA) is to determine whether the abnormal movement of the spine contributes to neck or back pain. This would inform clinical decision making about the appropriate intervention, either physical therapy or surgery. VMA might also be used to assess the success of fusion.

The question addressed in this evidence review is: Does the use of VMA provide additional information beyond that obtained with conventional imaging technology and does this additional information improve health outcomes?

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

Patients
The relevant population of interest is individuals who are being evaluated for back or neck pain and are being considered for standard flexion-extension radiographs.

Interventions
The test being considered is VMA.

Comparators
The following tests are currently being used to make decisions about managing abnormal movement contributing to back and neck pain: conventional radiography and MRI.

Outcomes
The outcomes of interest are whether VMA leads to new findings and whether these findings improve health outcomes, including pain and function.

Timing
Short-term outcomes after physical therapy or surgery.

Setting
VMA is administered in an outpatient setting.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires 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).

Cheng et al (2016) and Yeager et al (2014) reported that VMA decreased variability in the measurement of lumbar spinal movement compared with a digitized manual technique. Diagnostic performance of VMA was reported by Davis et al (2015) in a retrospective study of 509 symptomatic patients and 73 asymptomatic participants. The comparator was rotational and translational movement from flexion-extension radiographs. The investigators considered instability in symptomatic patients to be true-positive and instability in asymptomatic participants as false-positive, leading to reported
differences in diagnostic accuracy between standard flexion/extension radiographs and VMA. In the absence of a true reference standard, the interpretation of this study is limited.

**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 RCTs.

No RCTs were identified that support the clinical utility of VMA in this population.

**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 VMA has not been established for this indication, a chain of evidence cannot be constructed.

**Section Summary: Vertebral Motion Analysis**
Three studies with overlapping authors have been identified on VMA. These studies have reported that VMA reduces variability in the measurement of rotational and translational spine movement compared with standard flexion/extension radiographs. One study reported an improvement in diagnostic accuracy compared with flexion/extension radiographs, but the interpretation of this study is limited by the lack of a true reference standard.

**SUMMARY OF EVIDENCE**
For individuals who have neck or back pain who receive dynamic spinal visualization, the evidence includes comparative trials. Relevant outcomes are test accuracy, symptoms, and functional outcomes. Techniques include digital motion x-rays, cineradiography/videofluoroscopy, or dynamic magnetic resonance imaging of the spine and neck. The available studies compare spine kinetics in patients who had neck or back pain with that in healthy controls. No literature was identified on the diagnostic accuracy of dynamic visualization in a relevant patient population. No evidence was identified on the effect of this technology on symptoms or functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have back or neck pain who receive vertebral motion analysis, the evidence includes comparisons to standard flexion/extension radiographs. Relevant outcomes are test accuracy, symptoms, and functional outcomes. These studies reported that vertebral motion analysis reduces variability in measurement of rotational and translational spine movement compared with standard flexion/extension radiographs. Whether the reduction in variability improves diagnostic accuracy or health outcomes is uncertain. The single study that reported on diagnostic accuracy lacked a true criterion standard, limiting interpretation of findings. The evidence is insufficient to determine the effects of the technology on health outcomes.
SUPPLEMENTAL INFORMATION

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 August 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

REFERENCES

CODES

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<td>Cineradiography/videoradiography, except where specifically included</td>
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<td>76125</td>
<td>Cineradiography/videoradiography to complement routine examination (list separately in addition to code for primary)</td>
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**MP 6.01.46**  
Dynamic Spinal Visualization and Vertebral Motion Analysis

<table>
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<th>Procedure</th>
<th>Description</th>
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<td>76499</td>
<td>Unlisted diagnostic radiographic procedure</td>
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**HCPCS**  
**ICD-10-CM**  
M54.5 - Low back pain  
**ICD-10-PCS**  
BR10ZZZ, BR17ZZZ, BR19ZZZ, BR1GZZZ - Imaging, axial skeleton, fluoroscopy, codes for cervical, thoracic, lumbar and whole spine

**Type of service**  
Radiology  
**Place of service**  
Outpatient/inpatient

**POLICY HISTORY**

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<td>Blue Cross of Idaho adopted changes as noted, effective 12/15/2018. Policy updated with literature review through July 9, 2018; references 7-9 added. “Vertebral Motion Analysis” added to title and to policy; it is investigational.</td>
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