



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Dynamic Spinal Visualization and Vertebral Motion Analysis

Policy #: 511
Category: Radiology

Latest Review Date: October 2020
Policy Grade: C

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after October 1, 2018:

Blue Advantage will treat the use of dynamic spinal visualization as a non-covered benefit and as investigational.

Blue Advantage will treat the use of vertebral motion analysis as a non-covered benefit and as investigational.

Effective for dates of service prior to September 30, 2018:

Blue Advantage will treat the use of dynamic spinal visualization as a non-covered benefit and as investigational.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Dynamic spinal visualization is a general term addressing different imaging technologies 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 neck and back pain.

Patient Population

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 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

Digital Motion X-Ray

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

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

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 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.

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.

KEY POINTS:

This policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through July 29, 2020.

Summary of Evidence

For individuals who have back or neck 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. The available studies compare spine kinetics in patients with neck or back pain to that in healthy controls. 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.

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 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.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Cineradiography, Digital Motion X-ray, Videofluorography, Videofluoroscopy, Videoradiography, Vertebral Motion Analysis, VMA, KineGraph VMA

APPROVED BY GOVERNING BODIES:

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. Table 1 lists the spinal visualization and motion analysis devices currently cleared by the U.S. Food and Drug Administration.

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.	07/17/2020	K201465	For use in spinal visualization and motion analysis for neck and back pain
Bone VCAR	GE Medical	4/8/2019	K183204	For use in spinal

(BVCAR)	Systems SCS			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 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
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 SOLUTIONS INC.	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

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

76120	Cineradiography/videoradiography, except where specifically included
76125	Cineradiography/videoradiography to complement routine examination (list separately in addition to code for primary procedure)

**CPT code 76120 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.

REFERENCES:

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POLICY HISTORY:

Adopted for Blue Advantage, October 2012

Available for comment October 24 through December 10, 2012

Medical Policy Group, September 2013

Medical Policy Group, September 2014

Medical Policy Group, October 2015

Medical Policy Group, March 2017

Available for comment November 12, 2018 through December 29, 2018

Medical Policy Group, October 2019

Medical Policy Group, October 2020

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.