



Louisiana

Dynamic Spinal Visualization

Policy # 00197

Original Effective Date: 02/23/2006

Current Effective Date: 03/21/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers dynamic spinal visualization, including, but not limited to, digital motion x-ray of the spine, including digitization of spinal x-rays and computerized analysis of the back or spine, to be **investigational*** for all indications.

Based on review of available data, the Company considers cineradiography, also known as videofluoroscopy, when used to visualize movement of the back or spine, to be **investigational*** for all indications.

Background/Overview

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 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 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 1 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 (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.

FDA or Other Governmental Regulatory Approval **U.S. Food and Drug Administration (FDA)**

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In 2012, the KineGraph VMA^{TM‡} (Vertebral Motion Analyzer; Ortho Kinematics) was cleared for marketing by the U.S. FDA through the 510(k) process. The system includes a Motion Normalizer^{TM‡} for patient positioning, standard fluoroscopic imaging, and automated image recognition software. Processing of scans by Ortho Kinematics is charged separately. FDA product code: LLZ.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical performance (test-retest reliability or interrater reliability); (2) diagnostic accuracy (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) demonstration that the diagnostic information can be used to improve patient outcomes. In addition, subsequent use of a technology outside of the investigational setting may also be evaluated.

DYNAMIC SPINAL VISUALIZATION

Clinical Context and Test Purpose

The purpose of dynamic spinal visualization is to determine whether 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 question addressed in this evidence review is: Does use of dynamic spinal visualization provide additional information beyond that obtained with conventional imaging technology and does this additional information improve health outcomes?

The following PICOTS was used to select literature relevant to the review.

Patients

Individuals who are being evaluated for back or neck pain.

Interventions

The test is dynamic spinal visualization.

Comparators

The comparator is diagnosis without dynamic spinal visualization.

Outcomes

The outcomes of interest are whether dynamic spinal visualization leads to new findings, and whether these findings improve health outcomes, including pain and function.

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Timing

Short-term outcomes after physical therapy or surgery.

Setting

The outpatient setting.

Technical Performance

A feasibility study of dynamic MRI was reported in 2012. This study used a prototype of the NeuroSwing positioning device and evaluated cervical spine kinematics in 32 patients who had previously undergone anterior cervical discectomy and fusion (ACDF). The quality of images was considered to be adequate, although there were artifacts from the titanium implants used in ACDF.

Diagnostic Accuracy

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. For example, 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, while Ahmadi et al (2009) used digital videofluoroscopy to compare 15 patients with lower back pain to 15 controls to help define better criteria for diagnosing lumbar segmental instability.

Effect on Health Outcomes

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. No evidence was identified to indicate that clinical use improves health outcomes.

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 MRI of the spine and neck. 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 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.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Dynamic Spinal Visualization", 6.01.46, 3:2017.
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4. Ahmadi A, Maroufi N, Behtash H, et al. Kinematic analysis of dynamic lumbar motion in patients with lumbar segmental instability using digital videofluoroscopy. *Eur Spine J.* Nov 2009;18(11):1677-1685. PMID 19727854

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- Hino H, Abumi K, Kanayama M, et al. Dynamic motion analysis of normal and unstable cervical spines using cineradiography. An in vivo study. Spine (Phila Pa 1976). Jan 15 1999;24(2):163-168. PMID 9926388
- Takayanagi K, Takahashi K, Yamagata M, et al. Using cineradiography for continuous dynamic-motion analysis of the lumbar spine. Spine (Phila Pa 1976). Sep 1 2001;26(17):1858-1865. PMID 11568694
- Wong KW, Leong JC, Chan MK, et al. The flexion-extension profile of lumbar spine in 100 healthy volunteers. Spine (Phila Pa 1976). Aug 1 2004;29(15):1636-1641. PMID 15284509

Policy History

Original Effective Date: 02/23/2006

Current Effective Date: 03/21/2018

02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee review
02/23/2006	Quality Care Advisory Council approval
03/14/2007	Medical Director review
03/21/2007	Medical Policy Committee approval. Rationale updated. Title changed to Dynamic Spinal Visualization to match Blue Cross Blue Shield Association. No change to coverage eligibility.
03/05/2010	Medical Policy Committee approval
03/19/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/03/2016	Medical Policy Committee review
03/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2018	Medical Policy Committee review
03/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/02/2018	Coding update
Next Scheduled Review Date:	03/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)[®]†, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	76120, 76125, 76496, 76499
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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