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6.01.46	Dynamic Spinal Visualization and Vertebral Motion Analysis		
Original Policy Date:	March 30, 2015	Effective Date:	November 1, 2023
Section:	6.0 Radiology	Page:	Page 1 of 12

Policy Statement

- I. The use of dynamic spinal visualization is considered investigational.
- II. Vertebral motion analysis is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

The following CPT codes are specific for these techniques:

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

Cineradiography/videofluoroscopy 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.

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. In such circumstances, refer to the unlisted codes in the Codes table.

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.

Related Policies

• Positional Magnetic Resonance Imaging

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 FDA. FDA product code: LLZ.

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	4/8/2019	K183204	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
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 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
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	K142648	For use in spinal visualization and motion analysis for neck and back pain

Table 1. Spinal Visualization and Motion Analysis Devices Cleared by the U.S. Food and E)rug
Administration	

Rationale

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 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.

Literature Review

Evidence reviews 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. Evidence reviews 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. 6.01.46 Dynamic Spinal Visualization and Vertebral Motion Analysis Page 4 of 12

Dynamic Spinal Visualization

Clinical Context and Test Purpose

The purpose of dynamic spinal visualization in patients who have neck or back pain 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 question addressed in this evidence review is: Does the use of dynamic spinal visualization provide additional information beyond that obtained with conventional imaging technology and does this additional information improve the net health outcome?

The following PICO was used to select literature to inform this review.

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, with 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).

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Review of Evidence

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.

Review of Evidence

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.^{5,6,7,} 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.

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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 spine kinetics 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 in patients with neck or back pain 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. Vertebral motion analysis might also be used to assess the success of fusion.

The question addressed in this evidence review is: Does the use of vertebral motion analysis provide additional information beyond that obtained with conventional imaging technology and does this additional information improve the net health outcome?

The following PICO was used to select literature to inform this review.

Populations

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

Interventions

The test being considered is vertebral motion analysis.

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. The 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 vertebral motion analysis, 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 vertebral motion analysis, evidence for clinical validity is evaluated, with 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;

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• 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., ROC, 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).

Review of Evidence

Cheng et al (2016) and Yeager et al (2014) reported that vertebral motion analysis decreased variability in the measurement of lumbar spinal movement compared with a digitized manual technique.^{8,9,} Diagnostic performance of vertebral motion analysis 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 vertebral motion analysis. 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, more effective therapy, or avoid unnecessary therapy or testing.

Review of Evidence

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 vertebral motion analysis 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 vertebral motion analysis has not been established for this indication, a chain of evidence cannot be constructed.

Section Summary: Vertebral Motion Analysis

Three studies with overlapping authors have been identified on vertebral motion analysis. These studies have reported that vertebral motion analysis 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 MRI of the spine and neck. Most available studies compare spine kinetics in patients who had neck or back pain with spine kinetics in healthy controls. In a feasibility study of 21 patients examining dynamic MRI for the detection of spondylolithesis, 3 dynamic MRI protocols demonstrated

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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 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 outcome.

Supplemental Information

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

Practice Guidelines and Position Statements

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

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2022 did not identify any ongoing or unpublished trials that would likely influence this review.

References

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- Takayanagi K, Takahashi K, Yamagata M, et al. Using cineradiography for continuous dynamic-motion analysis of the lumbar spine. Spine (Phila Pa 1976). Sep 01 2001; 26(17): 1858-65. PMID 11568694
- 7. Wong KW, Leong JC, Chan MK, et al. The flexion-extension profile of lumbar spine in 100 healthy volunteers. Spine (Phila Pa 1976). Aug 01 2004; 29(15): 1636-41. PMID 15284509
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- Yeager MS, Cook DJ, Cheng BC. Reliability of computer-assisted lumbar intervertebral measurements using a novel vertebral motion analysis system. Spine J. Feb 01 2014; 14(2): 274-81. PMID 24239805
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Documentation for Clinical Review

• No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Туре	Code	Description	
	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	
CPT®	0743T	Bone strength and fracture risk using finite element analysis of	
		functional data and bone-mineral density, with concurrent vertebral	
		fracture assessment, utilizing data from a computed tomography scan,	
		retrieval and transmission of the scan data, measurement of bone	
		strength and bone mineral density and classification of any vertebral	
		fractures, with overall fracture risk assessment, interpretation, and	
		report <i>(Code effective 12/1/2022)</i>	
HCPCS	None		

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
03/30/2015	BCBSA Medical Policy adoption
12/30/2016	Policy revision without position change
05/07/2017	Policy revision without position change
06/01/2018	Policy revision without position change
11/01/2018	Policy title change from Dynamic Spinal Visualization
	Policy revision without position change
11/01/2019	Policy revision without position change
11/01/2020	Annual review. No change to policy statement. Literature review updated.
12/01/2021	Annual review. No change to policy statement. Literature review updated.
11/01/2022	Annual review. No change to policy statement. Literature review updated.
11/01/2023	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at <u>www.blueshieldca.com/provider</u>.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)		
BEFORE	AFTER	
Dynamic Spinal Visualization and Vertebral Motion Analysis 6.01.46	Dynamic Spinal Visualization and Vertebral Motion Analysis 6.01.46	
Policy Statement: I. The use of dynamic spinal visualization is considered investigational.	Policy Statement: I. The use of dynamic spinal visualization is considered investigational.	
II. Vertebral motion analysis is considered investigational.	II. Vertebral motion analysis is considered investigational.	