



Louisiana

Dynamic Spinal Visualization and Vertebral Motion Analysis

Policy # 00197

Original Effective Date: 02/23/2006

Current Effective Date: 04/13/2020

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

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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.

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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^{TM†} (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^{TM‡} 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.

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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Bone VCAR (BVCAR)	GE Medical Systems SCS	4/8/2019	K183204	For use in spinal visualization and motion analysis for neck and back pain
Visualase Thermal Therapy System	Medtronic Navigation Inc.	3/6/2019	K181859	For use in spinal visualization and motion analysis for neck and back pain
mediCAD 4.0	mediCAD Hectec Gmbh	9/7/2018	K170702	For use in spinal visualization and motion analysis for neck and back pain

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VirtuOst Vertebral Fracture Assessment	O.N. Diagnostics LLC.	8/3/2018	K171435	For use in spinal visualization and motion analysis for neck and back pain
SPIN-SWI	SpinTech Inc.	2/23/2018	K173224	For use in spinal visualization and motion analysis for neck and back pain
X-PSI Knee System	Orthosoft Inc. (d/b/a Zimmer CAS)	12/28/2017	K171269	For use in spinal visualization and motion analysis for neck and back pain
Surgical Planning Software Version 1.1	Ortho Kinematics Inc.	11/8/2017	K173247	For use in spinal visualization and motion analysis for neck and back pain
OrthoVision	Ewoo Soft Co. Ltd.	10/26/2017	K173094	For use in spinal visualization and motion analysis for neck and back pain
VMA System version 3.0	Ortho Kinematics Inc.	8/25/2017	K172327	For use in spinal visualization and motion analysis for neck and back pain
OKI Surgical Planning Software	Ortho Kinematics Inc.	8/22/2017	K171617	For use in spinal visualization and motion analysis for neck and back pain
UNiD Spine Analyzer	MEDICREA INTERNATIONAL	5/24/2017	K170172	For use in spinal visualization and motion analysis for neck and back pain

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Dynamika	IMAGE ANALYSIS LIMITED	5/17/2017	K161601	For use in spinal visualization and motion analysis for neck and back pain
QuantX	Quantitative Insights Inc.	5/17/2017	K170195	For use in spinal visualization and motion analysis for neck and back pain
Move Forward 3D Motion Simulation Service	BIOMET INC.	3/31/2017	K162559	For use in spinal visualization and motion analysis for neck and back pain
kneeEOS	ONEFIT Medical	10/3/2016	K161828	For use in spinal visualization and motion analysis for neck and back pain
JointPoint	JOINTPOINT INC.	8/3/2016	K160284	For use in spinal visualization and motion analysis for neck and back pain
EndoSize	Therenva SAS	4/12/2016	K160376	For use in spinal visualization and motion analysis for neck and back pain
spineEOS	ONEFIT MEDICAL	4/8/2016	K160407	For use in spinal visualization and motion analysis for neck and back pain
Philips Eleva Workspot with SkyFlow	Philips Medical Systems DMC GmbH	12/22/2015	K153318	For use in spinal visualization and motion analysis for neck and back pain

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OrthoVis Web Portal	CUSTOM ORTHOPAEDIC SOLUTIONSINC.	10/2/2015	K151501	For use in spinal visualization and motion analysis for neck and back pain
Arthrex OrthoVis Preoperative Plan	Custom Orthopaedic Solutions Inc.	7/31/2015	K151568	For use in spinal visualization and motion analysis for neck and back pain
Centricity Universal Viewer	GE HEALTHCARE	5/26/2015	K150420	For use in spinal visualization and motion analysis for neck and back pain
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

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. 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.

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For individuals who have back or neck pain who receive vertebral motion analysis, the evidence includes comparisons to standard flexion/extension radiographs. The 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 July 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

References

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Policy History

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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 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. |

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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.
03/05/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/03/2016	Medical Policy Committee review
03/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2018	Medical Policy Committee review
03/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/02/2018	Coding update
03/07/2019	Medical Policy Committee review
03/20/2019	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.
03/05/2020	Medical Policy Committee review

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03/11/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2021

Coding

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

Code Type	Code
CPT	76120, 76125, 76496, 76499
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

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*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 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.

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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.

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