

POLICY TITLE	DYNAMIC SPINAL VISUALIZATION AND VERTEBRAL MOTION ANALYSIS
POLICY NUMBER	MP 5.051

CLINICAL	☑ MINIMIZE SAFETY RISK OR CONCERN.
BENEFIT	☑ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.
	☐ ASSURE APPROPRIATE LEVEL OF CARE.
	☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.
	☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.
	☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	4/1/2024

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### I. POLICY

The use of dynamic spinal visualization is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Vertebral motion analysis is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

#### II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

#### III. DESCRIPTION/BACKGROUND

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### 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 (e.g., physical therapy, decompression, or spinal fusion) or to assess the efficacy of spinal fusion.

### **Dynamic Spinal Visualization**



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#### 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 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.

### 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 a sampling of the spinal visualization and motion analysis devices currently cleared by the FDA. Product code: LLZ.



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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
SuRgical Planner (SRP) BrainStorm	Surgical Theater, Inc.	7/17/2020	K201465	For use in spinal visualization and motion analysis for neck and back pain
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
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



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				analysis for neck and back pain	
VMAâ,,¢ 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	
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	



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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
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

# IV. RATIONALE <u>TOP</u>

### **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. In a feasibility study of twenty-one patients examining dynamic MRI for the detection of spondylolisthesis, three 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 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. The relevant outcomes are test accuracy, symptoms, and functional outcomes. These studies reported that vertebral motion



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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.

V. DEFINITIONS TOP

N/A

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

#### VIII. CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Investigational; therefore, not covered:

Procedu	re Codes				
76120	76125				

IX. REFERENCES TOP



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- 11. Walter WR, Alizai H, Bruno M, Portugal S, Burke CJ. Real-time dynamic 3-T MRI assessment of spine kinematics: a feasibility study utilizing three different fast pulse sequences. Acta Radiol. 2021;62(1):58-66. doi:10.1177/0284185120913000
- 12. Blue Cross Blue Shield Association Medical Policy Reference Manual. 6.01.46, Dynamic Spinal Visualization and Vertebral Motion Analysis. October, 2023.

# X. POLICY HISTORY TOP

MP 5.051	CAC 3/26/13 New policy adopting BCBSA investigational policy statement.
	Previously silent. CPT codes added to policy
	CAC 1/28/14 Consensus. No change to policy statements. References
	updated. Rationale section added.
	CAC 1/27/15 Consensus review. No changes go the policy statements.
	Rationale updated. Codes reviewed.
	CAC 1/26/16 Consensus review. No change to policy statements.
	References and rationale updated. Coding reviewed.
	11/10/16 Administrative update. Variation Reformatting



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CAC 3/28/17 Consensus review. No change to policy statements.
References and rationale reviewed. Coding Reviewed.
1/2/18 Consensus review. No change to the policy statement. Rationale
updated.
11/15/18 Minor review. Vertebral Motion Analysis added as investigational.
Title updated. Background and references updated. Rationale condensed.
Coding reviewed.
<b>10/2/19 Consensus review.</b> No change to the policy statements. References
reviewed. FEP variation removed since archived.
8/18/20 Consensus review. No change to the policy statements. References
reviewed.
5/3/21 Consensus review. No change to policy statements. Table 1 added
11/14/2022 Consensus review. No change to policy statement. Updated
rationale, references. No coding changes.
12/27/2023 Consensus review. No changes to policy statement. Updated
references. Coding reviewed, no changes.

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