Dynamic Spinal Visualization and Vertebral Motion Analysis

Policy Number: 6.01.46  Last Review: 2/2020

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for dynamic spinal visualization (digital motion x-ray, cineradiography, videofluoroscopy) and Vertebral Motion Analysis. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
The use of dynamic spinal visualization is considered investigational. Vertebral motion analysis is considered investigational.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tr>
<td>Individuals: • With neck or back pain</td>
<td>Interventions of interest are: • Dynamic spinal visualization</td>
<td>Comparators of interest are: • Conventional radiography • Magnetic resonance imaging</td>
<td>Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes</td>
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<tr>
<td>Individuals: • With neck or back pain</td>
<td>Interventions of interest are: • Vertebral motion analysis</td>
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Dynamic spinal visualization is a general term addressing different imaging technologies that simultaneously visualize spine (vertebrae) movements and external body movement. Vertebral motion analysis uses similar imaging as dynamic spinal visualization, with the addition of controlled movement and computerized tracking. These technologies have been proposed for the evaluation of spinal disorders including neck and back pain.
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.

**Background**

**Flexion/Extension Radiography**
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 a 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 one 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 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. Table 1 lists the spinal visualization and motion analysis devices currently cleared by the U.S. Food and Drug Administration. Food and Drug Administration product code: LLZ.

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<th>Device</th>
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<td>VirtuOst Vertebral Fracture Assessment</td>
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<td>X-PSI Knee System</td>
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<td>OrthoVision</td>
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<td>QuantX</td>
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<td>JointPoint</td>
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<td>Philips Eleva Workspot with SkyFlow</td>
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<td>OrthoVis Web Portal</td>
<td>CUSTOM ORTHOPAEDIC SOLUTIONSINC.</td>
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<td>Arthrex OrthoVis Preoperative Plan</td>
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<td>Centricity Universal Viewer</td>
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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 8, 2019.

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 PICOs were used to select literature relevant to the review.

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

Interventions
The test being considered is dynamic spinal visualization, which is administered in an outpatient setting.
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), which are administered in an outpatient setting.

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 of short-term outcomes is after completion of physical therapy or surgery.

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).

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 review 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. 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 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 PICOs were used to select literature relevant to the review.
Patients
The relevant population of interest are 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, which is administered in an outpatient setting.

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, which are administered in an outpatient setting.

Outcomes
The outcomes of interest are whether VMA leads to new findings and whether these findings improve health outcomes, including pain and function. Timing of short-term outcomes is after completion of physical therapy or surgery.

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).

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: VMA**
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. The 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 VMA, the evidence includes comparisons to standard flexion/extension radiographs. The relevant outcomes are test accuracy, symptoms, and functional outcomes. These studies reported that VMA 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 July 2019 did not identify any ongoing or
unpublished trials that would likely influence this review.

REFERENCES
1. Xu N, Wang S, Yuan H, et al. Does dynamic supine magnetic resonance imaging improve the
diagnostic accuracy of cervical spondylotic myelopathy? A review of the current evidence. World
Neurosurg. Apr 2017;100:474-479. PMID 28130164.
2. Teyhen DS, Flynn TW, Childs JD, et al. Arthrokinematics in a subgroup of patients likely to
PMID 17311885.
168. PMID 9926388.
5. Takayanagi K, Takahashi K, Yamagata M, et al. Using cineradiography for continuous dynamic-
PMID 11568694.
PMID 27441178.
8. Yeager MS, Cook DJ, Cheng BC. Reliability of computer-assisted lumbar intervertebral
measurements using a novel vertebral motion analysis system. Spine J. Feb 1 2014;14(2):274-
281. PMID 24239805.

Billing Coding/Physician Documentation Information
76120 Cineradiography/videoradiography, except where specifically included
76125 Cineradiography/videoradiography to complement routine examination
(List separately in addition to code for primary procedure)
76496 Unlisted fluoroscopic procedure (eg, diagnostic, interventional)
76499 Unlisted diagnostic radiographic procedure

ICD-10 Codes
M54.5 Low back pain
**Additional Policy Key Words**
Digital Spinal Analysis

**Policy Implementation/Update Information**

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