BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Manipulation under Anesthesia for Treatment of Chronic Spinal or Pelvic Pain

Policy #: 154
Category: Therapy

Latest Review Date: April 2019
Policy Grade: B

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

Manipulation under anesthesia (MUA) consists of a series of mobilization, stretching, and traction procedures performed while the patient receives anesthesia (usually general anesthesia or moderate sedation).

Manipulation is intended to break up fibrous and scar tissue to relieve pain and improve range of motion. 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. MUA is generally performed with an anesthesiologist in attendance. . MUA is an accepted treatment for isolated joint conditions, such as arthrofibrosis of the knee and adhesive capsulitis. It is also used to reduce fractures (e.g., vertebral, long bones) and dislocations.

MUA has been proposed as a treatment modality for acute and chronic pain conditions, particularly of the spinal region, when standard care, including manipulation, and other conservative measures have been unsuccessful. MUA 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 resulted in decreased use of the procedure in favor of other therapies. MUA was modified and revived in the 1990s. This revival is attributed to increased interest in spinal manipulative therapy and the advent of safer, shorter-acting anesthesia agents used for conscious sedation.

MUA of the spine is described as follows: after sedation is achieved, a series of mobilization, stretching, and traction procedures to the spine and lower extremities is 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. After the stretching and traction procedures, spinal manipulative therapy (SMT) is delivered with high-velocity; short-amplitude thrust applied to ta spinous process by hand, while the upper torso and lower extremities are stabilized. SMT may also be applied to the thoracolumbar or cervical area if considered necessary to address the low back pain.

The MUA 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 three or more consecutive days for best results. Care after MUA may include four to eight weeks of active rehabilitation with manual therapy, including SMT and other modalities. Manipulation has also been performed after injection of local anesthetic into lumbar zygapophyseal and/or sacroiliac joints under fluoroscopic guidance (manipulation under joint anesthesia/analgesia [MUJA]) and after epidural injection of corticosteroid and local anesthetic (manipulation post-epidural injection [MUES]}/spinal manipulation under anesthesia has also been combined with other joint manipulation during multiple sessions. Together, these may be referred to as medicine-assisted manipulation (MAM).

Policy:

Effective for dates of service on or after December 1, 2014:

Blue Advantage will treat **Spinal manipulation (**and manipulation of other joints, e.g., hip joint, performed during the procedure**) with the patient under anesthesia, spinal manipulation under joint anesthesia, and spinal manipulation after epidural anesthesia and corticosteroid injection** as a **non-covered** benefit and as **investigational for treatment of chronic spinal (cranial, cervical, thoracic, lumbar) pain and chronic sacroiliac and pelvic pain**.

Blue Advantage will treat **spinal manipulation under anesthesia involving serial treatment sessions** as a **non-covered benefit** and as **investigational**.

This policy does not address the use of spinal manipulation under anesthesia for the treatment of vertebral fracture or dislocation.

Please refer to policy #345 for the Manipulation of Other Joints under Anesthesia.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent update with literature review was performed using the MEDLINE database through February 18, 2019.

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 technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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 is preferred to

assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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.

Manipulation under Anesthesia

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 question addressed in this evidence review is: does manipulation under anesthesia improve the net health outcome in individuals with chronic spinal, sacroiliac, or pelvic pain?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are 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). MUA 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, and is managed by physical therapists and primary care providers in an outpatient clinical setting.

Outcomes

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

The most significant outcome of interest was improvement in quality of life, At 2 weeks, 52% of the patients reported clinically relevant improvement (better or much better), with 45.5% improved at 4 weeks. There was also a statistically significant reduction in numeric rating scale scores for pain at 4 weeks after the procedure.

Table 1. Outcomes of Interest for Individuals juvenile or adolescent idiopathic scoliosis at high risk of progression

Outcomes	Details
Change in Disease Status	The use of a standard brace showed significant improvement in spinal

	curvature and strength compared to observation alone
Quality of Life	The use of the standard brace requires wearing it for at least 12 hours a day which does limit motor function, however after the use of the brace motor function was reportedly increased

Timing
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 one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 6 months of follow-up is considered necessary to demonstrate efficacy.

Setting
Patients with chronic spinal, sacroiliac, or pelvic pain are actively managed by orthopedic surgeons and primary care providers in an outpatient clinical setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. b.In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. c.To assess longer 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.

Dagenais et al conducted a comprehensive review of the history of manipulation under anesthesia (MUA) or medicine-assisted manipulation and the published experimental literature. They noted that there was no research to confirm theories about a mechanism of action for these procedures and that the only randomized controlled trial identified was published in 1971 when the techniques for spinal manipulation differed from those used presently.

<u>Nonrandomized Comparative Studies</u>
No high quality randomized controlled trials have been identified. A 2013 comprehensive review of the literature describes studies by Kohlbeck et al. and Palmieri and Smoyak as being the best evidence available for MAM/MUA of the spine. Kohlbeck and colleagues carried out a prospective cohort study of 68 patients with chronic low back pain. All patients received an initial four to six week trial of spinal manipulation therapy (SMT), after which 42 patients received supplemental intervention with MUA and the remaining 26 patients continued with SMT. Low back pain and disability measures favored the MUA group over the SMT-only group at three months (adjusted mean difference of 4.4 points on a 100-point scale, 95% confidence interval [CI]: -2.2 to 11.0). This difference attenuated at one year (adjusted mean difference of 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 MUA group at three months (odds ratio [OR]: 4.1, 95% CI: 1.3-13.6) and at one year (OR: 1.9, 95% CI: 0.6-6.5).

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

Observational Studies

In 2014, Peterson et al reported a prospective study of 30 patients with chronic pain (17 low back and 13 neck) who underwent a single MUA session with follow-up at two and four weeks. The primary outcome measure was the Patient's Global Impression of Change (PGIC). At two weeks, 52% of the patients reported clinically relevant improvement (better or much better) with 45.5% improved at four weeks. There was a statistically significant reduction in numeric rating scale scores (NRS) at four weeks ($p=0.01$) from a mean score of 4.0 at one day before MUA to 3.5 at two weeks post-MUA. Bournemouth Questionnaire (BQ) scores improved from 24.17 to 20.38 at two ($p=0.008$) and 19.45 at four weeks ($p=0.001$). This study is limited by the lack of a sham group to control for a potential placebo effect. In addition, the clinical significance of the improvement in NRS and BQ scores is questioned.

In 1999, West et al 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. 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 retrospectively reviewed outcomes of 20 cervical and 60 lumbar radiculopathy patients who underwent spinal manipulation post-epidural injection. After epidural injection of lidocaine (guided fluoroscopically or with computed tomography), methylprednisolone acetate flexion distraction mobilization and then high-velocity, low-amplitude spinal manipulation was 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 cervical epidural injection, 10 (50%) had significant improvement, 6 (30%) had temporary relief, and 4 (20%) had no change.

The one study of manipulation under joint anesthesia/analgesia (MUJA) found in the literature search had only four subjects. Michaelsen noted in a paper published in 2000 that MUJA should be viewed with "guarded optimism because its success is based solely on anecdotal experience."

Summary of Evidence
For individuals who have chronic spinal, sacroiliac, or pelvic pain who receive MUA, the evidence includes case series and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Scientific evidence on spinal MUA, spinal manipulation with joint anesthesia, and spinal manipulation after epidural anesthesia and corticosteroid injection is very limited. No randomized controlled trials have been identified. Evidence on the efficacy of MUA over several sessions or for multiple joints is also lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
American Association of Manipulation Under Anesthesia Providers
The American Association of Manipulation Under Anesthesia Providers (2014) published consensus-based guidelines for the practice and performance of manipulation under anesthesia (MUA). The guidelines included patient selection criteria, establishing medical necessity, frequency and follow-up procedures, parameters for determining MUA progress, general post-MUA 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 MUA that includes all fibrosis release and manipulative procedures performed during the MUA procedure to help prevent re-adhesion.

American Academy of Osteopathy
The American Academy of Osteopathy (AAO) published a consensus statement in 2005 on osteopathic manipulation of somatic dysfunction under anesthesia and conscious sedation. The AAO states that manipulation under anesthesia may be appropriate in cases of restrictions and abnormalities of function that include recurrent muscle spasm, range-of-motion restrictions, persistent pain secondary to injury and/or repetitive motion trauma, and is in general limited to patients who have somatic dysfunction which:

1. Has failed to respond to conservative treatment in the office or hospital that has included the use of osteopathic manipulative therapy, physical therapy and medication; and/or
2. Is so severe that muscle relaxant medication, anti-inflammatory medication or analgesic medications are of little benefit; and/or
3. Results in biomechanical impairment which may be alleviated with use of the procedure.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force has not addressed MUA.

Key Words:
Spinal manipulation under anesthesia, SMUA, pelvic pain, MUA, MAM

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

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Coding:
CPT:

00640	Anesthesia for manipulation of the spine or for closed procedures on the cervical, thoracic or lumbar spine
22505	Manipulation of spine requiring anesthesia, any region

References:

1. American Academy of Osteopathy. Consensus statement for osteopathic manipulation of somatic dysfunction under anesthesia and conscious sedation. American Academy of Osteopathy Journal 2005; 15 (2); 26-27.
2. Aspegran DD, et al. Manipulation under epidural anesthesia with corticosteroid injection: Two case reports, Journal of Manipulative and Physiological Therapeutics, November 1997; 20(9): 618-621.
3. Ben-David B and Raboy M. Manipulation under anesthesia combined with epidural steroid injection, Journal of Manipulative and Physiological Therapeutics, November 1994; 17(9): 605-609.
4. Dagenais S, Mayer J, Wooley JR and Haldeman S. Evidence-informed management of chronic low back pain with medicine-assisted manipulation. Spine J, Jan-Feb 2008; 8(1): 142-149.
5. Digiorgi D. Spinal manipulation under anesthesia: a narrative review of the literature and commentary. Chiropr man Therap 2013; 21(1):14.
6. Dougherty P, Bajwa S, Burke J and Dishman JD. Spinal manipulation postepidural injection for lumbar and cervical radiculopathy: A retrospective case series. J Manipulative Physiol Ther, September 2004; 27(7): 449-456.
7. Dreyfuss P, et al. MUJA: Manipulation under joint anesthesia/analgesia: A treatment approach for recalcitrant low back pain of synovial joint origin. Journal of Manipulative and Physiological Therapeutics, October 1995; 18(8): 537-546.
8. Gordon RC. An evaluation of the experimental and investigational status and clinical validity of manipulation of patients under anesthesia: A contemporary opinion, Journal of Manipulative and Physiological Therapeutics, November 2001; 24(9): 603-611.
9. Gordon R, Cremata E, Hawk C. Guidelines for the practice and performance of manipulation under anesthesia. Chiropr Man Therap. 2014; 22 (1):7.
10. Haldeman S, Chapman-Smith D, and Petersen DM (eds). Guidelines for Chiropractic Quality Assurance and Practice Parameters: Proceedings of the Mercy Center Consensus Conference. January 25-30, 1992. Aspen Publishers, 1993.

11. Herzog J. Use of cervical spine manipulation under anesthesia for management of cervical dish herniation, cervical radiculopathy, and associated cervicogenic headache syndrome. Journal of Manipulative and Physiological Therapeutics, March 1999; 22(3): 166-170.
12. Kohlbech F and Haldeman S. Technical assessment: Medication assisted spinal manipulation. The Spine Journal, July/August 2002, Vol. 2, Issue 4.
13. Kohlbeck FJ, Haldeman S, et al. Supplemental care with medication-assisted manipulation versus spinal manipulation therapy alone for patients with chronic low back pain. J Manipulative Physiol Ther, May 2005; 28(4): 245-252.
14. Michaelsen MR. Manipulation under joint anesthesia/analgesia: A proposed interdisciplinary treatment approach for recalcitrant spinal axis pain of synovial joint origin. Journal of Manipulative and Physiological Therapeutics, February 2000; 23(2): 127-129.
15. National Academy of Manipulation under Anesthesia Physicians. Purpose statement and protocols and standards. 2002. Available online at: www.fcghealth.com/pages/mua_phys_corn_national_namua.htm.
16. National Academy of Manipulation under Anesthesia Physicians. Purpose statement and protocols and standards. 2012; //drcremata.com/research/62-american-association-of-manipulation-under-anesthesia-providers.
17. Palmieri NF and Smoyak S. Chronic low back pain: A study of the effects of manipulation under anesthesia. Journal of Manipulative and Physiological Therapeutics, October 2002; 25(8): E8-E17.
18. Peterson CK, Humphreys BK, Vollenweider R, et al. Outcomes for chronic neck and low back pain patients after manipulation under anesthesia: a prospective cohort study. J Manipulative Physiol Ther. Jul-Aug 2014; 37 (6):377-382.
19. West DT, et al. Effective management of spinal pain in one hundred seventy-seven patients evaluated for manipulation under anesthesia. Journal of Manipulative and Physiological Therapeutics, June 1999; 22(5): 299-308.

Policy History:

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Medical Policy Group, March 2006
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Medical Policy Group, August 2016
Medical Policy Group, September 2017
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Medical Policy Group, April 2019

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.