Dynamic Spinal Visualization

Description

Dynamic spinal visualization is a general term addressing different imaging technologies, including digital motion x-ray and videofluoroscopy (also known as cineradiography) that allow the simultaneous visualization of movement of internal body structures such as the spine (vertebrae) with external body movement. These technologies have been proposed for the evaluation of spinal disorders including low back pain.

Background

Most spinal visualization methods use x-rays to create images either on film, video monitor, or computer screen. Digital motion x-ray involves the use of either 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 put in order and then 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 a computer 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 are different names for the same procedure, which uses a technique called 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 analysis software.

Dynamic magnetic resonance imaging (MRI) is also being developed for imaging of the cervical spine. This technique uses an MRI-compatible stepless motorized positioning device (NeuroSwing, Fresenius/Siemens) and a real-time true fast imaging with steady-state precession (FISP) 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.
Regulatory Status

The KineGraph VMA™ (Vertebral Motion Analyzer, Ortho Kinematics) received clearance for marketing through the U.S. Food and Drug Administration’s (FDA) 510(k) process in 2012. 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. FDA product code: LLZ.

Related Policies

6.01.48 Positional Magnetic Resonance Imaging

Policy

“This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

The use of dynamic spinal visualization is considered not medically necessary.

Benefit Application

The BCBS FEP contract stipulates that FDA-approved biologics, drugs and certain devices may not be considered investigational when used for their intended purpose and thus these products may only be assessed based on medical necessity.

Rationale

At the time this policy was created, 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, was limited to a few studies involving small numbers of participants. (1-3) No evidence was identified to indicate that clinical use improves health outcomes.

While there were reports of the correlation of this technique to disc degeneration, (4) no studies had evaluated the incremental value of this information compared to the standard evaluation. In addition, although some studies had shown that abnormalities in spinal motion are found in individuals with low back pain, particularly those with spondylolisthesis, the test did not always separate those with disease from those without disease. (5)

As of the most recent literature update through July 24, 2014, the evidence on dynamic spinal visualization remains predominantly of comparisons of spine kinetics in patients with neck or back pain with healthy controls. For example, Teyhen et al. 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, (6) while Ahmadi and colleagues used digital videofluoroscopy to compare 15 patients with lower back pain and 15 controls to assist in identifying better criteria for diagnosis of lumbar segmental instability. (7) Breen et al. reported on objective spinal motion imaging assessment (OSMIA) in 30 healthy volunteers using a passive motion table and automated frame-to-frame registration of vertebral position. (8) Another study from 2009 used dynamic
fluoroscopy to assess lateral flexion in 30 healthy controls, noting that data pooling from multiple studies would be needed to establish a complete database of reference limits from asymptomatic individuals. (9)

A feasibility study of dynamic magnetic resonance imaging (MRI) was reported in 2012. (10) This study used a prototype of the NeuroSwing positioning device and evaluated cervical spine kinematics in 32 patients who had previously undergone anterior cervical discectomy and fusion (ACDF). The quality of images was considered to be adequate, although there was some artifact from the titanium implants used in ACDF.

**Practice Guidelines and Position Statements**

No guidelines or statements were identified.

**U.S. Preventive Services Task Force Recommendations**

Use of dynamic spinal visualization such as videofluoscopy or cineradiology is not a preventive service.

**Summary**

The evidence on dynamic spinal visualization in patients with back or neck pain includes comparisons of spine kinetics in patients with neck or back pain with healthy controls. Relevant outcomes are test accuracy, symptoms, morbid events, and functional outcomes. Techniques include digital motion x-rays, cineradiography/videofluoroscopy, or dynamic magnetic resonance imaging of the spine. No literature was identified on the diagnostic accuracy of this technology in a relevant population of patients. 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.

**Medicare National Coverage**

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

**References**


Policy History

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>March 2012</td>
<td>New Policy</td>
<td>Policy and references updated with literature review, policy statement unchanged</td>
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<tr>
<td>December 2012</td>
<td>Update Policy</td>
<td>Policy and references updated with literature review, policy statement unchanged</td>
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<tr>
<td>December 2013</td>
<td>Update Policy</td>
<td>Policy and references updated with literature review, reference 8 added. Regulatory status updated with FDA approval for KineGraph VMA™. Policy statement and summary revised from investigational to not medically necessary.</td>
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<tr>
<td>December 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review through August 11, 2015; no references added. Policy statement unchanged.</td>
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Keywords

Cineradiography
Digital Motion X-ray
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Dynamic Spinal Visualization
Spinal Videofluoroscopy
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Videoradiography
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 4, 2015 and is effective January 15, 2016.

Signature on File
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