Dynamic Spinal Visualization

Policy # 00197
Original Effective Date: 02/23/2006
Current Effective Date: 03/19/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers dynamic spinal visualization, including, but not limited to, digital motion x-ray of the spine, including digitization of spinal x-rays and computerized analysis of the back or spine, to be investigational* for all indications.

Based on review of available data, the Company considers cineradiography, also known as videofluoroscopy, when used to visualize movement of the back or spine, to be investigational* for all indications.

Background/Overview
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.

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.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)
The KineGraph VMA™‡ (Vertebral Motion Analyzer, Ortho Kinematics) received clearance for marketing through the U.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.

Centers for Medicare and Medicaid Services (CMS)
No national coverage determination.

**Rationale/Source**

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. 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, 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.

As of the most recent literature update through July 2012, 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, 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. 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.

A feasibility study of dynamic MRI was reported in 2012. 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.

**Summary**

The evidence at this time is insufficient to evaluate the effect on health outcomes of digital motion x-rays, cineradiography/videofluoroscopy, or dynamic MRI of the spine for any indication. Therefore, dynamic spinal visualization is considered investigational.
Dynamic Spinal Visualization

Policy # 00197
Original Effective Date: 02/23/2006
Current Effective Date: 03/19/2014

References

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>76120, 76125</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-9 Diagnosis</td>
<td>All relative diagnoses</td>
</tr>
<tr>
<td>ICD-9 Procedure</td>
<td>No codes</td>
</tr>
</tbody>
</table>
Dynamic Spinal Visualization

Policy # 00197
Original Effective Date: 02/23/2006
Current Effective Date: 03/19/2014

**Policy History**

<table>
<thead>
<tr>
<th>Original Effective Date:</th>
<th>Current Effective Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/23/2006</td>
<td>03/19/2014</td>
</tr>
</tbody>
</table>

- 02/01/2006 Medical Director review
- 02/15/2006 Medical Policy Committee review
- 02/23/2006 Quality Care Advisory Council approval
- 03/14/2007 Medical Director review
- 03/21/2007 Medical Policy Committee approval. Rationale updated. Title changed to Dynamic Spinal Visualization to match Blue Cross Blue Shield Association. No change to coverage eligibility.
- 03/05/2010 Medical Policy Committee approval
- 03/19/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 03/03/2011 Medical Policy Committee review
- 03/16/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 03/01/2012 Medical Policy Committee review
- 03/21/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 03/07/2013 Medical Policy Committee review
- 03/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 03/06/2014 Medical Policy Committee review
- 03/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.