Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Spinal Manipulation Under Anesthesia

Description/Background

MANIPULATION UNDER ANESTHESIA

Manipulation is intended to break up fibrous and scar tissue to relieve pain and improve range of motion[1]. Anesthesia or sedation is used to reduce pain, spasm, and reflex muscle guarding that may interfere with the delivery of therapies and to allow the therapist to break up joint and soft tissue adhesions with less force than would be required to overcome patient resistance or apprehension. Manipulation under anesthesia is generally performed with an anesthesiologist in attendance. Manipulation under anesthesia is an accepted treatment for isolated joint conditions, such as arthrofibrosis of the knee and adhesive capsulitis. It is also used to reduce fractures (eg, vertebral, long bones) and dislocations.

Manipulation under anesthesia has been proposed as a treatment modality for acute and chronic pain conditions, particularly of the spine, when standard care, including manipulation, and other conservative measures have failed. Manipulation under anesthesia of the spine has been used in various forms since the 1930s. Complications from general anesthesia and forceful long-lever, high-amplitude nonspecific manipulation procedures led to decreased use of the procedure in favor of other therapies. Manipulation under anesthesia was modified and revived in the 1990s. This revival has been attributed to increased interest in spinal manipulative therapy and the advent of safer, shorter-acting anesthesia agents used for conscious sedation.

Manipulation Under Anesthesia Administration

Manipulation under anesthesia of the spine is described as follows: after sedation, a series of mobilization, stretching, and traction procedures to the spine and lower extremities are performed and may include passive stretching of the gluteal and hamstring muscles with

straight-leg raise, hip capsule stretching and mobilization, lumbosacral traction, and stretching of the lateral abdominal and paraspinal muscles.[1,] After the stretching and traction procedures, spinal manipulative therapy is delivered with high-velocity, short-amplitude thrust applied to a spinous process by hand, while the upper torso and lower extremities are stabilized. Spinal manipulative therapy may also be applied to the thoracolumbar or cervical area when necessary to address low back pain.

Manipulation under anesthesia takes 15 to 20 minutes, and after recovery from anesthesia, the patient is discharged with instructions to remain active and use heat or ice for short-term analgesic control. Some practitioners recommend performing the procedure on 3 or more consecutive days for best results. Care after manipulation under anesthesia may include 4 to 8 weeks of active rehabilitation with manual therapy, including spinal manipulative therapy and other modalities. Manipulation has also been performed after injection of local anesthetic into lumbar zygapophyseal (facet) and/or sacroiliac joints under fluoroscopic guidance (manipulation under joint anesthesia/analgesia) and after epidural injection of corticosteroid and local anesthetic (manipulation postepidural injection). Spinal manipulation under anesthesia has also been combined with other joint manipulation during multiple sessions. Together, these therapies may be referred to as medicine-assisted manipulation.

This review does not address manipulation under anesthesia for fractures, completely dislocated joints, adhesive capsulitis (eg, frozen shoulder), and/or fibrosis of a joint that may occur following total joint replacement.

Regulatory Status

Manipulative procedures are not subject to regulation by the U.S. Food and Drug Administration.

Medical Policy Statement

Spinal manipulation under anesthesia for the treatment of chronic spinal and low back pain is considered experimental/investigational. There is insufficient evidence to determine whether it improves health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

00640 22505

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Clinical Context and Therapy Purpose

The purpose of manipulation under anesthesia is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative management, in patients with chronic spinal, sacroiliac, or pelvic pain.

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

Populations

The relevant population of interest is individuals with chronic spinal, sacroiliac, or pelvic pain.

Interventions

The therapy being considered is manipulation under anesthesia.

Manipulation under anesthesia consists of a series of mobilization, stretching, and traction procedures performed while the patient is sedated (usually with general anesthesia or moderate sedation). Manipulation under anesthesia takes 15 to 20 minutes, and after recovery from anesthesia, the patient is discharged with instructions to remain active and use heat or ice for short-term analgesic control.

Comparators

Comparators of interest include conservative management.

Conservative management includes steroid regimens, blood pressure medication, muscle relaxers, and physical therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

The existing literature evaluating manipulation under anesthesia as a treatment for chronic spinal, sacroiliac, or pelvic pain has varying lengths of follow-up, ranging from 2 weeks to 6 months. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 6 months of follow-up is considered necessary to demonstrate efficacy.

Table 1 summarizes the patient-reported outcome measures described in this review.

Table 1. Patient Self-Administered Outcome Measure Tools

Name	Description	Scoring	MCID
Numeric Pain Scale[2]	Numbered scale by which patients rate their pain, similar to VAS	0-10 scale: • 10=excruciating pain • 0=no pain	Reduction of ≥2 points (≈30%) to be clinically important
Roland-Morris Disability Questionnaire[3]	24 questions that measure low back pain-related disability	"Yes" answers are totaled to determine disability (1-24) Score of ≥14 represents significant disability	Change of ≥4 points required for clinically applicable change to be measured accurately

Bournemouth Questionnaire[4]	7-question, multidimensional tool to assess outcome of care in a routine clinical setting Takes into account cognitive and affective aspects of pain Two versions: low back pain and nonspecific neck pain	Each question rated on a numeric rating scale from 0 to 10: • 0=much better • 5=no change • 10=much worse Scores are totaled, for minimum of 0 and maximum of 70	Percentage improvement of 47% in back pain and 34% neck pain
Patient's Global Impression of Change[4]	7-point scale of how a patient perceives the efficacy of treatment, a rating of overall improvement from baseline	Scale of 1 to 7: • 1=no change or condition is worse • 2=almost the same • 3=a little better, but no noticeable change • 4=somewhat better, but no real difference • 5=moderately better, slight noticeable change • 6=better, definite improvement with real difference • 7=a great deal better, considerable improvement	Clinically relevant improvement, response of ±6

MCID: minimal clinically important difference; VAS: visual analog scale.

Study Selection Criteria

Methodologically credible studies were selected using the following principles

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Dagenais et al (2008) conducted a comprehensive review of the history of manipulation under anesthesia or medicine-assisted manipulation and the published experimental literature.[5] They noted there was no research to confirm theories about a mechanism of action for these procedures and that the only RCT identified was published in 1971 when the techniques for spinal manipulation differed from those used presently. The possibility of serious complications related to manipulative force is also noted, including reported cases of cauda equina syndrome, paralysis, and vertebral fracture and dislocation; the authors state that such complications may be more likely with older techniques, but otherwise note that most reported studies do not describe safety outcomes.

Nonrandomized Comparative Studies

No high-quality RCTs have been identified. A comprehensive review of the literature by Digiorgi (2013)[6] described studies by Kohlbeck et al (2005)[7] and Palmieri and Smoyak (2002)[3] as being the best evidence available for medicine-assisted manipulation and manipulation under anesthesia of the spine.

Kohlbeck et al (2005) reported on a nonrandomized comparative study that included 68 patients with chronic low back pain.[7] All patients received an initial 4- to 6-week trial of spinal manipulation therapy, after which 42 patients received supplemental intervention with manipulation under anesthesia and 26 continued with spinal manipulative therapy. Low back pain and disability measures favored the manipulation under anesthesia group over the spinal manipulative therapy-only group at 3 months (adjusted mean difference on a 100-point scale, 4.4 points; 95% confidence interval [CI], -2.2 to 11.0). This difference attenuated at 1 year (adjusted mean difference, 0.3 points; 95% CI, -8.6 to 9.2). The relative odds of experiencing a 10-point improvement in pain and disability favored the manipulation under anesthesia group at 3 months (odds ratio [OR], 4.1; 95% CI, 1.3 to 13.6) and 1 year (OR, 1.9; 95% CI, 0.6 to 6.5).

Palmieri and Smoyak (2002) evaluated the efficacy of self-reported questionnaires to study manipulation under anesthesia in a convenience sample of 87 subjects from 2 ambulatory surgery centers and 2 chiropractic clinics.[3] Thirty-eight patients with low back pain received manipulation under anesthesia and 49 received traditional chiropractic treatment. A numeric rating scale for pain and the Roland-Morris Disability Questionnaire were administered at baseline, after the procedure, and 4 weeks later. Average pain scale scores in the manipulation under anesthesia group decreased by 50% and by 26% in the traditional treatment group; Roland-Morris Disability Questionnaire scores decreased by 51% and 38%, respectively. Although the authors concluded that the study supported the need for large-scale studies on manipulation under anesthesia and that the assessments were easily administered and dependable, no large-scale studies comparing manipulation under anesthesia with traditional chiropractic treatment have been identified.

Observational Studies

Peterson et al (2014) reported a prospective study of 30 patients with chronic pain (17 lower back, 13 neck) who underwent a single manipulation under anesthesia session with follow-up at 2 and 4 weeks.[8] The primary outcome measure was the Patient's Global Impression of Change. At 2 weeks, 52% of the patients reported clinically relevant improvement (better or

much better), with 45.5% improved at 4 weeks. There was a statistically significant reduction in numeric rating scale scores for pain at 4 weeks (p=.01), from a mean baseline score of 4.0 to 3.5 at 2 weeks post-manipulation under anesthesia. Bournemouth Questionnaire scores improved from 24.17 to 20.38 at 2 (p=.008) and to 19.45 at 4 weeks (p=.001). This study lacked a sham group to control for a potential placebo effect. Also, the clinical significance of improved numeric rating scale and Bournemouth Questionnaire scores is unclear, although Hurst and Bolton (2004) described the Bournemouth Questionnaire as a percentage improvement of 47% in back pain and 34% in neck pain.[4]

West et al (1999) reported on a series of 177 patients with pain arising from the cranial, cervical, thoracic, and lumbar spine, as well as the sacroiliac and pelvic regions who had failed conservative and surgical treatment.[9] Patients underwent 3 sequential manipulations with intravenous sedation followed by 4 to 6 weeks of spinal manipulation and therapeutic modalities; all had 6 months of follow-up. On average, visual analog scale ratings improved by 62% in patients with cervical pain and by 60% in patients with lumbar pain. Dougherty et al (2004) retrospectively reviewed outcomes of 20 cervical and 60 lumbar radiculopathy patients who underwent spinal manipulation after epidural injection.[10] After epidural injection of lidocaine (guided fluoroscopically or with computed tomography), methylprednisolone acetate flexion distraction mobilization and then high-velocity, low-amplitude spinal manipulation were delivered to the affected spinal regions. Outcome criteria were empirically defined as significant improvement, temporary improvement, or no change. Among lumbar spine patients, 22 (37%) noted significant improvement, 25 (42%) reported temporary improvement, and 13 (22%) no change. Among patients receiving a cervical epidural injection, 10 (50%) had significant improvement, 6 (30%) had temporary relief, and 4 (20%) had no change.

The only study on manipulation under joint anesthesia or analgesia evaluated 4 subjects; it was reported by Dreyfuss et al (1995).[11] Later, Michaelsen (2000) noted that joint-related manipulation under anesthesia should be viewed with “guarded optimism because its success is based solely on anecdotal experience.”[12]

Digiorgi (2018)[14] There is no published evidence to suggest that the modern Spinal Manipulation Under Anesthesia approach provides for better outcomes for disc herniation/protrusion versus the methods and protocols used by early osteopathic investigators. Within the more recent chiropractic literature there are only a few isolated retrospective case reports regarding the sedated variety of SMUA for disc herniation, protrusion/bulge, or degeneration. In the study conducted by Palmieri and Smoyak[3], some of the 38 chronic low back pain patients who received MUA may have had a lumbar disc condition. However, the various causes of pain, which included “disc syndrome”, were apparently obtained by demographic questionnaire. There is no account of investigator verification of the cause of back pain via clinical examination or imaging. Moreover, as the decreased pain and disability scores with MUA are not correlated with an identified cause of pain, the outcomes for the “disc syndrome” category of patients are not evident. Elsewhere, for the 42 chronic low back pain patients who received medication-assisted manipulation after MRI, the presence or absence of disc pathology is not reported in revealing the nature of the conditions under study.

Table 2. Summary of Characteristics of Key Observational Studies of Manipulation Under Anesthesia

Study	Study Type	Country	Dates	Participants	Treatment	Follow-Up
Peterson (2014)[8]	Prospective	Switzerland	NR	Patients (N=30) with chronic pain who underwent single MUA session	MUA for those with low back pain (N=17); MUA for those with neck pain (n=13)	2 and 4 weeks
West (1999)[9]	Case series	US	July 1995-Feb 1997	177 patients with pain arising from the cranial, cervical, thoracic, and lumbar spine, as well as the sacroiliac and pelvic regions who had failed conservative and surgical treatment	Patients underwent 3 sequential manipulations with intravenous sedation followed by 4 to 6 weeks of spinal manipulation and therapeutic modalities	6 months
Dougherty (2004)[10]	Retrospective	US	Nov 1996-Nov 2000	20 cervical and 60 lumbar radiculopathy patients who underwent spinal manipulation after epidural injection. The patients ranged in age from 21-76 years with an average age of 43 years. Forty-three % of the patients were female and 57% were male.	Following epidural injection of lidocaine (guided fluoroscopically or with computed tomography), methylprednisolone acetate flexion distraction mobilization and high-velocity, low-amplitude spinal manipulation were delivered to the affected spinal regions	1-year

MUA: manipulation under anesthesia; NR: not reported

Table 3. Summary of Results of Key Observational Studies of Manipulation under Anesthesia

Study	Improvement as Reported by Participant	Bournemouth Questionnaire Scores	Patient's Global Impression of Change
Peterson (2014)[8,]			
Baseline		24.17	
2-weeks post		20.38 (p=0.008)	
4-weeks post		19.45 (p=0.001)	
"better or much better" reported at 2 weeks post			52%
"better or much better" reported at 4 weeks post			45.5%
West (1999)[9,]			
% of cervical pts with improvement			62%
% of lumbar pts with improvement			60%
Dougherty (2004)[10,]			

Lumbar spine pts.			
% noting significant improvement	22 (37%)		
% noting temporary improvement	25 (42%)		
% noting no improvement	13 (22%)		
Pts. Receiving cervical epidural injection			
% noting significant improvement	10 (50%)		
% noting temporary improvement	6 (30%)		
% noting no improvement	4 (20%)		

SUMMARY OF EVIDENCE

For individuals who have chronic spinal, sacroiliac, or pelvic pain who receive manipulation under anesthesia, the evidence includes case series, observational studies, and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Scientific evidence on spinal manipulation under anesthesia, spinal manipulation with joint anesthesia, and spinal manipulation after epidural anesthesia and corticosteroid injection is very limited. No RCTs have been identified. Evidence on the efficacy of manipulation under anesthesia over several sessions or for multiple joints is also lacking. Safety outcomes in these settings are poorly described. 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.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, Blue Cross Blue Shield Association received input from 2 physician specialty societies and 4 academic medical centers while their policy was under review in 2009. Input from the 7 reviewers agreed that manipulation under anesthesia for chronic spinal and pelvic pain is investigational.

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.

American Association of Manipulation Under Anesthesia Providers
In 2014, the American Association of Manipulation Under Anesthesia Providers published consensus-based guidelines for the practice and performance of manipulation under anesthsia.[13] The guidelines included patient selection criteria (see below), establishing medical necessity, frequency and follow-up procedures, parameters for determining manipulation under anesthesia progress, general post-manipulation under anesthesia therapy, and safety. The guidelines recommended 3 consecutive days of treatment, based on the premise that serial procedures allow a gentler yet effective treatment plan with better control of biomechanical force. The guidelines also recommended follow-up therapy without anesthesia over 8 weeks after manipulation under anesthesia that includes all fibrosis release and manipulative procedures performed during the manipulation under anesthesia procedure to help prevent re-adhesion.

Patient selection criteria include, but are not limited to, the following:

- "The patient has undergone an adequate trial of appropriate care…and continues to experience intractable pain, interference to activities of daily living, and/or biomechanical dysfunction.
- "Sufficient care has been rendered prior to recommending manipulation under anesthesia. A sufficient time period is usually considered a minimum of 4-8 weeks, but exceptions may apply depending on the patient's individual needs….
- "Physical medicine procedures have been utilized in a clinical setting during the 6-8 week period prior to recommending manipulation under anesthesia.
- "Diagnosed conditions must fall within the recognized categories of conditions responsive to manipulation under anesthesia. The following disorders are classified as acceptable conditions for utilization of manipulation under anesthesia:
    1. "Patients for whom manipulation of the spine or other articulations is the treatment of choice; however, the patient's pain threshold inhibits the effectiveness of conservative manipulation.
    2. "Patients for whom manipulation of the spine or other articulations is the treatment of choice; however, due to the extent of the injury mechanism, conservative manipulation has been minimally effective…and a greater degree of movement of the affected joint(s) is needed to obtain patient progress.
    3. "Patients for whom manipulation of the spine or other articulations is the treatment of choice by the doctor; however due to the chronicity of the problem, and/or the fibrous tissue adhesions present, in-office manipulation has been incomplete and the plateau in the patient's improvement is unsatisfactory.
    4. "When the patient is considered for surgical intervention, manipulation under anesthesia is an alternative and/or an interim treatment and may be used as a therapeutic and/or diagnostic tool in the overall consideration of the patient's condition.
    5. "When there are no better treatment options available for the patient in the opinions of the treating doctor and patient."[13]

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
There were no ongoing or unpublished trials regarding this policy as of April 2024.

Government Regulations
National/Local:

There is no national or local coverage determination for manipulation under anesthesia.

The CMS 2024
Physician Fee Schedule has a fee for procedure code 22505.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Spinal Manipulation Services (Retired)

References

1. Kohlbeck FJ, Haldeman S. Medication-assisted spinal manipulation. Spine J. 2002; 2(4): 288-302. PMID 14589481
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13. Gordon R, Cremata E, Hawk C. Guidelines for the practice and performance of manipulation under anesthesia. Chiropr Man Therap. 2014; 22(1):7. PMID 24490957
14. DiGiorgi, D., Cerf, J.L. & Bowerman, D.S. Outcomes indicators and a risk classification system for spinal manipulation under anesthesia: a narrative review and proposal. *Chiropr Man Therap* **26**, 9 (2018). Assessed 4/8/24 https://doi.org/10.1186/s12998-018-0177-z

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/8/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/11	3/17/11	3/3/11	Joint policy established
9/1/15	6/16/15	7/16/15	Routine maintenance
9/1/16	6/21/16	6/21/16	Routine maintenance
9/1/17	6/20/17	6/20/17	Routine maintenance
9/1/18	6/19/18	6/19/18	Routine maintenance
9/1/19	6/18/19		Routine maintenance
9/1/20	6/16/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance
9/1/22	6/21/22		Routine maintenance
9/1/23	6/13/23		Routine maintenance (jf) Vendor Managed: Turning Point policy: OR1040 Manipulation Under Anesthesia. Discusses when this is appropriate; not medically necessary for the spine. (aligned) Ref: 1 and 13 added
9/1/24	6/11/24		Routine maintenance (jf) Vendor Managed: NA

Next Review Date: 2nd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SPINAL MANIPULATION UNDER ANESTHESIA

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not Covered
BCNA (Medicare Advantage)	See Government Regulations section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.