Protocol

Dynamic Spinal Visualization and Vertebral Motion Analysis

(60146)

Medical Benefit		**Effective Date**: 06/01/19	**Next Review Date**: 03/21
Preauthorization	No	**Review Dates**: 09/07, 09/08, 09/09, 05/10, 03/11, 03/12, 03/13, 03/14, 03/15, 03/16, 03/17, 03/18, 03/19, 03/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With neck or back pain	Interventions of interest are: • Dynamic spinal visualization	Comparators of interest are: • Conventional radiography • Magnetic resonance imaging	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes
Individuals: • With neck or back pain	Interventions of interest are: • Vertebral motion analysis	Comparators of interest are: • Conventional radiography • Magnetic resonance imaging	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes

DESCRIPTION

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.

SUMMARY OF EVIDENCE

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. 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.

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.

POLICY

The use of dynamic spinal visualization is considered **investigational**.

Vertebral motion analysis is considered **investigational**.

BACKGROUND

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

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 step less 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 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
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
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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
				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 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

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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