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Dynamic Spinal Visualization and Vertebral Motion Analysis

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

The use of dynamic spinal visualization **is considered experimental, investigational and/or unproven**.

Vertebral motion analysis **is considered experimental, investigational and/or unproven**.

Policy Guidelines

These procedures have both a technical and a professional component.

There is no specific code for vertebral motion analysis and some dynamic spinal visualization techniques.

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.

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 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 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 (FDA) 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 U.S. FDA. FDA 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
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 (BVCAR)	GE Medical Systems SCS	04/08/2019	K183204	For use in spinal visualization and motion analysis for neck and back pain.
mediCAD 4.0	mediCAD Hectec Gmbh	09/07/2018	K170702	For use in spinal visualization and motion analysis for neck and back pain.
VirtuOst Vertebral Fracture Assessment	O.N. Diagnostics LLC.	08/03/2018	K171435	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.

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 INTERNALTIONAL	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.
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.
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	K152648	For use in spinal visualization and motion analysis for neck and back pain.

Rationale

This medical policy was created in 2006 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through August 4, 2023.

Medical policies assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Medical policies assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Dynamic Spinal Visualization

Clinical Context and Test Purpose

The purpose of dynamic spinal visualization is to determine whether the abnormal movement of the spine contributes to neck or back pain. This would inform clinical decision making about the appropriate intervention, either physical therapy or surgery.

The following PICO was used to select literature to inform policy.

Populations

The relevant population of interest is individuals with back or neck pain.

Interventions

The test being considered is dynamic spinal visualization.

Comparators

The following tests are currently being used to make decisions about managing abnormal movement contributing to back and neck pain: conventional radiography and magnetic resonance imaging (MRI).

Outcomes

The general outcomes of interest are test accuracy, symptoms, and functional outcomes. Specific outcomes of interest are whether dynamic spinal visualization leads to new findings and whether these findings improve health outcomes, including pain and function. Timing of short-term outcomes is after completion of physical therapy or surgery.

Study Selection Criteria

For the evaluation of the clinical utility of dynamic spinal visualization, studies would need to use the technology as either an adjunct or a replacement to current tests being used to make decisions about managing abnormal movement in patients with neck and back pain. Outcomes would be symptoms and functional outcomes.

In the absence of direct evidence for the clinical utility of dynamic spinal visualization, evidence for clinical validity is evaluated, in which we can make inferences on clinical utility. Below are selection criteria for studies to assess clinical validity:

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.

- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristics [ROC], area under ROC curve [AUROC], c-statistic, likelihood ratios) may be included but are less informative.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

As of the most recent literature update, the evidence on dynamic spinal visualization remains predominantly comparisons of spine kinetics in patients with neck or back pain to healthy controls.

Systematic Reviews

A systematic review by Xu et al. (2017) reviewed 13 studies on dynamic supine MRI for patients with cervical spondylotic myelopathy, although it appears that the studies evaluated flexion/extension images rather than continuous motion. (1)

Case-Control Studies

Teyhen et al. (2007) compared 20 patients with lower back pain to 20 healthy controls to provide construct validity for a clinical prediction rule that would identify patients likely to benefit from stabilization exercises, (2) while Ahmadi et al. (2009) used digital videofluoroscopy to compare 15 patients who had lower back pain with 15 controls to refine criteria for diagnosing lumbar segmental instability. (3)

Retrospective Studies

Walter et al. (2021) conducted a feasibility study in 21 patients to assess the diagnostic accuracy and sensitivity of 3 different dynamic MRI protocols for diagnosing spondylolisthesis in the cervical or lumbar spine, using flexion-extension radiographs as the reference standard. (4) The 3 dynamic MRI protocols examined were Half-Fourier acquisition single-shot turbo spin-echo imaging (HASTE), continuous real-time radial gradient-echo (GRE), and true fast imaging with steady state precession (True FISP). In this study, overall diagnostic accuracy was 92.9%, 90.5%, and 92.9% with HASTE, GRE, and True FISP, respectively. Overall sensitivity for detecting spondylolisthesis was 68.8%, 68.8%, and 78.6%, respectively.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No RCTs were identified that support the clinical utility of dynamic spinal visualization for this population.

The literature evaluating the clinical utility of dynamic spinal visualization techniques, including digital motion x-ray and cineradiography (videofluoroscopy) for the evaluation and assessment of the spine, is limited to a few studies involving small numbers of participants. (5-7) No evidence was identified to indicate that clinical use improves health outcomes.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of dynamic spinal visualization has not been established, a chain of evidence cannot be constructed.

Section Summary: Dynamic Spinal Visualization
The literature evaluating the clinical utility of dynamic spinal visualization techniques, including digital motion x-ray and cineradiography (videofluoroscopy) and dynamic MRI, for the evaluation and assessment of the spine, is limited to a few studies involving small numbers of participants. Most available studies have compared spine kinetics in patients who had neck or back pain with that in healthy controls. In a feasibility study of 21 patients examining dynamic MRI for the detection of spondylolisthesis, 3 dynamic MRI protocols demonstrated sensitivities of 68.8% to 78.6% when compared to standard flexion-extension radiographs. No evidence was identified to indicate that clinical use improves health outcomes such as symptoms or function.

Vertebral Motion Analysis
Clinical Context and Test Purpose
The purpose of vertebral motion analysis (VMA) is to determine whether the abnormal movement of the spine contributes to neck or back pain. This would inform clinical decision making about the appropriate intervention, either physical therapy or surgery. VMA might also be used to assess the success of fusion.

The following PICO was used to select literature relevant to the policy.

Populations
The relevant population of interest is individuals who are being evaluated for back or neck pain and are being considered for standard flexion/extension radiographs.

Interventions
The test being considered is VMA.

Comparators
The following tests are currently being used to make decisions about managing abnormal movement contributing to back and neck pain: conventional radiography and MRI.

Outcomes
The general outcomes of interest are test accuracy, symptoms, and functional outcomes. Specific outcomes of interest are whether vertebral motion analysis leads to new findings and whether these findings improve health outcomes, including pain and function. Timing of short-term outcomes is after completion of physical therapy or surgery.

Study Selection Criteria
For the evaluation of the clinical utility of VMA, studies would need to use the technology as either an adjunct or a replacement to current tests being used to make decisions about managing abnormal movement in patients with neck and back pain. Outcomes would be symptoms and functional outcomes.

In the absence of direct evidence for the clinical utility of VMA, evidence for clinical validity is evaluated, in which we can make inferences on clinical utility. Below are selection criteria for studies to assess clinical validity:

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristics [ROC], area under ROC curve [AUROC], c-statistic, likelihood ratios) may be included but are less informative.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Cheng et al. (2016) and Yeager et al. (2014) reported that VMA decreased variability in the measurement of lumbar spinal movement compared with a digitized manual technique. (8, 9) Diagnostic performance of VMA was reported by Davis et al. (2015) in a retrospective study of 509 symptomatic patients and 73 asymptomatic participants. (10) The comparator was rotational and translational movement from flexion/extension radiographs. The investigators considered instability in symptomatic patients to be true-positive and instability in asymptomatic participants as false-positive, leading to reported differences in diagnostic accuracy between standard flexion/extension radiographs and VMA. In the absence of a true reference standard, the interpretation of this study is limited.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No RCTs were identified that support the clinical utility of VMA in this population.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of VMA has not been established for this indication, a chain of evidence cannot be constructed.

Section Summary: Vertebral Motion Analysis (VMA)

Three studies with overlapping authors have been identified on VMA. These studies have reported that VMA reduces variability in the measurement of rotational and translational spine movement compared with standard flexion/extension radiographs. One study reported an improvement in diagnostic accuracy compared with flexion/extension radiographs, but the interpretation of this study is limited by the lack of a true reference standard.

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 (MRI) of the spine and neck. Most available studies compare spine kinetics in patients who had neck or back pain with that in healthy controls. In a feasibility study of 21 patients 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 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 that the technology results in an improvement in the net health outcomes.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in August 2023 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0743T, 76120, 76125, 76496, 76499
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
02/01/2024	Document updated with literature review. No change to coverage. No new references added.
12/01/2022	Reviewed. No changes.
11/01/2021	Document updated with literature review. Coverage unchanged. Added reference 4.
01/15/2021	Reviewed. No changes.
09/15/2020	Document updated with literature review. Coverage unchanged. No new references added.
1/15/2020	Reviewed. No changes.
03/01/2019	Document updated with literature review. The following changes were made to Coverage: 1) Removed examples of dynamic spinal visualization, 2) Added "Vertebral motion analysis is considered experimental, investigational and/or unproven." Added references 1 and 7-9. Title changed from: Dynamic Spinal Visualization.
07/15/2017	Document updated with literature review. Coverage unchanged.

02/15/2016	Reviewed. No changes.
05/15/2015	Document updated with literature review. Coverage unchanged.
11/15/2014	Reviewed. No changes.
10/15/2013	Document updated with literature review. Coverage unchanged.
03/01/2009	Revised/Updated Entire Document. This policy is no longer scheduled for routine literature review and update.
10/01/2006	New Medical Document