Dynamic Spinal Visualization and Vertebral Motion Analysis

Policy # 00197
Original Effective Date: 02/23/2006
Current Effective Date: 04/10/2023

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.

Based on review of available data, the Company considers vertebral motion analysis to be 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.

Background/Overview
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 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.

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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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
In 2012, the KineGraph VMA™‡ (Vertebral Motion Analyzer; Ortho Kinematics) was cleared for marketing by the U.S. Food and Drug Administration (FDA) 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 a sampling of the spinal visualization and motion analysis devices currently cleared by the FDA. FDA product code: LLZ.

Table 1. Spinal Visualization and Motion Analysis Devices Cleared by the U.S. Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>SuRgical Planner (SRP) BrainStorm</td>
<td>Surgical Theater, Inc.</td>
<td>07/17/2020</td>
<td>K201465</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>Bone VCAR (BVCAR)</td>
<td>GE Medical Systems SCS</td>
<td>4/8/2019</td>
<td>K183204</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>mediCAD 4.0</td>
<td>mediCAD Hectec Gmbh</td>
<td>9/7/2018</td>
<td>K170702</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
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</tbody>
</table>

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<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Date</th>
<th>K-Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>VirtuOst Vertebral Fracture Assessment</td>
<td>O.N. Diagnostics LLC.</td>
<td>8/3/2018</td>
<td>K171435</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>Surgical Planning Software Version 1.1</td>
<td>Ortho Kinematics Inc.</td>
<td>11/8/2017</td>
<td>K173247</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>VMA System version 3.0</td>
<td>Ortho Kinematics Inc.</td>
<td>8/25/2017</td>
<td>K172327</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>OKI Surgical Planning Software</td>
<td>Ortho Kinematics Inc.</td>
<td>8/22/2017</td>
<td>K171617</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>UNiD Spine Analyzer</td>
<td>MEDICREA INTERNATIONAL</td>
<td>5/24/2017</td>
<td>K170172</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>Dynamika</td>
<td>IMAGE ANALYSIS LIMITED</td>
<td>5/17/2017</td>
<td>K161601</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
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<tr>
<td>spineEOS</td>
<td>ONEFIT MEDICAL</td>
<td>4/8/2016</td>
<td>K160407</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>Philips Eleva Workspot with SkyFlow</td>
<td>Philips Medical Systems DMC GmbH</td>
<td>12/22/2015</td>
<td>K153318</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
</tr>
<tr>
<td>Centricity Universal Viewer</td>
<td>GE HEALTHCARE</td>
<td>5/26/2015</td>
<td>K150420</td>
<td>For use in spinal visualization and motion analysis for neck and back pain</td>
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</tbody>
</table>
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| SPINEDESIGN Spine Surgery Planning (Software Application) | MEDTRONIC SOFAMOR DANEK USA INC. | 5/22/2015 | K142648 | For use in spinal visualization and motion analysis for neck and back pain |

### Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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. Most available studies compare spine kinetics in patients who had neck or back pain with spine kinetics in healthy controls. In a feasibility study of 21 patients examining dynamic magnetic resonance imaging (MRI) for the detection of spondylolisthesis, 3 dynamic MRI protocols demonstrated sensitivities of 68.8% to 78.6% when compared to standard flexion-extension radiographs. No evidence was identified on the effect of this technology on symptoms or functional outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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
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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 that the technology results in an improvement in the net health outcome.

Supplemental Information
Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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 2022 did not identify any ongoing or unpublished trials that would likely influence this review.

References
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**Policy History**

Original Effective Date:  02/23/2006
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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. No change to coverage eligibility.
03/05/2010  Medical Policy Committee approval

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<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>03/19/2010</td>
<td>Medical Policy Implementation Committee approval. Coverage eligibility unchanged.</td>
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<tr>
<td>03/03/2011</td>
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<tr>
<td>03/16/2011</td>
<td>Medical Policy Implementation Committee approval. Coverage eligibility unchanged.</td>
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<tr>
<td>03/01/2012</td>
<td>Medical Policy Committee review</td>
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<tr>
<td>03/21/2012</td>
<td>Medical Policy Implementation Committee approval. Coverage eligibility unchanged.</td>
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<tr>
<td>03/07/2013</td>
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<td>03/20/2013</td>
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<td>03/06/2014</td>
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<td>03/19/2014</td>
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<tr>
<td>03/05/2015</td>
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<td>03/20/2015</td>
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<tr>
<td>08/03/2015</td>
<td>Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.</td>
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<td>03/16/2016</td>
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<tr>
<td>01/01/2017</td>
<td>Coding update: Removing ICD-9 Diagnosis Codes</td>
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<tr>
<td>03/02/2017</td>
<td>Medical Policy Committee review</td>
</tr>
<tr>
<td>03/15/2017</td>
<td>Medical Policy Implementation Committee approval. Coverage eligibility unchanged.</td>
</tr>
<tr>
<td>03/01/2018</td>
<td>Medical Policy Committee review</td>
</tr>
<tr>
<td>03/21/2018</td>
<td>Medical Policy Implementation Committee approval. Coverage eligibility unchanged.</td>
</tr>
<tr>
<td>10/02/2018</td>
<td>Coding update</td>
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<tr>
<td>03/07/2019</td>
<td>Medical Policy Committee review</td>
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<tr>
<td>03/20/2019</td>
<td>Medical Policy Implementation Committee approval. Added “and Vertebral Motion Analysis” to the end of the title. Added a coverage statement for vertebral motion analysis to be investigational.</td>
</tr>
</tbody>
</table>
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03/05/2020 Medical Policy Committee review
03/11/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2021 Medical Policy Committee review
03/10/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/20/2021 Coding update
03/03/2022 Medical Policy Committee review
03/09/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/02/2023 Medical Policy Committee review
03/08/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2024

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 2022 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
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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>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0693T, 76120, 76125, 76496, 76499</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

*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. Food and Drug Administration (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 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.
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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.