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## MEDICAL POLICY – 6.01.46 Dynamic Spinal Visualization and Vertebral Motion Analysis

BCBSA Ref. Policy: 6.01.46

| Effective Date: | Dec. 1, 2024  | RELATED MEDICAL POLICIES:      |
|-----------------|---------------|--------------------------------|
| Last Revised:   | Nov. 11, 2024 | 8.03.501 Chiropractic Services |
| Replaces:       | 6.01.508      |                                |

## Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

## Introduction

Dynamic spinal visualization is a way to see how the spine moves as a person bends or twists. It's thought that looking at moving images could help a healthcare professional diagnose the cause of neck or back pain or other problems with the spine. There are several different ways to create moving images as the spine twists or turns. Most techniques use x-ray to create images on film, a video monitor, or computer screen. Several x-rays are taken, assembled in order, and then played to create a moving image. Other technologies use fluoroscopy and magnetic resonance imaging. Because there are not enough medical studies to show how well dynamic spinal visualization works, it's considered unproven.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## **Policy Coverage Criteria**

| Service                   | Investigational  |
|---------------------------|--|
| Dynamic spinal            | The following dynamic spinal visualization techniques are  |
| visualization             | considered investigational, including, but not limited to: |
|                           | Digital motion x-ray of the spine                          |
|                           | Cineradiography/videofluoroscopy                           |
|                           | Dynamic magnetic resonance imaging                         |
| Vertebral motion analysis | Vertebral motion analysis is considered investigational.   |
| (e.g., The KineGraph VMA) |  |

## Coding

| Code  | Description  |
|-------|--|
| СРТ   |  |
| 76120 | Cineradiography/videoradiography, except where specifically included   |
| 76125 | Cineradiography/videoradiography to complement routine examination (list separately in addition to code for primary procedure) |
| 76496 | Unlisted fluoroscopic procedure (e.g., diagnostic, interventional)   |
| 76499 | Unlisted diagnostic radiographic procedure   |

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

#### **Related Information**

N/A

**Evidence Review** 



## 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.

## 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 passive external force or by the individual'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 either film x-ray or computer-based x-ray "snapshots" taken in sequence as an individual 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 individual-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.

## **Summary of Evidence**

For individuals who have back or neck 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 MRI of the spine and neck. Most available studies compare spine kinetics in individuals with neck or back pain with spine kinetics in healthy controls. In a



feasibility study of 21 individuals examining dynamic MRI for the detection of spondylolithesis, 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 VMA, the evidence includes comparisons to standard flexion/extension radiographs. The relevant outcomes are test accuracy, symptoms, and functional outcomes. These studies reported that VMA 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 that the technology results in an improvement in the net health outcome.

## **Ongoing and Unpublished Clinical Trials**

A search of **ClinicalTrials.gov** in August 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

## **Practice Guidelines and Position Statements**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a United States (US) professional society, an international society with US representation, or National Institute for Health and Care Excellence. 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.

## Medicare National Coverage

There is no national coverage determination.



## **Regulatory Status**

In 2012, The KineGraph VMA (Vertebral Motion Analyzer, Ortho Kinematics) was cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process (k133875). The system includes a Motion Normalizer for individual 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 theUS Food and Drug Administration

| Device                                    | Manufacturer              | Date       | 510(k)  | Indication   |
|---|---------------------------|------------|---------|--|
|   |                           | Cleared    | No.     |  |
| SuRgical Planner (SRP)<br>BrainStorm      | Surgical Theater,<br>Inc. | 07/17/2020 | K201465 | For use in spinal visualization and motion analysis for neck and back pain |
| Bone VCAR (BVCAR)                         | GE Medical Systems<br>SCS | 4/8/2019   | K183204 | For use in spinal visualization and motion analysis for neck and back pain |
| mediCAD 4.0                               | mediCAD Hectec<br>Gmbh    | 9/7/2018   | K170702 | For use in spinal visualization and motion analysis for neck and back pain |
| VirtuOst Vertebral<br>Fracture Assessment | O.N. Diagnostics<br>LLC.  | 8/3/2018   | K171435 | For use in spinal visualization and motion analysis for neck and back pain |
| Surgical Planning<br>Software Version 1.1 | Ortho Kinematics<br>Inc.  | 11/8/2017  | K173247 | For use in spinal visualization and motion analysis for neck and back pain |
| VMA System version<br>3.0                 | Ortho Kinematics<br>Inc.  | 8/25/2017  | K172327 | For use in spinal visualization and motion analysis for neck and back pain |
| OKI Surgical Planning<br>Software         | Ortho Kinematics<br>Inc.  | 8/22/2017  | K171617 | For use in spinal visualization and motion analysis for neck and back pain |
| UNiD Spine Analyzer                       | MEDICREA<br>INTERNATIONAL | 5/24/2017  | K170172 | For use in spinal visualization and motion analysis for neck and back pain |
| Dynamika                                  | IMAGE ANALYSIS<br>LIMITED | 5/17/2017  | K161601 | For use in spinal visualization and motion analysis for neck and back pain |



| Device  | Manufacturer                           | Date       | 510(k)  | Indication   |
|---|--|------------|---------|--|
|   |  | Cleared    | No.     |  |
| spineEOS  | ONEFIT MEDICAL                         | 4/8/2016   | K160407 | For use in spinal visualization and motion analysis for neck and back pain |
| Philips Eleva Workspot<br>with SkyFlow                          | Philips Medical<br>Systems DMC<br>GmbH | 12/22/2015 | K153318 | For use in spinal visualization and motion analysis for neck and back pain |
| Centricity Universal<br>Viewer                                  | GE HEALTHCARE                          | 5/26/2015  | K150420 | For use in spinal visualization and motion analysis for neck and back pain |
| SPINEDESIGN Spine<br>Surgery Planning<br>(Software Application) | MEDTRONIC<br>SOFAMOR DANEK<br>USA INC. | 5/22/2015  | K142648 | For use in spinal visualization and motion analysis for neck and back pain |

#### References

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12. Davis RJ, Lee DC, Wade C, et al. Measurement Performance of a Computer Assisted Vertebral Motion Analysis System. Int J Spine Surg. 2015; 9: 36. PMID 26273554

## History

| Date     | Comments  |
|----------|---|
| 02/13/07 | Add to Radiology Section - New Policy   |
| 04/08/08 | Replace policy - Policy updated with literature search; no change to the policy statement. References added.  |
| 11/10/09 | Replace policy - Policy updated with literature search; no change to the policy statement.  |
| 11/09/10 | Replace policy - Policy updated with literature review; references 7 and 8 have been added, others removed and reordered. The policy statement remains unchanged.                   |
| 11/10/11 | Replace policy – Policy updated with literature review through July 2011; no new references added; policy statement unchanged. ICD-10 codes added.                                  |
| 06/26/12 | Related policies updated with the addition of 6.01.513.   |
| 09/26/12 | Update Related Policy – Add 7.01.126; ICD-10 codes are now effective 10/01/2014.  |
| 11/27/12 | Replace policy - Policy updated with literature review through July 2012; reference 9 added; policy statement unchanged.  |
| 02/01/13 | Update Related Policies, add 8.03.501.  |
| 06/14/13 | Update Related Policies. Remove 6.01.513 as it was archived.  |
| 12/04/13 | Replace policy. Policy updated with literature review through August 15, 2013.Reference 8 added; others renumbered/removed. Policy statement unchanged.                             |
| 01/21/14 | Update Related Policies. Add 7.01.551.  |
| 11/20/14 | Annual Review. Policy updated with literature review through July 24, 2014; policy statement unchanged.   |
| 11/10/15 | Annual Review. Policy updated with literature review through August 11, 2015; no references added. Policy statement unchanged.  |
| 08/31/16 | Coding Update. Add CPT code 76496.  |
| 12/01/16 | Annual Review, approved November 8, 2016. Policy updated with literature review through October 7, 2016. Reference 12 added. No change to the policy statement.                     |
| 06/01/17 | Annual Review, approved May 2, 2017. Policy moved into new format. Policy updated with literature review through January 25, 2017; no references added. Policy statement unchanged. |



| Date     | Comments   |
|----------|--|
| 12/01/17 | Interim Review, approved November 14, 2017. Policy statement clarified to now include specific dynamic spinal visualization techniques, Hayes reference added.   |
| 12/01/18 | Annual Review, approved November 6, 2018. Policy updated with literature review<br>through July 2018; references 7-9 added. Policy title changed from "Dynamic Spinal<br>Visualization" to "Dynamic Spinal Visualization and Vertebral Motion Analysis"<br>Vertebral motion analysis added to policy as investigational. |
| 12/01/19 | Annual Review, approved November 6, 2019. Policy updated with literature review through July 2019; no references added. Policy statements unchanged.   |
| 01/01/21 | Annual Review, approved December 1, 2020. Policy updated with literature review through July 29, 2020; no references added. Policy statements unchanged.   |
| 12/01/21 | Annual Review, approved November 2, 2021. Policy updated with literature review through July 23, 2021; reference added. Policy statements unchanged.   |
| 12/13/21 | Corrected the Last Revised date on the policy header.  |
| 01/01/23 | Annual Review, approved December 12, 2022. Policy updated with literature review through July 30, 2022, no references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.  |
| 12/01/23 | Annual Review, approved November 6, 2023. Policy updated with literature review through August 4, 2023; no references added. Policy statements unchanged.  |
| 12/01/24 | Annual Review, approved November 11, 2024. Policy updated with literature review through August 5, 2024; references added. Policy statements unchanged.  |

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

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