Manipulative Therapy (for Idaho Only)

Policy Number: CS076ID.B
Effective Date: August 1, 2025

➲ Instructions for Use

Table of Contents **Page**

Related Policies

- Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Idaho Only)
- Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (for Idaho Only)
- Home Traction Therapy (for Idaho Only)
- Manipulation Under Anesthesia (for Idaho Only)
- Motorized Spinal Traction (for Idaho Only)
- Treatment of Temporomandibular Joint Disorders (for Idaho Only)

Application

This Medical Policy only applies the state of Idaho, including Idaho Medicaid Plus plans.

Coverage Rationale

State-Specific Criteria

For medical necessity clinical coverage criteria for chiropractic Manipulative Therapy, refer to the Idaho Medicaid Provider Handbook, Chiropractor.

Non State-Specific Criteria

Osteopathic Manipulative Therapy

Osteopathic Manipulative Therapy is proven and medically necessary for treating Musculoskeletal Disorders, except as noted below.

Osteopathic Manipulative Therapy is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy. These include but are not limited to the following:

- Non-Musculoskeletal Disorders (e.g., asthma, otitis media, infantile colic, internal organ disorders, etc.)
- Prevention/maintenance/custodial care
- Craniosacral therapy (cranial manipulation/Upledger Technique)
- Temporomandibular joint (TMJ) disorder
- Scoliosis
- Manipulative services that utilize nonstandard techniques [e.g., applied kinesiology, including the neural organizational technique and the National Upper Cervical Chiropractic Association (NUCCA) process]

This policy does not address manipulation under anesthesia; refer to the Medical Policy titled Manipulation Under Anesthesia (for Idaho Only).

Definitions

Manipulative Therapy: Manipulative Therapy, osteopathic manipulative treatment (OMT), osteopathic manipulative medicine (OMM), manipulative and body-based practice, manual therapy, or physical touch methods is defined as a therapeutic application of manual pressure or force in which the practitioner moves or manipulates one or more parts of the patient's body to achieve and maintain patient health as part of a whole system of evaluation and treatment. Manipulative Therapy can be used to treat structural and functional issues in the bones, joints, tissues, and muscles of the body. Examples include chiropractic treatments, physical therapy, and massage therapy (AACOM, 2023; NCI, 2022).

Musculoskeletal Disorders: For the purposes of this policy, Musculoskeletal Disorders (MSDs) are injuries or conditions originating from joints, muscles, ligaments, discs, or other soft tissues in the spine or limbs, and produce clinically relevant symptoms (e.g., pain, numbness, etc.) and functional limitations (e.g., ability to perform daily activities) (El-Tallawy et al., 2021).

Upledger Technique: A complementary, light-touch, whole-body treatment technique developed by John E. Upledger, DO, OMM, that works with the body's craniosacral system to support and nourish the central nervous system which helps to alleviate the aches, pains, and strains of life to improve coping mechanisms and allow for better management of stress and improve the body's ability to self-care (Upledger, 1978).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: Refer to the Medical Policy titled Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech (for Idaho Only) for information regarding CPT code 97140 [manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes].

CPT Code	Description
98925	Osteopathic manipulative treatment (OMT); 1-2 body regions involved
98926	Osteopathic manipulative treatment (OMT); 3-4 body regions involved
98927	Osteopathic manipulative treatment (OMT); 5-6 body regions involved
98928	Osteopathic manipulative treatment (OMT); 7-8 body regions involved
98929	Osteopathic manipulative treatment (OMT); 9-10 body regions involved
98940	Chiropractic manipulative treatment (CMT); spinal, 1-2 regions
98941	Chiropractic manipulative treatment (CMT); spinal, 3-4 regions
98942	Chiropractic manipulative treatment (CMT); spinal, 5 regions
98943	Chiropractic manipulative treatment (CMT); extraspinal, 1 or more regions

CPT® is a registered trademark of the American Medical Association

HCPCS Code	Description
S8990	Physical or manipulative therapy performed for maintenance rather than restoration

Description of Services

Manipulative Treatment, also called Osteopathic Manipulative Treatment (OMT), is a treatment typically used by a Doctor of Osteopathic Medicine to diagnose, treat, and prevent illnesses and injuries. Practitioners move patients' muscles and joints using stretching, gentle pressure, and resistance. This treatment can be used alone or as a complement to, or replacement for, drugs and/or surgery (AOA). Manipulative treatment may be a primary method of treatment for some medical conditions, and for others it may complement or support medical treatment.

Craniosacral therapy (CST) is a noninvasive osteopathic technique that involves touch to detect pulsations and rhythms of flow of cerebrospinal fluid (CSF). The therapist then gently works with the skull and spine, with the goal to effect release of

potential restrictions to the flow of CSF, without the use of forceful physical manipulation (Hayes, 2018). It is alleged as a treatment for a variety of conditions, such as multiple sclerosis, asthma, pelvic pain, fibromyalgia, and tension-type and migraine headaches.

A variety of non-standard Manipulative Therapy techniques exist such as applied kinesiology, which includes the neural organizational technique that claims to organize the central nervous system, and the National Upper Cervical Chiropractic Association (NUCCA) technique that specifically aligns the head and neck to improve spinal stability and balanced mobility.

Clinical Evidence

Musculoskeletal

Back

Bagagiolo et al. (2022) performed an overview of systematic reviews (SRs) and meta-analyses (MAs) to summarize the available clinical evidence on the efficacy and safety of osteopathic manipulative treatment (OMT) for various conditions. The literature search revealed nine SRs or MAs conducted between 2013 and 2020, with 55 primary trials involving 3,740 participants. The SRs reported a wide range of conditions including acute and chronic non-specific low back pain (NSLBP, four SRs), chronic non-specific neck pain (CNSNP, one SR), chronic non-cancer pain (CNCP, one SR), pediatric (one SR), neurological (primary headache, one SR) and irritable bowel syndrome (IBS, one SR). Although with a different effect size and quality of evidence, MAs reported that OMT is more effective than comparators in reducing pain and improving functional status in acute/chronic NSLBP, CNSNP and CNCP. No adverse events were reported in most SRs. According to AMSTAR-2, the methodological quality of the included SRs was rated low or critically low. The authors concluded that based on the currently available SRs and MAs, promising evidence suggests the possible effectiveness of OMT for musculoskeletal disorders. Limited and inconclusive evidence occurs for pediatric conditions, primary headache and IBS. Due to small sample size, presence of conflicting results and high heterogeneity and questionable evidence existed on OMT efficacy for pediatric conditions, primary headache and IBS. The available evidence is limited with overall poor-quality methodology and design, and diversity in reporting outcome measures. Therefore, no conclusions can be made regarding the relative efficacy, effectiveness or safety of treatment. [Authors Posadzki et al. (2013), Müller et al. (2014), and Franke et al. (2014; 2017), which were previously cited in this policy, are included in this systematic and meta-analysis review].

Santos et al. (2022) conducted a systematic review and meta-analysis to determine whether or not manual therapy (MT) causes postural changes. In March 2022, the authors performed a search in the PUBMED, CINAHL, Embase, PEDro, and Cochrane Central databases that yielded 6,627 articles, of which 38 including 1,597 participants were eligible; of these, 35 could be grouped into 12 meta-analyses. The risk of bias was assessed using the PEDro scale and the certainty in the scientific evidence rated through the GRADE system. The clinical trials included in this review used different doses of MT sessions, ranging from one to 18 sessions. When compared to no intervention or sham, in the short and medium term, MT reduced the forward head posture (14 studies, 584 individuals, 95% CI 0.38, 1.06), reduced thoracic kyphosis (5 studies, 217 individuals, 95% CI 0.37, 0.94), improved lateral pelvic tilt (5 studies, 211 individuals, 95% CI 0.11, 0.67) and pelvic torsion (2 studies, 120 individuals, 95% CI 0.44, 1.19) and increased plantar area (3 studies, 134 individuals, 95% CI 0.04, 0.74). With moderate certainty, there was no significant effect on shoulder protrusion (5 studies, 176 individuals, 95% CI -0.11, 0.61), shoulder alignment in the frontal plane (3 studies, 160 individuals, 95% CI -0.15, 0.52), scoliosis (2 studies, 26 individuals, 95% CI -1.57, 2.19), and pelvic anteversion (5 studies, 233 individuals, 95% CI -0.02, 0.51). With low certainty, MT had no effect on scapular upward rotation (2 studies, 74 individuals, 95% CI -0.76, 2.17). With low to very low certainty, it is possible to conclude that MT was not superior to other interventions in the short or medium term regarding the improvement of forward head posture (5 studies, 170 individuals, 95% CI -1.39, 0.67) and shoulder protrusion (3 studies, 94 individuals, 95% CI -4.04, 0.97). The authors concluded MT can be recommended to improve forward head posture, thoracic kyphosis and pelvic alignment in the short and medium term, but not shoulder posture and scoliosis. MT reduces the height of the plantar arch. Further research is needed to determine the clinical relevance of these findings.

In a randomized, sham-controlled group trial, Nguyen et al. (2021) compared the efficacy of standard osteopathic manipulative treatment (OMT) versus sham OMT for reducing low back pain (LBP) in individuals with nonspecific subacute and chronic LBP. 394 participants were randomized into two groups with a primary end point of reducing LBP which was measured with the Quebec Back Pain Disability Index (QBPDI). The experimental group received standard OMT; the sham control group received a priori inert procedure which consisted of light touch which stimulated OMT without stimulating physiotherapy or massage. Both groups received therapy for six sessions, two weeks apart. The mean QBPDI score for the standard OMT group was 31.5 at baseline and 25.3 at three months; and in the sham OMT group the mean score was 27.2 at baseline and 26.1 at three months. At twelve months, both groups experienced a decrease in

pain, however, the standard OMT group reported increased pain relief. The authors concluded OMT had a slightly better clinical effect than the sham for participants with LBP. Limitations included a focus on standard OMT only and large loss to follow-up.

In a randomized clinical trial, Schulz et al. (2019) assessed the comparative effectiveness of adding spinal manipulative therapy (SMT) or supervised rehabilitative exercise to home exercise in adults 65 or older with sub-acute or chronic low back pain (LBP). 550 individuals were evaluated with 241 participants recruited and randomized. All participants received 12 weeks of care in one of three treatment groups: 1) Home Exercise Program (HEP); 2) Supervised Exercise (SEP)+HEP; or 3) Spinal Manipulative Therapy (SMT)+HEP. The HEP and SEP programs were delivered by nine exercise therapists and two chiropractors, and the SMT was delivered by 11 licensed chiropractors. Outcomes were measured by patient self-report questionnaires, blinded objective assessment, and in-person and telephone interviews. Patient self-report questionnaires were collected at baseline, and 4, 12, 26, and 52 weeks post-randomization. The authors concluded adding spinal manipulation or supervised rehabilitative exercise to home exercise alone does not appear to improve pain or disability outcomes in either the short- or long-term in older adults with chronic LBP but did enhance satisfaction with care. While the trial had several strengths including adequate sample size and rigorous design, the limitations included blinding participants and providers, absence of measuring outcomes specific to the age of participants and unable to control contextual effects which may explain differences in patient satisfaction.

Rubinstein et al. (2019) conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) to assess the benefits and harms of spinal manipulative therapy (SMT) for the treatment of chronic low back pain. Two reviewers independently selected studies, extracted data, and assessed risk of bias and quality of the evidence. The effect of SMT was compared with recommended therapies, non-recommended therapies, sham (placebo) SMT, and SMT as an adjuvant therapy. Main outcomes were pain and back specific functional status, examined as mean differences and standardized mean differences (SMD), respectively. Outcomes were examined at one, six, and 12 months. Forty-seven RCTs including a total of 9,211 participants were identified, who were on average middle aged (35-60 years). Most trials compared SMT with recommended therapies. Moderate quality evidence suggested that SMT has similar effects to other recommended therapies for short term pain relief (mean difference -3.17, 95% confidence interval -7.85 to 1.51) and a small, clinically better improvement in function (SMD -0.25, 95% confidence interval -0.41 to -0.09). High quality evidence suggested that compared with non-recommended therapies SMT results in small, not clinically better effects for short term pain relief (mean difference -7.48, -11.50 to -3.47) and small to moderate clinically better improvement in function (SMD -0.41, -0.67 to -0.15). In general, these results were similar for the intermediate and long-term outcomes as were the effects of SMT as an adjuvant therapy. Evidence for sham SMT was low to very low quality; therefore these effects should be considered uncertain. Statistical heterogeneity could not be explained. About half of the studies examined adverse and serious adverse events, but in most of these it was unclear how and whether these events were registered systematically. Most of the observed adverse events were musculoskeletal related, transient in nature, and of mild to moderate severity. One study with a low risk of selection bias and powered to examine risk (n = 183) found no increased risk of an adverse event (relative risk 1.24, 95% confidence interval 0.85 to 1.81) or duration of the event (1.13, 0.59 to 2.18) compared with sham SMT. In one study, the Data Safety Monitoring Board judged one serious adverse event to be possibly related to SMT. The authors concluded that SMT produces similar effects to recommended therapies for chronic low back pain, whereas SMT seems to be better than non-recommended interventions for improvement in function in the short term. Clinicians should inform their patients of the potential risks of adverse events associated with SMT. The study is limited due to a heterogeneous patient population, and risk of bias. Well designed, adequately powered, prospective, controlled clinical trials of SMT are needed to further describe safety and clinical efficacy. [Authors Ulger et al. (2017) which were previously cited in this policy, are included in this systematic and meta-analysis review].

A comparative effectiveness report was published under the auspices of the Agency for Healthcare Research and Quality (AHRQ), which assessed the durable effects on pain and function with different noninvasive nonpharmacological treatments for selected chronic pain conditions (Skelly et al., 2018). The authors found low quality evidence supporting the effectiveness of spinal manipulation for improving pain and function up to 12 months post-intervention in treating chronic low back pain. No serious adverse events or withdrawals due to adverse events were reported. Non-serious adverse events with manipulation (primarily increased pain) were reported in three trials. An updated and final surveillance report (2022) revealed no change in conclusions.

Coulter et al. (2018) conducted a systematic literature review and meta-analysis to determine the efficacy, effectiveness, and safety of various mobilization and manipulation therapies for treatment of chronic low back pain. A total of 64 publications were included in this systematic review. The studies measured self-reported pain, function, health-related quality of life, and adverse events; the most common tool for pain evaluation of measurement was the VAS (26 of 51) and the numeric pain rating scale (12 of 51). The authors concluded a small to moderate effect on pain in favor of manipulation, which increased over time at three and six months follow-up for reducing pain compared with other active comparators (exercise and physical therapy).

Ulger et al. (2017) conducted a randomized controlled trial to determine the effects of spinal stabilization exercises (SSE) and manual therapy methods on pain, function, and quality of life (QoL) levels in individuals with chronic low back pain (CLBP). A total of 113 participants diagnosed as CLBP were enrolled to the study and allocated into Spinal Stabilization group (SG) and manual therapy group (MG), randomly. While SSE performed in SG, soft tissue mobilizations, muscle-energy techniques, joint mobilizations, and manipulations were performed in MG. While the severity of pain was assessed with Visual Analog Scale (VAS), Oswestry Disability Index (ODI) and Short Form 36 (SF-36) assessments were performed to evaluate the functional status and QoL, respectively. All assessments were repeated before and after the treatment. The outcomes of this study showed that SSE and manual therapy methods have the same effects on QoL, while the manual treatment is more effective on the pain and functional parameters. Additional randomized controlled trials with longer term outcomes are needed to evaluate manual therapies in the treatment of CLBP.

In a systematic review and meta-analysis, Paige et al. (2017) evaluated the effectiveness of spinal manipulative therapy (SMT) for acute (≤ six weeks) low back pain. Study quality was assessed using the Cochrane Back and Neck (CBN) Risk of Bias tool. Pain (measured by either the 100 mm visual analog scale, 11 point numeric rating scale, or other numeric pain scale), function [measured by the 24-point Roland Morris Disability Questionnaire or ODI (range, 0-100)], or any harms measured within six weeks. Of 26 eligible RCTs identified, 15 RCTs (1,699 participants) provided moderate-quality evidence that SMT has a statistically significant association with improvements in pain [pooled mean improvement in the 100 mm visual analog pain scale, −9.95 (95% CI, −15.6 to −4.3)]. According to the authors, among patients with acute low back pain, spinal manipulative therapy was associated with modest improvements in pain and function at up to six weeks, with transient minor musculoskeletal harms. However, heterogeneity in study results was large. Other limitations of this study are that the type of manipulation, study quality, or whether SMT was given alone or as part of a package of therapies was not disclosed.

Franke et al. (2017) conducted a systematic review and meta-analysis on the effectiveness of OMT for low back pain and pelvic girdle pain during and after pregnancy. Of 102 studies, five examined OMT for LBP during pregnancy and three for postpartum. The authors found moderate-quality evidence suggesting OMT had a significant medium-sized effect on decreasing pain (MD, -16.65) and increasing functional status (SMD, -0.50) in pregnant women with LBP; low-quality evidence suggested OMT had a significant moderate-sized effect on decreasing pain (MD, -38.00) and increasing functional status (SMD, -2.12) in postpartum women with LBP. While there is growing evidence that OMT may be beneficial for treatment of pregnancy related or postpartum LBP, the author's findings included small sample sizes, mixed studies of different designs, duplicate data, lack of long-term follow-up and both OMT and non-osteopathic manual therapies utilized so the conclusions should be reviewed with caution. Further research may change estimates of effect, and larger, high-quality RCTs with robust comparison groups are recommended.

A comparative effectiveness report was published under the auspices of the Agency for Healthcare Research and Quality (AHRQ), which updated the 2007 meta-analysis (Chou et al., 2016). The authors qualitatively examined whether the results of new studies were consistent with pooled or qualitative findings from prior systematic reviews. For acute low back pain, there was limited evidence that spinal manipulation is associated with some beneficial effects versus a sham therapy, no intervention, or usual care. The beneficial effects of manipulative therapy were small to moderate in magnitude for the treatment of chronic low back pain. The assessment and reporting of harms for non-pharmacological therapies including spinal manipulation were suboptimal but indicated no serious harms. Reported harms were generally related to superficial symptoms at the application site or a temporary increase in pain.

Scoliosis

The available evidence for manual therapy including, but not limited to, the CLEAR (Chiropractic Leadership, Educational Advancement, and Research) scoliosis treatment protocol, and spinal manipulation for the treatment of adolescent and adult idiopathic scoliosis is insufficient to consider the procedure proven to be safe and effective.

Wenxia et al. (2024) conducted a randomized controlled trial (RCT) to investigate the impact of combined physiotherapeutic scoliosis-specific exercises (PSSE) and manual therapy (MT) on trunk deformity, spinal function, mobility, and mental health in patients with adolescent idiopathic scoliosis (AIS). Thirty-one participants who were diagnosed with AIS whose Cobb angle was between 10–45°were enrolled in the study. Participants in the intervention group received 50 min of PSSE combined with 10 min of MT, while the control group performed 50 min of PSSE as their home exercise program. Both treatments were implemented three times a week for four weeks. Cobb angle, spinal mobility, trunk morphology (vertebral rotation angle, apical deviation, pelvic obliquity distance and angle), movement capability, and quality of life (QOL) were assessed at baseline and post intervention. The treatment effects between the intervention and control groups were analyzed using a two-way repeated measures ANOVA. Following a four-week treatment period, Cobb angle was reduced from 21.58° to 18.58° in intervention group and increased from 18.00° at baseline and 19.14° post intervention in the control group. Improvements were also observed in spinal mobility, movement capability, quality of life, and some of the trunk morphology indices in the intervention group compared to baseline

($p < 0.05$). Improvements were higher in the intervention group than the control group. The authors concluded that combining PSSE and MT shows potential benefits in alleviating AIS symptoms and improving QOL. Further studies to substantiate these findings are warranted. The results of the present study should be interpreted with cautions due to the limitations. The absence of a control group, comprising either a general exercise group or individual PSSE and MT training groups, limits the direct comparisons which hinder the interpretation on the specific impact of each intervention. Larger clinical trials are recommended to substantiate the findings of this study and to further explore the long-term benefits of the combined approach.

Théroux et al. (2017) conducted a systematic review of four studies which met the inclusion criteria of prospective trials evaluating spinal manipulative therapy (e.g., chiropractic, osteopathic, physical therapy) for adolescent idiopathic scoliosis. The findings of the included studies indicated that spinal manipulative therapy might be effective for preventing curve progression or reducing Cobb angle. However, the lack of controls and small sample sizes precluded robust estimation of the interventions' effect sizes. The authors concluded that there is currently insufficient evidence to establish whether spinal manipulative therapy may be beneficial for adolescent idiopathic scoliosis. The results of the included studies suggest that spinal manipulative therapy may be a promising treatment, but these studies were all at substantial risk of bias. Further high-quality studies are warranted to conclusively determine if spinal manipulative therapy may be effective in the management of adolescent idiopathic scoliosis.

In a systematic review to evaluate the current body of literature on chiropractic treatment of IS, Morningstar et al. (2017) identified 15 case reports, 10 case series, one prospective cohort, and one RCT. Of the 27 studies, only two described their outcomes as recommended in a 2014 SOSORT and the SRS Non-Operative Management Committee consensus paper. The consensus paper details the format and types of outcomes they collectively believe are the most important and relevant to the patient. Among the chiropractic studies located in this review, two described outcomes consistent with how SOSORT recommends they be reported. Given that these consensus papers form the basis for nonoperative treatment recommendations and outcome reporting, future chiropractic studies should seek to report their outcomes as recommended by these papers. This may allow for better interprofessional collaboration and methodologic comparison.

Additional systematic reviews reported on manual therapy for the treatment of idiopathic scoliosis (Everett and Patel, 2007; Romano and Negrini, 2008; Gleberzon et al., 2012; Posadzki et al., 2013). All the reviews arrived at similar conclusions; there is a lack of evidence, which does not permit conclusions on the efficacy of manual therapy including spinal manipulation for the treatment of adolescent and adult idiopathic scoliosis.

Neck

In a 2023 systematic review and meta-analysis of randomized controlled trials, Liu et al., sought to determine the effectiveness of manipulative therapy for chronic neck pain. Seventeen articles comprised of 1,190 participants with patients with chronic neck pain for more than three months in which manipulative therapy was the primary treatment were included. The results showed for overall effects of pain intensity, manipulative therapy resulted in significantly decreased pain intensity and disability when compared to exercise and control groups with no significant differences in adverse events reported. The authors concluded that despite high heterogeneity in treatment outcomes, manipulative therapy is effective in relieving chronic neck pain and disability. Future research should include the impact of patient selection and type of treatment on the heterogeneity of the treatment effects.

Dal Farra et al. (2022) conducted a systematic review and meta-analysis to evaluate whether osteopathic manipulative interventions can reduce pain levels and enhance the functional status in patients with non-specific neck pain (NS-NP). Five articles were included in the review, and none of these was completely judged at low risk of bias (RoB). Four of these were included in the meta-analysis. Osteopathic interventions compared to no intervention/sham treatment showed statistically noteworthy results for pain levels [ES = -1.57 (-2.50, -0.65); p = 0.0008] and functional status [ES = -1.71 (-3.12, -0.31); p = 0.02]. The quality of evidence was "very low" for all the assessed outcomes. Other results were presented in a qualitative synthesis. The authors concluded that osteopathic interventions could be effective for pain levels and functional status improvements in adults with NS-NP. However, these findings are affected by a very low quality of evidence. Further research with randomized controlled trials is needed to validate these findings. [Authors Haller et al. (2016), and Groisman et al. (2020), which were previously cited in this policy, are included in this systematic and meta-analysis review].

In a randomized control trial, Groisman et al. (2020) assessed the effectiveness of OMT combined with stretching and strengthening exercises in the cervical region on patients with non-specific chronic neck pain. This single-blinded trial randomized 90 participants into two groups: either an exercise only group or an exercise group combined with OMT. The study included weekly exercise and/or OMT for four weeks. The primary outcomes were pain and disability which were evaluated by the Numeric Pain Rate Scale (NPRS) and Neck Disability Index (NDI). Secondary outcomes included Pressure Pain Threshold (PPT), range of motion, Fear-Avoidance Beliefs Questionnaire (FABQ), and pain self-efficacy.

The authors found the group that had received exercise combined with OMT had greater reductions in pain and disability than the group that received exercise only; this was evidenced by the lower NPRS and NDI scores. There were no significant differences in the secondary outcomes. Limitations included lack of long-term effects, difficulty in blinding patients with osteopaths and those that received OMT had increased contact with osteopaths leading to potential placebo effect.

Leaver et al. (2010) conducted a randomized controlled trial comparing manipulation with mobilization for recent onset of neck pain in 182 participants. Participants were randomly assigned to receive four treatments of either neck manipulation (n = 91) or mobilization (n = 91) over two weeks. Outcomes were measured by the number of days taken to recover from the episode of neck pain. Median days to recovery were 47 for the manipulation group and 43 days for the mobilization group. The authors concluded that manipulation was no more effective than mobilization in treating recent onset of neck pain. A potential limitation of this study was the inability to blind practitioners or participants to treatment allocation.

Extremity Disorders

Shoulder

In a randomized control trial, Iqbal et al. (2020) compared the effects of the Spencer muscle energy technique (SMET) and passive stretching on 60 participants with idiopathic frozen shoulder or a stiff painful shoulder joint for at least three months. The participants were randomized into two equal groups. Group 1 contained participants that were treated with a hot pack for seven to 10 minutes and then received the SMET; this was repeated three to five times with rest intervals over three sessions/week on alternate days for four weeks. Group 2 contained participants that were treated with a hot pack for seven to 10 minutes and then received specific passive stretching exercises. The shoulder was stretched and rotated for 20 seconds with a ten second rest interval and then repeated ten times over the course of three sessions per week every other day. Shoulder pain was assessed with the numeric pain rating scale (NPRS) which assessed eleven items ranging from zero (no pain) to 10 (worst pain). The authors found that SMET was more effective than passive stretching for decreasing pain shoulder pain and increasing ROM. Limitations included short duration of the study and the lack of appropriate registration with trail registry. It was concluded that future additional long-term RCTs are needed along with long-term follow ups.

Schwerla and colleagues (2020) evaluated the effectiveness of osteopathic treatments in 70 participants suffering from shoulder pain. Participants were randomized into either the intervention group that received osteopathic treatment or a control group (which remained untreated for eight weeks but later treated with osteopathic treatment upon conclusion of the study). The main outcome was shoulder pain, and this was assessed using the standard VAS for self-pain measurement. Secondary outcomes were specific shoulder pain and disability determined by the should pain and disability index (SPADI) and quality of life assessed by a SF-36 generic questionnaire. Participants in the intervention group received five osteopathic examinations and treatments of 40-60 minutes each delivered every two weeks for eight weeks. Before each visit and two weeks after the last visit, the VAS and SPADI were completed. The SF-36 generic questionnaire was completed at four and 10 weeks. The control group was required to fill out the VAS, SPADI and generic questionnaire at their baseline visit and then told they would be placed on the waiting list for osteopathic treatment to be scheduled eight weeks later. In both groups, on demand pain mediation was allowed. In the control group, 21 participants had no change in their pain and only eight participants showed improvement; in comparison the intervention group had a decrease in pain frequency for 33 participants. Secondary outcome measures had similar findings between the two groups; improvement in quality of life was seen for the intervention group but not the control group. The authors concluded osteopathic treatments over a defined period might be beneficial for patients suffering from shoulder pain, but further studies are needed to validate this finding. Limitations included the control group itself (receiving no treatment until after the study), small sample size and lack of long-term data.

In a systematic review, Steuri et al. (2017) investigated the effectiveness of conservative interventions for pain, function, and range of motion in adults with shoulder impingement syndrome (SIS). For pain, exercise was superior to non-exercise control interventions, but when manual therapy was combined with exercise, it was superior to just exercise alone. Limitations included a broad clinical diversity, lack of control groups, varying length of follow-up, heterogeneity, and trials with high risk of bias. Even though the authors found the quality of evidence was low, exercise should be considered for patients with shoulder impingement symptoms; manual therapy may be added as well.

In an updated Cochrane review on the effectiveness of manual therapy and exercise for rotator cuff disease compared to placebo, no intervention, or other therapies, Page et al. (2016) did not identify any clinically important differences between groups in any outcome. The authors recommend that novel combinations of manual therapy and exercise be compared with a realistic placebo in future trials, and that further trials of manual therapy alone or exercise alone for rotator cuff disease should be based upon a strong rationale and consideration of whether they would alter the conclusions of their review.

Noten et al. (2016) performed a systematic review of the literature for efficacy of isolated articular mobilization techniques in patients with primary adhesive capsulitis (AC) of the shoulder. Twelve randomized controlled trials involving 810 participants were included. The efficacy of seven different types of mobilization techniques was evaluated. Overall, the authors found mobilization techniques have beneficial effects in patients with primary AC of the shoulder. The main weakness of this review is the risk of bias; most studies failed to achieve blinding of the participants, therapist, and assessor. Additional limitations included heterogeneity and variation among follow-up, total duration, and frequency of the therapy.

Elbow, Wrist, or Hand

Five systematic reviews assessed the efficacy of manipulation or mobilization for elbow lateral epicondyle pain disorders (Heiser, et al. 2013; Hoogvliet, et al. 2013; Lucado, et al. 2018; Piper, et al. 2016; Sutton, et al. 2016). Collectively, mobilization and manipulation techniques directed at the elbow, as a single intervention or as part of multimodal care, were more beneficial than comparison groups at clinically improving pain in the short term (< three months) and intermediate term (up to six-months). Mobilization appeared to be more beneficial than control groups at improving grip strength in the short term. Comparators included corticosteroid injection, exercise, physical modalities, sham, placebo, and no treatment. The body of evidence was limited to relatively few studies that were largely of low quality.

Burnham et al. (2015) conducted a single-blinded quasi-controlled trial to evaluate the effectiveness of OMT in the management of carpal tunnel syndrome. Participants underwent weekly OMT sessions for six consecutive weeks. The main outcome measures were the Boston Carpal Tunnel Syndrome Questionnaire (BCTQ), a sensory symptom diagram (SSD), patient estimate of overall change, electrophysiologic testing of the median nerve (trans-carpal tunnel motor and sensory nerve conduction velocity and amplitude ratio), and carpal tunnel ultrasound imaging of the cross-sectional area of the median nerve and transverse carpal ligament length and bowing. The authors reported that OMT resulted in participant-perceived improvement in symptoms and function associated with CTS. However, median nerve function and morphology at the carpal tunnel did not change, possibly indicating a different mechanism by which OMT acted, such as central nervous system processes. Limitations of this study include unknown patient population and short follow-up period.

Hip Osteoarthritis

Terrell et al. (2022) conducted a two-group, randomized controlled trial (RCT) to determine whether a single session of osteopathic manipulative treatment (OMT) or OMT plus osteopathic cranial manipulative medicine (OCMM) can improve the gait of individuals with Parkinson's disease (PD) by addressing joint restrictions in the sagittal plane and by increasing range of motion (ROM) in the lower limb. A total of 90 participants, individuals with PD (n = 45), and age-matched healthy control participants (n = 45) were included in this RCT. PD participants were included if they were otherwise healthy, able to stand and walk independently, had not received OMT or physical therapy (PT) within 30 days of data collection, and had idiopathic PD in Hoehn and Yahr stages 1.0-3.0. PD participants were randomly assigned to one of three experimental treatment protocols: a 'whole-body' OMT protocol (OMT-WB), which included OMT and OCMM techniques; a 'neck-down' OMT protocol (OMT-ND), including only OMT techniques; and a sham treatment protocol. Control participants were age-matched to a PD participant and were provided the same OMT experimental protocol. An 18-camera motion analysis system was utilized to capture 3-dimensional (3D) position data in a treadmill walking trial before and after the assigned treatment protocol. Pretreatment and posttreatment hip, knee, and ankle ROM were compared with paired t-tests, and joint angle waveforms during the gait cycle were analyzed with statistical parametric mapping (SPM), which is a type of waveform analysis. Individuals with PD had reduced hip and knee extension in the stance phase compared to controls (32.9-71.2% and 32.4-56.0% of the gait cycle, respectively). Individuals with PD experienced an increase in total sagittal hip ROM ($p = 0.038$) following a single session of the standardized OMT-WB treatment protocol. However, waveform analysis found no differences in sagittal hip, knee, or ankle angles at individual points of the gait cycle following OMT-WB, OMT-ND, or sham treatment protocols. The authors concluded the increase in hip ROM observed following a single session of OMT-WB suggests that OCMM in conjunction with OMT may be useful for improving gait kinematics in individuals with PD. Limitations include assessing the effects of only a single session of OMT and OCMM on Parkinsonian gait, and no follow-up. To determine the clinical relevance of these findings, longitudinal studies over multiple visits are needed to determine the long-term effect of regular OMT and OMT+OCMM treatments on Parkinsonian gait characteristics.

Systematic reviews and meta-analyses were conducted by Sampath et al. (2016) and Beumer et al. (2016) to explore the effects of exercise and manual therapy on pain associated with hip osteoarthritis (OA). Best available evidence in both studies indicated that exercise therapy is more effective than minimal control in managing pain associated with hip OA in the short term. Low quality evidence in the Sampath et al. study showed a benefit of manual therapy in short-term pain control. Larger high-quality RCTs are needed to establish the effectiveness of exercise and manual therapies in the medium and long term in the treatment of hip OA.

A randomized clinical trial by Hoeksma et al. (2004) evaluated 109 participants with osteoarthritis of the hip to compare the effectiveness of a manual therapy (n = 56) with exercise therapy (n = 53) with a mean age of 72 years. The manual therapy group received therapy including manipulations and vigorous stretching while the control group received standard exercise therapy, which may have included stretching but did not include manipulation. The treatment period was five weeks (nine sessions). Outcomes were measured by general perceived improvement after treatment, level of pain, hip function, walking speed, range of motion, and quality of life. No major differences were found on baseline characteristics between groups. Success rates (primary outcome) after five weeks were 81% in the manual therapy group and 50% in the exercise group. Furthermore, participants in the manual therapy group had significantly better outcomes on pain, stiffness, hip function, and range of motion with results maintained after 29 weeks. The authors concluded that manual therapy is superior to exercise therapy for patients with OA of the hip.

Knee Osteoarthritis

Zhou et al. (2022) conducted a systematic review to highlight the therapeutic benefits osteopathic manipulative treatment (OMT) can have in the postoperative management of total knee arthroplasty with respect to range of motion, edema, pain perception, and ability to perform activities of daily living. All manuscripts that were published in English in the past 30 years were included in this systematic review, with the earliest in 1996. Eighteen studies met inclusion criteria and encompassed a wide variety, with the majority of studies performed being prospective studies (n = 10), followed by case reports (n = 3), cross-sectional studies (n = 2), literature reviews (n = 2), and case-control studies (n = 1). Among the prospective studies, the sample sizes ranged from 43 patients to 621 patients. Two cohort studies were used with a sample size of 8,325 patients. All studies were examined to evaluate at least one aspect of postsurgical complication or sequelae as the quality of the study: hospital stay, pain control, activities of daily living (ADLs), and mobility. The authors concluded that the use of OMT would positively influence range of motion by manipulation of localized musculature and can result in decreased demand for analgesics. This can, in turn, shorten hospital stay and return the ability of patients to perform activities of daily living earlier than without OMT. Increased research is needed to strengthen these findings on the benefits of OMT in the postoperative management of arthroplasty. Long-term evaluations of the results and prospective randomized studies are still needed. [Authors Licciardone et al. (2004), which were previously cited in this policy, are included in this systematic and meta-analysis review].

A randomized control trial was performed by Reza et al. (2021). It contained two-arm parallel-group with a total of (n = 32) individuals with known knee osteoarthritis. Group A received a supervised exercise protocol; and Group B received specified manual therapies in combination with a supervised exercise protocol. Pain intensity and functional disability were primary outcomes and assessed with the numeric pain rating scale (NPRS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The data was collected at baseline, two weeks, and four weeks post-intervention; all data was collected by the same assessor who was blind to the study. Group A was given specific strengthening exercises that included static quad knee extensions, standing terminal knee extension, seated leg press, partial squats, and step ups; stretching exercises included calf, hamstring and quadricep stretches. Group A performed three sessions every other day for two weeks. Group B received myofascial mobilization technique 10 times/session every other day for two weeks. The outcomes for NPRS and WOMAC demonstrated superiority for group B over group A. The authors concluded group B's interventions were found to be more effective than group A's for improving the pain intensity and functional status of participants with knee osteoarthritis. Future studies are suggested to study the retention effects of the intervention protocols. Limitations included short intervention time frame, small sample size and no observation for long-term data. The study was limited due to the availability of the intervention protocols and the interventions not able to be carried out for a long period, such as four to eight weeks. Future research is recommended to include studies that measure long-term effects and retention effects.

Altinbilek et al. (2018) conducted a single-blind, randomized controlled trial (RCT) to compare the efficacy of osteopathic manipulative treatment (OMT) to exercise treatment in knee osteoarthritis (OA). A total of 100 participants (nine males, 76 females; mean age 54.8 ±8.5 years; range, 40 to 70 years) with Stage II-III bilateral knee OA were enrolled in the study and randomized into two groups between January 2015 and June 2015. Group 1 (n = 50) performed exercise and received OMT, and Group 2 (n = 50) performed exercise alone. Clinical parameters with Western Ontario MacMaster Questionnaire (WOMAC) pain score, WOMAC joint stiffness score, WOMAC physical function score, Visual Analog Scale (VAS) and 50-m walking time were evaluated. All participants were assessed at the beginning of the study, just after the treatment, and four weeks after the treatment. Exercises included quadriceps isometric strengthening straight leg lifting, iliotibial band, hamstring stretching, and strengthening abductor and adductor muscle of the hip. Fifteen participants (exercise group = 9), (OMT + exercise = 6), dropped out of the study leaving 85. Results showed no difference between groups in terms of physical examination and clinical assessment parameters before treatment. Upon completion, functional improvement ($p < 0.05$) and pain relief ($p < 0.05$) were higher in the exercise + OMT group. The authors concluded that OMT is beneficial in relieving knee pain when used to complement conventional treatment of OA of the knee. Short terms follow-up did not allow for assessment of intermediate and long-term outcomes. The findings of this study need to be validated by future well-designed studies.

In a systematic review and meta-analysis of manual therapy for the treatment of OA of the knee, Salamh et al. (2017) reported that their findings support the use of manual therapy versus several different comparators for improvement in self-reported knee function. As lesser support is present for pain reduction, the authors were not able to make an endorsement of functional performance at the time. The conclusions were based on 12 studies; four of which were felt to have a low risk for bias and high treatment fidelity.

Ankle and Foot

Plaza-Manzano et al. (2016) conducted a randomized single-blind controlled clinical trial to analyze the effects of proprioceptive strengthening exercises versus the same exercises and manual therapy in the management of recurrent ankle sprains (n = 56). The control group performed four weeks of proprioceptive strengthening exercises; the experimental group performed four weeks of the same exercises combined with manual therapy (mobilizations to influence joint and nerve structures). Pain, self-reported functional ankle instability, pressure pain threshold (PPT), ankle muscle strength, and active range of motion (ROM) were evaluated in the ankle joint before, just after and one month after the interventions. The authors concluded that the protocol involving proprioceptive and strengthening exercises and manual therapy resulted in greater improvements in pain, self-reported functional joint stability, strength, and ROM compared to exercises alone. Larger studies with longer follow-up periods are needed.

A randomized trial by du Plessis et al. (2011) compared manual and manipulative therapy (MMT) with standard care of a night splint(s) for symptomatic mild to moderate hallux abducto valgus (HAV). Thirty participants were equally assigned to each group. The control group used a night splint(s) while the experimental group (MMT) received four MMT treatments over a two-week period. Outcomes were measured with visual analogue scale, foot function index and hallux dorsiflexion. Outcome measure scores in the control group (night splint) regressed between the one-week follow-up and one-month follow-up when participants did not use the night splint, while the scores in the experimental group (MMT) were sustained up to the one-month follow-up. The authors concluded that a structured protocol of manual and manipulative therapy is equivalent to standard care of a night splint(s) for symptomatic mild to moderate HAV in the short term.

Cleland et al. (2009) conducted a multicenter randomized clinical trial of 60 participants with plantar heel pain to compare the effectiveness of electrophysical agents and exercise (EPAX) which included iontophoresis with dexamethasone and stretching of the gastrocnemius muscle and/or plantar fascia or a manual physical therapy and exercise (MTEX) which included aggressive soft tissue mobilization directed at the triceps surae and the insertion of the plantar fascia at the medial calcaneal tubercle. Participants were equally split between the control and treatment groups and followed for six months. Outcomes were measured utilizing several patient self-report questionnaires, including the Lower Extremity Functional Scale (LEFS), the Foot and Ankle Ability Measure (FAAM), and the Numeric Pain Rating Scale (NPRS). The primary aim (effects of treatment on pain and disability) was examined with a mixed-model analysis of variance (ANOVA). Both groups demonstrated a significant improvement over time; however, the participants receiving in the MTEX group experienced greater clinical benefits in terms of function and pain than the participants in the EPAX group.

Headache

Núñez-Cabaleiro and Leirós-Rodríguez (2022) conducted a systematic review to identify the manual therapy (MT) methods and techniques that have been evaluated for the treatment of cervicogenic headache (CH) and their effectiveness. Two reviewers independently screened 365 articles for demographic information, characteristics of study design, study-specific intervention, and results. The Oxford 2011 Levels of Evidence and the Jadad scale were used. Of a total of 14 articles selected, 11 were randomized control trials and three were quasi-experimental studies published from 2015 to the present, that studied interventions with MT techniques in patients with CH. The techniques studied were spinal manipulative therapy, Mulligan's Sustained Natural Apophyseal Glides, muscle techniques, and translatory vertebral mobilization. In the short-term, the Jones technique on the trapezius and ischemic compression on the sternocleidomastoid achieved immediate improvements, whereas adding spinal manipulative therapy to the treatment can maintain long-term results. The authors concluded that manual therapy techniques could be effective in the treatment of patients with CH. The combined use of MT techniques improved the results compared with using them separately. This review has methodological limitations, such as the inclusion of quasi-experimental studies and studies with small sample sizes that reduced the generalizability of the results obtained. Further investigation is needed before clinical usefulness of this procedure is proven. [Authors Chaibi et al. (2017), which were previously cited in this policy, are included in this systematic review].

Rist et al. (2019) performed a systematic review and meta-analysis of published randomized clinical trials (RCTs) to evaluate the evidence regarding spinal manipulation as an alternative therapy in reducing migraine pain and disability. The search identified six RCTs with a total of 677 participants eligible for meta-analysis. Outcomes included measures of migraine days, migraine pain/intensity, and migraine disability. Methodological quality varied across the studies. For example, some studies received high or unclear bias scores for methodological features such as compliance, blinding,

and completeness of outcome data. Heterogeneity across the studies was low. The authors observed that spinal manipulation may be an effective therapeutic technique in reducing migraine days and pain/intensity. The results are preliminary and future rigorous, large-scale RCTs are warranted to further evaluate spinal manipulation as a treatment for migraine. [Author Chaibi 2017a/b, which was previously cited in this policy, is included in the Rist et al. (2019) and Rani et al. (2019) meta-analysis].

Rani et al. (2019) published an evidence synthesis of previously reported systematic reviews that described the effectiveness of physical therapy interventions for the treatment of individuals diagnosed with cervicogenic headache. This approach allowed for the inclusion of systematic reviews of overlapping interventions such as manipulation, manual therapy, and mobilization. Additionally, this 'overview' of existing reviews incorporated a qualitative appraisal of the strengths and limitations of existing systematic reviews. Based on six moderate to high quality systematic reviews, the authors concluded that manipulation and mobilization therapies are effective in reducing pain and functional disability in patients having cervicogenic headache.

The effectiveness of mobilization and manipulation was compared to other conservative treatments on reducing pain intensity, frequency, and disability in patients with cervicogenic and tension-type headaches in a systematic review and meta-analysis (Coelho et al., 2019). Nine RCTs totaling 793 participants were included in the systematic review. Of these, only three trials were judged to have a low risk of bias. Manipulation/mobilization was found to be equally as effective as other conservative treatments in reducing pain, disability, and frequency of headache in individuals with cervicogenic headache. Manipulation/mobilization was found to be more effective than comparative conservative care over the short-term (up to four weeks) and like other interventions at three months follow-up for individuals with tension-type headache.

A systematic review and meta-analysis evaluated the effectiveness of manual therapies, including manipulation, on health-related quality of life in patients with tension-type headache, migraine or cervicogenic headache (Maistrello et al., 2019). Manual therapy obtained more favorable clinically significant effects compared to usual care and placebo in terms of quality-of-life patients with tension-type and migraine headaches. The results should be viewed with caution due to the very low overall level of evidence and high risk of bias of the most influential studies. In patients with cervicogenic headache, the results were inconsistent. There is a need to make new specific studies for this type of headache. The authors concluded, "In the face of significant improvements compared to baseline and the absence of adverse effects, manual therapy should, therefore, be considered as a valid approach, being able to positively affect the quality of life of patients with headache."

Comprehensive evidence syntheses of the effectiveness of manual therapies including manipulation were published by Bronfort et al. (2010) and updated by Clar et al. (2014). Both reported that spinal manipulation is effective for the treatment of acute low back pain, acute/subacute neck pain, and chronic neck pain (when combined with exercise). Neither report found conclusive evidence for cervical manipulation/mobilization for tension type headaches as well as manipulation alone for coccydynia, sciatica and fibromyalgia. In contrast to the earlier report by Bronfort, et al. (2010), the evidence synthesis by Clar, et al (2014) concluded there is moderate (positive) evidence for mobilization techniques for the treatment of cervicogenic headache.

Temporomandibular Joint (TMJ) Disorders (TMD)

The available evidence for use of manual therapy in the treatment of TMJ disorders is insufficient to consider the procedure safe and effective; additional quality long-term randomized control trials are needed.

In 2024, Al-Moraissi et al., conducted a network meta-analysis of randomized clinical trials on the best treatment for painful TMJ disc displacement with reduction (DDwR). Multiple treatments for this condition were evaluated and included the results for manual therapy compared to conservative treatments. A total of 202 participants with DDwR included in three randomized controlled trials, with follow up time ranging from two weeks to four months were included. The results showed that participants who received manual therapy experienced a significantly greater reduction in TMJ pain than those that received conservative therapy. This meta-analysis was limited by small numbers of participants in the included RCTs, and research with larger numbers are needed to validate these findings.

Dunning et al. (2024) conducted a multi-center randomized controlled trial (RCT) to compare the effects of dry needling and upper cervical spinal manipulation with interocclusal splint therapy, diclofenac, and temporomandibular joint (TMJ) mobilization in patients with temporomandibular disorder (TMD). One hundred-twenty participants with TMD were randomized to receive six treatment sessions of dry needling plus upper cervical spinal manipulation (n = 62) or interocclusal splint therapy, diclofenac, and joint mobilization to the TMJ (n = 58). Participants receiving dry needling and upper cervical spinal manipulation experienced greater reductions in jaw pain intensity over the last seven days (VAS: $F = 23.696$; $p < 0.001$) and active pain-free mouth opening ($F = 29.902$; $p < 0.001$) than those receiving interocclusal splint therapy, diclofenac, and TMJ mobilization at the three-month follow-up. The authors concluded that dry needling and

upper cervical spinal manipulation was more effective than interocclusal splint therapy, diclofenac, and TMJ mobilization in patients with TMD. This study has limitations. First, the present study did not use a placebo needling or control group. Second, there is a risk of treatment bias secondary to all treating therapists being associated with the same post-graduate fellowship program in orthopedic manual physical therapy. Third, the interocclusal appliances in the comparison group were prepared by general dentists based on the needs of each individual participant. As such, different types of appliances may have been used. Moreover, some appliances may have required more frequent and/or involved adjustments for some participants than others, which may have caused some variability within the comparison group. The findings of this study need to be validated by well-designed studies. Further investigation is needed before clinical usefulness of this procedure is proven.

Lam et al. (2023) conducted a systematic review and meta-analysis to evaluate the efficacy of upper cervical joint mobilization/manipulation on reducing pain, pressure pain thresholds (PPTs) and increasing maximal mouth opening (MMO) compared to sham or other interventions in adults with TMD. Eight randomized controlled trials with 437 participants evaluating manual therapy (MT) vs sham and MT vs other interventions were included. The results for MT compared with sham intervention were included in two trials and showed that MT reduced pain intensity, results of three trials showed that MT significantly increased MMO but did not significantly reduce PPTs. Compared to other interventions (what these interventions are not indicated) MT reduced pain, improved MMO, with no significant improvement in the PPTS. The authors concluded that MT of the upper cervical spine does not significantly reduce symptoms of TMD compared to other interventions or sham treatment. Additional high-quality trials are needed.

Asquini et al. (2022) performed a systematic review to evaluate the effectiveness of manual therapy applied to the craniomandibular structures [Cranio-Mandibular Manual Therapy (CMMT)] on pain and maximum mouth opening in people with temporomandibular disorders (TMD). Randomized controlled trials (RCTs) comparing the effect of CMMT on pain and maximum mouth opening versus other types of treatment in TMDs were included from inception until October 2020. Two reviewers independently screened articles for inclusion, extracted data, assessed risk of bias with the revised Cochrane risk of bias tool for randomized trials and evaluated the overall quality of evidence with the Grading of Recommendations, Assessment, Development and Evaluations. A total of 2,720 records were screened, of which only six (293 participants) satisfied the inclusion criteria. All studies showed improvement in pain and maximum mouth opening for CMMT from baseline in the mid-term, but only two showed superiorities compared to other interventions. A quantitative synthesis was not performed. The authors concluded there is a need for future high methodology research investigating different manual therapy techniques applied to different regions and different populations (e.g., chronic versus acute TMD) to determine what is most effective for pain and maximum mouth opening in patients with TMDs. This study was limited by its heterogeneous patient population, risk of bias, and small sample sizes. Further research is needed to determine the clinical relevance of these findings. (Authors Brochado et al. (2018), which were previously cited in this policy, are included in this systematic review).

Detoni et al. (2022) conducted a randomized, controlled, double-blinded study to assess the effect of osteopathic manipulative treatment (OMT) of the temporomandibular joint (TMJ) and the orthostatic posture using the molar shim (MS) as a postural adjustment factor. Twenty individuals classified with temporomandibular disorder (TMD) were randomly assigned to a treated group (TG, n = 10) and placebo (PG, n = 10). The independent variables were MS and OMT of the TMJ. The dependent variables were DC-TMD data; local pressure pain using algometry; and orthostatic posture assessed by the distribution of plantar pressures (baropodometry), in the evaluation periods before and immediately after the interventions. Pain did not show a statistically significant difference after the interventions. However, when comparing the Effect Size (ES) between the groups in the post-intervention moment, a moderate relationship was observed for the left trapezius muscle (0.51) and right and left TMJ (0.41 and 0.54 respectively). When correlating the pain and percentage of anteroposterior postural dislocation variables, a moderate inverse correlation was observed in the post-intervention moment. The results of the MS pointed to a decrease ($p \leq 0.05$) of the average peak pressure (Medium P) during the use of the MS (503.4 ±44.1 kgf/cm2) and after performing the OMT (516.5 ±49.6 kgf/cm2), both for the TG compared to the pre intervention moment (519.3 ±42.9 kgf/cm2). The authors concluded that there is a correlation between TMJ and orthostatic posture. OMT of the TMJ influences orthostatic posture. The MS can be added to the evaluative context of TMD. Study limitations included the following: the dysfunctional side of the TMJ was not addressed, and ROMs and masticatory predominance were not part of the pre- and post-intervention comparison. In addition, the feet were not evaluated, which prevented the foot correlation in relation to the baropodometric variables. Long-term evaluations of the results and prospective randomized studies are still needed.

Two systematic reviews evaluated the effectiveness of manual therapy in the treatment of pain related to temporomandibular joint disorder (TMD). The systematic review by Herrera Valenci et al. (2020) found six RCTs; two studies were of low quality and the other four were considered high quality. While the analysis concluded that manual therapy was an effective treatment for TMD, the positive effect seems to decrease over time unless paired with therapeutic exercise (TE) which seem to favor long term effects on decreasing pain. The de Melo et al. (2020) systematic

review consisted of five studies which found manual therapy to be effective for pain relief, however there was a high risk of bias. Both studies concluded due to the low number of studies and the variability within each, the conclusion was further research is needed on the topic to validate the efficacy and long-term effects of manual therapy for TMD.

Nagata et al. (2019) performed a randomized controlled trial (RCT) to evaluate the efficacy of mandibular manipulation therapy used for the treatment of patients with temporomandibular disorders (TMD) with mouth-opening limitations. A total of 61 TMD participants who had mouth-opening limitation (upper and lower middle incisor distance 35 mm) were selected. They were divided into two treatment groups: conventional treatment (n = 30) and conventional treatment plus manipulation (n = 31). The conventional treatment included two types of self-exercise: cognitive behavioral therapy for bruxism and education. Mouth-opening limitation, orofacial pain, and temporomandibular joint (TMJ) sounds were recorded from baseline to 18 weeks after baseline. These parameters were statistically compared between the two treatment groups by using analysis of variance (ANOVA) and Scheffe's test to assess mouth opening distance and pain; TMJ sounds were compared using Mann–Whitney U test. No statistical difference was observed between the two treatment groups except for mouth-opening limitation after treatment at the first visit. Subgroup analyses, stratified according to the pathological type of TMD, indicated a similar trend. The authors concluded that the efficacy of manipulation is limited, and in contrast to expectations, improved execution of therapeutic exercises has a similar effect to that of manipulation during long-term observation. The advantage of manipulation was observed only during the first treatment session. Evidence on the efficacy of manipulative therapy for the treatment of TMD is limited in quantity and for the prevention of TMD is limited in both quality and quantity.

In a 2018 RCT, Brochado et al., evaluated the effectiveness of photobiomodulation (PBM) and manual therapy (MT) alone or combined on pain intensity, mandibular movement, psychosocial aspects, and anxiety in patients with TMDs. Fifty-one participants were randomized and 18 received PBM, 16 received MT, and 17 received combined therapy. The results showed significant pain relief, jaw movement and anxiety relief in the treatment groups. This RCT is limited by a very small number of participants for a very common condition, and larger well-designed research is needed to validate these findings.

Preventive Manipulative Treatment

There is insufficient evidence to conclude manipulative therapy is effective for prevention, maintenance, or custodial care. Additional research involving larger, well-designed studies is needed to establish its safety and efficacy.

Chow et al. (2021) conducted a systematic review which investigated the association between spinal manipulative therapy (SMT) and its efficacy and effectiveness in preventing or improving the immune system and infectious disease outcomes. The analysis included 529 participants from eight high quality articles. While SMT has been associated with immediate changes in the levels of selected immunological biomarkers, the duration of these changes and their clinical significance is unknown. The authors concluded the evidence analyzed neither supported nor refuted the effectiveness of SMT and its association with lymphocyte levels among patients with low back pain; further studies of high RCTs are warranted. Limitations included English published studies only and that study screening was performed by only one investigator rather than two.

A randomized controlled trial by Senna and Machaly (2011) investigated the effects of maintenance spinal manipulation therapy for chronic non-specific low back pain. Subjects were randomized into three groups and followed for 10 months. Group 1 (n = 40) received sham manipulation during the first month and no treatment over the subsequent nine months. Group 2 (n = 27) received manipulation during the first month but no treatment during the following nine months. Group 3 (n = 26) received manipulation during the first month and 'maintenance' manipulation every two weeks for an additional nine months. At the end of 10 months, 33 subjects declined follow-up. Five withdrew in the first phrase before treatment began. Of the remaining 88 subjects, 80 were evaluated at four months, 71 at seven months and 60 at 10 months. Subjects in Groups 2 and 3 experienced significantly lower pain and disability scores compared to the control group after the initial one-month treatment period. At the end of 10 months, Group 3 reported significantly lower pain and disability scores compared to Group 2. The authors concluded that spinal manipulation is an effective treatment for chronic non-specific low back pain. While Group 3 reported better outcomes, the basis of this improvement could not be determined as to whether it was the manipulation or the placebo effect of continued visits. The study is further limited by serious methodological flaws e.g., 35% drop-out rate; incomplete outcome data; lack of blinding; and uncertainty about allocation concealment, use of co-interventions, and compliance across groups.

Non-Musculoskeletal Disorders (e.g., Asthma, Otitis Media, Infantile Colic, etc.)

The long-term safety and effectiveness of manual therapies in the treatment of non-neuromusculoskeletal conditions, including but not limited to hypertension, asthma, colic, and otitis media have not been shown to be effective in the medical literature. While the outcomes favored subjects receiving manual therapy interventions, additional high-quality

research, such as long-term, randomized, controlled clinical trials or comparative studies are needed to validate these findings.

Hope-Bell et al. (2024) conducted a mixed-methods feasibility randomized controlled trial (RCT) evaluating the efficacy of four osteopathic interventions on psychophysiological and mental health outcomes. A mixed-methods feasibility study with an explanatory sequential design was implemented. The quantitative phase involved randomizing 42 participants into four intervention groups: (1) high-velocity and articulation techniques (HVAT), (2) soft-tissue massage (STM), (3) craniosacral therapy (CST), and (4) a combination approach. Primary outcome measures encompassed recruitment rate, assessment duration, questionnaire completion, intervention attrition, and adverse events. Secondary outcomes included validated assessments of depression, anxiety, stress, psychological flexibility, heart rate variability (HRV), and interoception, administered pre- and post-intervention. Analysis of variance (ANOVA) was employed to evaluate pre-post intervention changes. The qualitative phase comprised semi-structured interviews analyzed using thematic analysis. The study achieved a recruitment rate of 21 eligible participants per month, with 54.8% of respondents meeting eligibility criteria. All 33 participants who completed the study underwent interventions and assessments within the allocated one-hour timeframe, with full questionnaire completion. The attrition rate was 21%. No adverse events were reported. Qualitative analysis revealed positive participant experiences, with themes highlighting good practitioner communication, intervention accessibility, and increased bodily awareness. Some participants found the questionnaire battery burdensome. Exploratory quantitative analyses showed variations in effects across interventions for heart rate variability, interoceptive accuracy, and mental health measures, but these results should be interpreted cautiously due to the small sample size. The authors concluded that this study provides evidence supporting the feasibility and acceptability of a larger-scale RCT investigating osteopathic interventions for individuals presenting with mild psychological symptoms. The preliminary findings suggest potential efficacy in improving mental health outcomes, warranting further investigation. A small sample size makes it difficult to decide whether these conclusions can be generalized to a larger population. In addition, the short terms follow-up did not allow for assessment of intermediate and long-term outcomes. Further research with randomized controlled trials is needed to validate these findings.

Pala et al. (2024) conducted a randomized double-blind, placebo-controlled trial to evaluate the effectiveness of the osteopathic sympathetic harmonization (OSH) on the sympathetic nervous system (SNS) and the hypothalamic-pituitary-adrenal (HPA) axis in youth with major depressive disorder (MDD). The study included 39 youths aged 15-21 years and diagnosed with MDD. The participants were randomly assigned into either the OSH or the placebo group. Stimulation was performed on the sympathetic truncus and prevertebral ganglia in the OSH group. The stimulation of the placebo group was performed with a lighter touch and a shorter duration in similar areas. Each participant completed the Beck Depression Inventory (BDI) and the State and Trait Anxiety Inventory (SAI and TAI) before the application. Blood pressure (BP) and pulse measurements were made, and saliva samples were taken before, immediately after, and 20 min after application. The baseline BDI ($p = 0.617$) and TAI ($p = 0.322$) scores were similar in both groups. Although the SAI scores decreased in both groups postintervention, no statistical difference was found between the two groups. Subjects who received OSH had a decrease in α-amylase level ($p = 0.028$) and an increase in cortisol level ($p = 0.009$) 20 min after the procedure. The authors concluded that following OSH application in depressed youth, SNS activity may decrease, whereas HPA axis activity may increase. Future studies may examine the therapeutic efficacy of repeated OSH applications in depressed individuals. This study has limitations. The first limitation is that mechanoreceptors sensitive to touch and pressure will be stimulated, creating the same input to the cortex, in both groups. The second limitation is that any intervention to the ribs may affect the sympathetic chain. Although the placebo intervention was performed away from the costovertebral joints, the ribs may have been mobilized, which is a limitation of this study. To overcome this effect, study designs with a third group with control intervention that does not involve touching are needed in the future.

Buffone et al. (2022) conducted a systematic review and meta-analysis to evaluate the effectiveness of osteopathic manipulative treatment (OMT) for gastrointestinal disorders in term and preterm infants. Eligible studies were searched on PubMed, Scopus, Embase, Cochrane, CINAHL, and PEDro. Two reviewers independently assessed if the studies were randomized controlled trials (RCTs) and retrospective studies with OMT compared with any kind of control in term or preterm infants to improve gastrointestinal disorders. Nine articles met eligibility criteria, investigating OMT compared with no intervention, five involving term infants, and the remaining treating preterm infants. Five studies showed low risk of bias. In the meta-analysis, two studies were included to analyze the hours of crying due to infantile colic, showing statistically notable results [ES = -2.46 (-3.05, -1.87); $p < 0.00001$]. Quality of evidence was "moderate". Other outcomes, such as time to oral feeding, meconium excretion, weight gain, and sucking, were presented in a qualitative synthesis. The authors concluded that OMT was safe, and showed efficacy in some cases, however, conflicting evidence and lack of high-quality replication studies prevent generalization. This systematic review and meta-analysis were limited by its heterogeneous patient population. Further research with randomized controlled trials is needed to validate these findings. (Authors Castejón-Castejón et al. (2019), which were previously cited in this policy, are included in this systematic and meta-analysis review).

Rehman et al. (2022) conducted a systematic review to evaluate the safety and effectiveness of osteopathic manipulative therapy (OMT) and comparable techniques in the treatment of dizziness. From inception to March 2021, there were 3,375 studies identified and screened, with only 12 meeting inclusion criteria for data extraction. Moderate-quality evidence showed that articular OMT techniques were associated with decreases (all $p < 0.01$) in disability associated with dizziness [n = 141, mean difference (MD) = -11, 95% confidence interval (CI) = -16.2 to -5.9], dizziness severity (n = 158, MD = -1.6, 95% CI = -2.4 to -0.7), and dizziness frequency (n = 136, MD = -0.6, 95% CI = -1.1 to -0.2). Low-quality evidence showed that articular OMT was not associated with all case dropouts (ACD) rates [odds ratio (OR) = 2.2, 95% CI = 0.5 to 10.2, $p = 0.31$]. When data were pooled for any type of OMT technique, findings were similar; however, disability associated with dizziness and ACD rates had high heterogeneity ($I2 = 59$ and 46%). No studies met all of the criteria for risk of bias. The authors concluded the current review found moderate-quality evidence that treatment with articular OMT techniques was associated with decreased disability associated with dizziness, dizziness severity, and dizziness frequency. Limitations include a small sample size (11 RCTs, one observational study, n = 367 participants) and high risk of bias. Further research is needed to determine the clinical relevance of these findings.

Côté et al. (2021) convened a Global Summit of international scientists to conduct a systematic review of the literature to determine the efficacy and effectiveness of spinal manipulative therapy (SMT) for the primary, secondary and tertiary prevention of non-musculoskeletal disorders. The Global Summit took place on September 14-15, 2019, in Toronto, Canada. It was attended by 50 researchers from eight countries and 28 observers from 18 chiropractic organizations. At the summit, participants critically appraised the literature and synthesized the evidence. The authors searched MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, the Cumulative Index to Nursing and Allied Health, and the Index to Chiropractic Literature from inception to May 15, 2019, using subject headings specific to each database and free text words relevant to manipulation/manual therapy, effectiveness, prevention, treatment, and non-musculoskeletal disorders. Eligible for review were randomized controlled trials published in English. The methodological quality of eligible studies was assessed independently by reviewers using the Scottish Intercollegiate Guidelines Network (SIGN) criteria for randomized controlled trials. The authors synthesized the evidence from articles with high or acceptable methodological quality according to the Synthesis without Meta-Analysis (SWiM) Guideline. The final risk of bias and evidence tables were reviewed by researchers who attended the Global Summit and 75% (38/50) had to approve the content to reach consensus. The authors retrieved 4,997 citations, removed 1,123 duplicates, and screened 3,874 citations. Of those, the eligibility of 32 articles was evaluated at the Global Summit and 16 articles were included in this systematic review. The synthesis included six randomized controlled trials (RCTs) with acceptable or high methodological quality (reported in seven articles). These trials investigated the efficacy or effectiveness of SMT for the management of infantile colic, childhood asthma, hypertension, primary dysmenorrhea, and migraine. None of the trials evaluated the effectiveness of SMT in preventing the occurrence of non-musculoskeletal disorders. Consensus was reached on the content of all risk of bias and evidence tables. All RCTs with high or acceptable quality found that SMT was not superior to sham interventions for the treatment of these non-musculoskeletal disorders. Six of 50 participants (12%) in the Global Summit did not approve the final report. The authors concluded that this systematic review included six randomized clinical trials (534 participants) of acceptable or high quality investigating the efficacy or effectiveness of SMT for the treatment of non-musculoskeletal disorders. The authors found no evidence of an effect of SMT for the management of non-musculoskeletal disorders including infantile colic, childhood asthma, hypertension, primary dysmenorrhea, and migraine. This finding challenges the validity of the theory that treating spinal dysfunctions with SMT has a physiological effect on organs and their function. Governments, payers, regulators, educators, and clinicians should consider this evidence when developing policies about the use and reimbursement of SMT for non-musculoskeletal disorders. This systematic review and meta-analysis have limitations. The critical appraisal of articles may vary among reviewers. In addition, publication bias compromised the validity of the results because studies most unlikely to be published are those that failed to obtain a 'positive' result. Further, all the low risk of bias RCTs included in this review show that SMT is not effective for the management of non-musculoskeletal disorders. The authors recommend that their systematic review be updated every two to three years when new evidence becomes available. This is necessary to ensure that their findings are up to date with the most recent published literature. This is particularly important since our findings and conclusions are based on a limited number of high and acceptable quality trials, and only single trials for all but one conditions. Therefore, future trials can potentially alter the findings and conclusions.

Neuroimmunoendocrine Effects

A rapid evidence review examined research cited in support of claims of effectiveness for spinal manipulation in conferring or enhancing immunity (Kawchuk et al., 2020). The authors critically assessed seven cited studies. They found no credible, scientific evidence that spinal manipulation has any clinically relevant effect on the immune system. The available studies had small sample sizes and lacked symptomatic subjects. The authors concluded there exists no credible scientific evidence of effectiveness for conferring or enhancing immunity through spinal manipulation. Therefore, the use of spinal manipulation to treat or prevent infectious diseases is unproven.

Visceral Disorders

The available evidence is limited and insufficient to conclude that manipulative therapy is effective for disorders of the internal organs. Additional robust, high-quality studies are needed to establish safety and efficacy.

In a 2023 randomized controlled trial, Boas Fernandes et al. investigated the effect of osteopathic visceral manipulation (OVM) on functional constipation and chronic non-specific low back pain. Seventy participants were included and randomized 1:1. Assessors and participants were blinded. The primary clinical outcome was pain intensity measured using a numeric rating scale (NRS) and disability measured using the Oswestry Disability Index (ODI). Secondary outcomes were electromyographic signals measured during the flexion-extension cycle, the finger-to-floor distance during complete flexion of the trunk and the Fear-Avoidance Beliefs Questionnaire (FABQ). All outcomes were measured after six weeks of treatment and at three months. Treatment was provided in 15-minute sessions once a week for six weeks. The results showed that the treatment group reported a reduction in pain and improved ODI after six weeks and at follow up. The sham group did not report pain reduction at six weeks but did report it at three month follow up. Secondary outcomes assessed showed statistically significant improvement in EMG activity. The authors concluded that OVM improves outcomes in these patients, statistically. However, the ODI change was not clinically relevant to participants. Future research should include adding OVM to other treatments for this population.

A randomized, double blind, placebo-controlled trial was conducted by Eguaras et al. (2019) to evaluate the effects osteopathic visceral treatment on patients with Gastroesophageal Reflux Disease (GERD). Sixty participants were recruited and randomized into two groups, each receiving two sessions of treatment with a weeklong lapse between each. The GerdQ questionnaire was used to assess symptom changes. The experimental group received a visceral osteopathic technique conducted by a professional osteopath. The sham group had the same osteopath, however only physical contact was made with the participants; no pressure was applied, nor any actual osteopathic treatment was applied. The scores of the GerdQ test showed the application of the osteopathic manual treatment produced a significant improvement in symptoms for the experimental group compared to the sham group. The authors concluded that the osteopathic visceral technique may be useful on patients for improvement in their GERD symptoms. Limitations included lack of long-term follow-up, restriction to one technique for only two sessions and absence of practitioner blinding.

Silva et al. (2018) conducted a randomized, double-blind, placebo-controlled pilot study to evaluate the effect of osteopathic visceral manipulation (OVM) on pain, cervical range of motion, and upper trapezius (UT) muscle activity in patients with chronic nonspecific neck pain (NS-NP) and functional dyspepsia. Twenty-eight NS-NP participants were randomly assigned into two groups: treated with OVM (OVMG; n = 14) and treated with placebo visceral manipulation (PVMG; n = 14). The effects were evaluated immediately and seven days after treatment through pain, cervical range, and electromyographic activity of the UT muscle. Significant effects were confirmed for both groups immediately after treatment (OVMG and PVMG) for numeric rating scale scores ($p < 0.001$) and pain area ($p < 0.001$). Significant increases in EMG amplitude were identified immediately and seven days after treatment for the OVMG ($p < 0.001$). No differences were identified between the OVMG and the PVMG for cervical range of motion ($p > 0.05$). The authors' concluded that this study demonstrated that a single visceral mobilization session for the stomach and liver reduces cervical pain and increases the amplitude of the EMG signal of the UT muscle immediately and seven days after treatment in patients with nonspecific neck pain and functional dyspepsia. Limitations of this study include small sample size, lack of blinding, and short follow-up period. These findings need to be independently reproduced with focus on group difference rather than before-after changes.

In a randomized, placebo-controlled trial, Panagopoulos et al. (2015) investigated whether the addition of visceral manipulation, to a standard physiotherapy algorithm, improved outcomes in patients with low back pain. Sixty-four participants with low back pain who presented for treatment at a private physiotherapy clinic were randomized to one of two groups: standard physiotherapy plus visceral manipulation (n = 32) or standard physiotherapy plus placebo visceral manipulation (n = 32). The primary outcome was pain (measured with the 0-10 Numerical Pain Rating Scale) at six weeks. Secondary outcomes were pain at two and 52 weeks, disability (measured with the Roland-Morris Disability Questionnaire) at two, six, and 52 weeks and function (measured with the Patient-Specific Functional Scale) at two, six, and 52 weeks. The addition of visceral manipulation did not affect the primary outcome of pain at six weeks (-0.12, 95% CI = -1.45 to 1.21). There were no significant between-group differences for the secondary outcomes of pain at two weeks or disability and function at two, six, or 52 weeks. The group receiving addition of visceral manipulation had less pain than the placebo group at 52 weeks (mean 1.57, 95% CI = 0.32 to 2.82). The results suggest that visceral manipulation in addition to standard care is not effective in changing short-term outcomes but may produce clinically worthwhile improvements in pain at one year.

Craniosacral Therapy (CST)

CST is considered unproven as there is insufficient evidence to support its efficacy; additional robust, high-quality studies are needed.

Amendolara et al. (2024) conducted an updated systematic review and meta-analysis of randomized controlled trials (RCTs) to assess the clinical effectiveness of craniosacral therapy (CST) compared to standard care, sham treatment, or no treatment in adults and children. All RCTs employing CST for any clinical outcome were included. Studies not available in English as well as studies that did not report adequate data were excluded. Multiple reviewers were used to assess for inclusions, disagreements were settled by consensus. PRISMA guidelines were followed in the reporting of this meta-analysis. Cochrane's Risk of Bias 2 tool was used to assess for risk of bias. All data were extracted by multiple independent observers. Effect sizes were calculated using a Hedge's G value (standardized mean difference) and aggregated using random effects models. The GRADE system was used to assess quality of evidence. The primary study outcome was the effectiveness of CST for selected outcomes as applied to non-healthy adults or children and measured by standardized mean difference effect size. Twenty-four RCTs were included in the final meta-analysis with a total of 1,613 participants. When subgroup analyses were performed by primary outcome only, no significant effects were found. When secondary outcomes were included in subgroup analyses, results showed that only Neonate health, structure [g = 0.66, 95% CI (0.30; 1.02), Prediction Interval (−0.73; 2.05)] and Pain, chronic somatic [g = 0.34, 95% CI (0.18; 0.50), Prediction Interval (−0.41; 1.09)] show reliable, statistically significant effect. However, these should not be interpreted as positive results as wide prediction intervals, high bias, and statistical limitations temper the real-world implications of this finding. The authors concluded that CST demonstrated no significant effects in this meta-analysis, indicating a lack of usefulness in patient care for any of the studied indications. This analysis is also limited by problems inherent to the included studies. From a statistical perspective, many papers reporting a positive effect failed to account for repeated measures and multiple time point measures. Additionally, several of the included studies did not provide detailed descriptions of the techniques used and many studies mixed CST with other osteopathic treatments. Rather, precise treatment plans were left to the discretion of the practitioner providing care. Both these factors may have impacted the calculated effect sizes, though likely in the positive direction. What is more, many included papers suffered from poor blinding, poor randomization, and incomplete result reporting. The limitations in the available literature warrant reservation in considering CST as part of evidence-based treatment plans until substantially higher-quality evidence emerges.

Ceballos-Laita et al. (2024) conducted a systematic review and meta-analysis to evaluate the clinical effectiveness of craniosacral therapy (CST) in the management of any conditions. Two independent reviewers searched the PubMed, Physiotherapy Evidence Database, Cochrane Library, Web of Science, and Osteopathic Medicine Digital Library databases and extracted data from randomized controlled trials (RCTs) evaluating the clinical effectiveness of CST. The PEDro scale and Cochrane Risk of Bias 2 tool were used to assess the potential risk of bias in the included studies. The certainty of the evidence of each outcome variable was determined using GRADEpro. Quantitative synthesis was carried out with RevMan 5.4 software using random effect models. Fifteen RCTs were included in the qualitative and seven in the quantitative synthesis. For musculoskeletal disorders, the qualitative and quantitative synthesis suggested that CST produces no statistically significant or clinically relevant changes in pain and/or disability/impact in patients with headache disorders, neck pain, low back pain, pelvic girdle pain, or fibromyalgia. For non-musculoskeletal disorders, the qualitative and quantitative synthesis showed that CST was not effective for managing infant colic, preterm infants, cerebral palsy, or visual function deficits. The authors concluded that the qualitative and quantitative synthesis of the evidence suggest that CST produces no benefits in any of the musculoskeletal or non-musculoskeletal conditions assessed. Two RCTs suggested benefits of CST in children. However, both studies are seriously flawed, and their findings are thus likely to be false positive. This systematic review and meta-analysis have several limitations. First, even though the literature searches were thorough, the authors stated they can never be sure that no relevant studies have been missed. Second, the inclusion of many diverse conditions in one review complicates the interpretation of the results and might weaken the strength of the conclusions. Third, considerable heterogeneity exists across the included RCTs in terms of treatment duration and outcome variables. These factors might limit the validity of the quantitative syntheses. The available evidence is limited with overall poor-quality methodology and design, and diversity in reporting outcome measures. Therefore, no conclusions can be made regarding the relative efficacy, effectiveness, or safety of treatment.

Cook et al. (2024) conducted a systematic review and meta-analysis to assess heart rate variability (HRV) as a measure of cardiovascular stress and autonomic system activity proposed as a tool to evaluate the neurophysiologic effects of craniosacral therapy (CST). HRV can be analyzed in two different bands, high-frequency (HF) and low-frequency (LF) power associated with a parasympathetic and sympathetic response. In this meta-analysis, the authors provide a brief introduction to CST, analyze three primary studies, and summarize the therapeutic benefits and pitfalls of this alternative treatment on the autonomic nervous system (ANS). A significant negative HF standardized mean difference after CST was observed; standardized mean difference = -0.46; 95% CI (-0.79,-0.14). No significant effect on LF power was observed. The authors conclude that CST does provide a moderate short-term increase in parasympathetic activity. These findings suggest that CST may be used to treat patients with an overactive sympathetic state. Further studies

should be conducted for comparison against a control group to eliminate the possibility of a placebo effect and to elucidate long-term effects. This study has limitations including the possibility that changes in HRV may derive from the placebo effect of receiving a treatment rather than the facilitation of the CRI itself. Further, the small number of studies included in the meta-analysis and the variation in treatment protocols and patient populations may limit the generalizability of the findings. Additionally, the authors only assessed the short-term effects of CST on HRV. Medium and long-term effects will require further studies. Overall, this meta-analysis provides preliminary evidence supporting the potential of CST to modulate parasympathetic activity as evidenced by the HF analysis. Clinically, this suggests there may be an acute benefit of CST in patients with an unbalanced overactive sympathetic state. However, further research utilizing standardized protocols, larger sample sizes, and long-term follow-up is warranted to illustrate its clinical implications for various health conditions.

Castejón-Castejón et al. (2022) conducted a randomized controlled trial (RCT) to evaluate the number of craniosacral therapy sessions that can be helpful to obtain a resolution of the symptoms of infantile colic. And in addition, to observe if there are any differences in the evolution obtained by the groups that received a different number of Craniosacral Therapy sessions at 24 days of treatment, compared with the control group which did not receive any treatment. A total of 58 infants with colic were randomized into two groups of which 29 babies in the control group received no treatment, and those in the experimental group received one to three sessions of craniosacral therapy (CST) until symptoms were resolved. Evaluations were performed until day 24 of the study. In this RCT, crying hours served as primary outcome. The secondary outcome were the hours of sleep and the severity, measured by an Infantile Colic Severity Questionnaire (ICSQ). Differences were observed in favor of experimental group compared to the control group on day 24 in crying hours (mean difference = 2.94, at 95 %CI = 2.30-3.58; $p < 0.001$) primary outcome, and also in hours of sleep (mean difference = 2.80; at 95 %CI = - 3.85 to - 1.73; $p < 0.001$) and colic severity (mean difference = 17.24; at 95 %CI = 14.42-20.05; $p < 0.001$) secondary outcomes. Also, the differences between the groups ≤ two CST sessions (n = 19), three CST sessions (n = 10) and control (n = 25) were statistically noteworthy on day 24 of the treatment for crying, sleep, and colic severity outcomes ($p < 0.001$). The authors concluded that babies with infantile colic may obtain a complete resolution of symptoms on day 24 by receiving two or three CST sessions compared to the control group, which did not receive any treatment. This RCT is a small, unblinded study. Further investigation is needed before clinical usefulness of this procedure is proven.

Muñoz-Gómez et al. (2022) conducted a randomized controlled trial (RCT) to evaluate the effectiveness of a craniosacral therapy protocol on different features in patients with migraine. Fifty individuals with migraine were randomly divided into two groups (n = 25 per group): (i) craniosacral therapy group (CTG), following a craniosacral therapy protocol, and (ii) sham control group (SCG), with a sham treatment. The analyzed variables were pain, migraine severity and frequency of episodes, functional, emotional, and overall disability, medication intake, and self-reported perceived changes, at baseline, after a four-week intervention, and at eight-week follow-up. After the intervention, the CTG reduced pain ($p = 0.01$), frequency of episodes ($p = 0.001$), functional ($p = 0.001$) and overall disability ($p = 0.02$), and medication intake ($p = 0.01$), as well as led to a higher self-reported perception of change ($p = 0.01$), when compared to SCG. In addition, the results were maintained at follow-up evaluation in all variables. The authors concluded that a protocol based on craniosacral therapy is effective in improving pain, frequency of episodes, functional and overall disability, and medication intake in migraineurs. This protocol may be considered as a therapeutic approach in patients with migraine. Limitations include a small sample size which makes it difficult to decide whether these conclusions can be generalized to a larger population, and a lack of follow-up did not allow for assessment of intermediate and long-term outcomes. The findings of this study need to be validated by well-designed studies.

A prospective cohort study performed by Haller et al. (2021) examined the use, benefits, and safety of craniosacral therapy (CST) in primary health care. Consecutive out-patient participants utilizing CST from 2015 to 2019 were asked to provide anonymized data on symptom intensity, functional disability, and quality of life before and after treatment using an adapted 11-point numerical rating scale (NRS) version of the Measure Yourself Medical Outcome Profile (MYMOP). CST therapists submitted 220 patient records (71.4 % female) including 15.5 % infants and toddlers, 7.7 % children, and 76.8 % adolescents and adults. Participants received on average 7.0 ±7.3 CST sessions to treat 114 different, acute, and chronic conditions. Symptom intensity decreased by -4.38 NRS (95 %CI = - 4.69/-4.07), disability by -4.41 NRS (95 %CI = -4.78/-4.05), and quality of life improved by 2.94 NRS (95 %CI = 2.62/3.27). Furthermore, CST enhanced personal resources by 3.10 NRS (95 %CI = 1.99/4.21). Independent positive predictors of change in the adapted total MYMOP score included participants' expectations ($p = .001$) and therapists' CST experience ($p = .013$), negative predictors were symptom duration ($p < .002$) and patient age ($p = .021$); a final categorical predictor was CST type ($p = .023$). Minor but no serious adverse events occurred. The authors concluded that the utilization of CST may provide a promising additional treatment option for primary care patients who are interested in complementary therapies to treat a wide range of physical and mental symptoms in all age groups from infants to older adults. Further trials using randomized controlled designs are needed to confirm the exploratory study results in different patient populations.

The effectiveness and safety of craniosacral therapy for chronic pain conditions was investigated by Haller, et al (2020). Ten RCTs of 681 participants with neck and back pain, migraine, headache, fibromyalgia, epicondylitis, and pelvic girdle pain were included. Craniosacral therapy showed small/moderate greater post intervention effects on pain intensity and disability compared to treatment as usual care, sham, and active manual treatments. Effects were maintained through six-months follow-up. The implications of the findings were viewed by the authors as preliminary due to the small number of studies included in the meta-analysis. Most individual analyses included only two studies with a median pooled sample of 138 (range 119-230) participants, which produced imprecise results across primary and secondary outcomes. It is likely that additional studies will change the estimates of effect. Confidence in the reported estimates of effect was also reduced due to the frequent unclear risk of bias profile of the included RCTs. Many RCTs did not report allocation concealment, blinding of outcome assessment, and alternative methods of decreasing the risk of performance bias. Additionally, the study does not allow for making conclusions about the effectiveness of craniosacral therapy for specific pain conditions. (Author Haller et al. (2016) which was previously cited in this policy, is included in the Haller et al. (2020) meta-analysis).

Castejón-Castejón, et al (2019) conducted a small RCT (n = 58) to assess the effectiveness of craniosacral therapy in the treatment of infantile colic. The authors reported clinically significant benefits for crying time (hours), colic severity and sleep duration favoring craniosacral therapy at seven, 14, and 24 days follow up assessments. Confidence in the conclusions was limited due to a high risk of detection, performance, and attrition bias. In addition to methodologic limitations, the results are likely not generalizable as the study was conducted at a single site by one clinician.

Guillaud, et al (2016) critically evaluated the scientific literature describing with the reliability of diagnosis and the clinical efficacy of cranial osteopathy techniques (craniosacral therapy). The systematic review included nine studies concerning the reliability of diagnosis and 14 RCTs that described the efficacy of craniosacral therapy for a range of musculoskeletal and non-musculoskeletal conditions. The authors found no evidence to support the reliability of diagnoses made using craniosacral therapy. Most studies were vulnerable to a high risk of bias and failed to demonstrate any reliability for the selected outcomes. The authors also concluded there were very few well conducted trials demonstrating the clinical efficacy of techniques and therapeutic strategies used in craniosacral therapy. Most were seriously flawed and those with a low risk of bias reported only modest results that cannot be ruled out as being due to the non-specific effects of treatments. The authors concluded, there is insufficient evidence to support craniosacral therapy as being relevant for the diagnosis or treatment of patients.

In a 2014 Hayes technology assessment, updated in 2018, on craniosacral therapy, it was concluded that based on five very low quality RCTs, craniosacral therapy shows no benefit over standard treatments for a variety of conditions including asthma, MS, fibromyalgia migraine and pelvic girdle pain. While CST is likely to be benign as a complementary approach, it should not be used in place of conventional medical care.

In a preliminary report on the utility of CST techniques in the treatment of patients with lumbosacral spine overload Białoszewski et al., (2014) compared its effectiveness to that of trigger point therapy, another type of therapeutic approach. The study enrolled 55 selected patients with low back pain. The participants were randomly assigned to one of two groups: participants treated with craniosacral therapy (G-CST) and participants treated with trigger point therapy (G-TPT). The authors concluded that both CST and trigger point therapy may be clinically effective in the treatment of patients with non-specific lumbosacral spine pain, and that the present findings represent a basis for conducting further and prospective studies of larger and randomized samples.

Manipulative Therapy With Non-Standard Techniques

Published peer-reviewed literature was not identified for non-standard manipulative therapy techniques such as applied kinesiology, National Upper Cervical Chiropractic Association (NUCCA), and neural organizational technique (NOT).

Clinical Practice Guidelines

American Osteopathic Association (AOA)

In an updated review on the use of osteopathic manipulative treatment (OMT) in patients with low back pain (LBP), the AOA's clinical guideline concludes that the evidence for the efficacy of OMT in the management of chronic LBP is considered weak by systematic reviews, because it is generally based on low-quality studies. The AOA recommends that larger randomized controlled trials with a low risk of bias be conducted to further validate the effects of OMT on LBP. In addition, more research is needed to understand the mechanics of OMT and its short- and long-term effects, as well as the cost-effectiveness of such treatment (Popovich et al., 2024).

American College of Physicians (ACP)/American Pain Society (APS)

The American College of Physicians clinical practice guideline “Noninvasive Treatments for Acute, Subacute, and Chronic Low Back” recommends nonpharmacologic treatment including manipulative therapy as a first line approach for individuals with acute, subacute or chronic LBP (Qaseem et al., 2017).

Clinical guidelines published jointly by the ACP and the APS for the diagnosis and treatment of low back pain recommend spinal manipulation for patients who do not improve with self-care options along with several other nonpharmacological therapies, (Chou et al., 2017).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Manipulative therapy and craniosacral therapy are procedures and not subject to FDA regulation.

References

Al-Moraissi EA, Almaweri AA, Al-Tairi NH, et al. Treatments for painful temporomandibular disc displacement with reduction: a network meta-analysis of randomized clinical trials. Int J Oral Maxillofac Surg. 2024 Jan;53(1):45-56.

Altınbilek T, Murat S, Yumuşakhuylu Y, et al. Osteopathic manipulative treatment improves function and relieves pain in knee osteoarthritis: a single-blind, randomized-controlled trial. Turk J Phys Med Rehabil. 2018 Mar 9;64(2):114-120.

Amendolara A, Sheppert A, Powers R, et al. Effectiveness of osteopathic craniosacral techniques: A meta-analysis. Front Med (Lausanne). 2024 Oct 3;11:1452465.

American Association of Colleges of Osteopathic Medicine (AACOM). Osteopathic manipulative medicine explained. AACOM 2023. Available at: https://www.aacom.org/become-a-doctor/about-osteopathic-medicine/omm-explained. Accessed February 5, 2025.

American Osteopathic Association (AOA). Task Force on the Low Back Pain Clinical Practice Guidelines. American Osteopathic Association guidelines for osteopathic manipulative treatment (OMT) for patients with low back pain. J Am Osteopath Assoc. 2016 Aug 1;116(8):536-49.

American Osteopathic Association (AOA). What is Osteopathic Manipulative Treatment? 2024.

Asquini G, Pitance L, Michelotti A, et al. Effectiveness of manual therapy applied to craniomandibular structures in temporomandibular disorders: a systematic review. J Oral Rehabil. 2022 Apr;49(4):442-455.

Bagagiolo D, Rosa D, Borrelli F. Efficacy and safety of osteopathic manipulative treatment: an overview of systematic reviews. BMJ Open. 2022 Apr 12;12(4):e053468.

Beumer L, Wong J, Warden SJ, et al. Effects of exercise and manual therapy on pain associated with hip osteoarthritis: a systematic review and meta-analysis. Br J Sports Med. 2016 Apr;50(8):458-63.

Białoszewski D, Bebelski M, Lewandowska M, et al. Utility of craniosacral therapy in treatment of patients with non-specific low back pain. Preliminary report. Ortop Traumatol Rehabil. 2014 Nov-Dec;16(6):605-15.

Boas Fernandes WV, Politti F, Blanco CR, et al. Effect of osteopathic visceral manipulation for individuals with functional constipation and chronic nonspecific low back pain: Randomized controlled trial. J Bodyw Mov Ther. 2023 Apr;34:96-103.

Brochado FT, Jesus LH, Carrard VC, et al. Comparative effectiveness of photobiomodulation and manual therapy alone or combined in TMD patients: a randomized clinical trial. Brazilian Oral Research 2018;32:e50.

Buffone F, Monacis D, Tarantino AG, et al. Osteopathic treatment for gastrointestinal disorders in term and preterm infants: a systematic review and meta-analysis. Healthcare (Basel). 2022 Aug 12;10(8):1525.

Burnham T, Higgins DC, Burnham RS, et al. Effectiveness of osteopathic manipulative treatment for carpal tunnel syndrome: a pilot project. J Am Osteopath Assoc. 2015 Mar;115(3):138-48.

Castejón-Castejón M, Murcia-González MA, Gil JM, et al. Effectiveness of craniosacral therapy in the treatment of infantile colic. A randomized controlled trial. Complementary Therapies in Medicine 2019;47:102164.

Castejón-Castejón M, Murcia-González MA, Todri J, et al. Treatment of infant colic with craniosacral therapy. A randomized controlled trial. Complement Ther Med. 2022 Dec;71:102885.

Ceballos-Laita L, Ernst E, Carrasco-Uribarren A, et al. Is craniosacral therapy effective? A systematic review and meta-analysis. Healthcare (Basel). 2024 Mar 18;12(6):679.

Chaibi A, Benth JŠ, Tuchin PJ, et al. Chiropractic spinal manipulative therapy for migraine: a three-armed, single-blinded, placebo, randomized controlled trial. Eur J Neurol. 2017b Jan;24(1):143-153.

Chaibi A, Knackstedt H, Tuchin PJ, et al. Chiropractic spinal manipulative therapy for cervicogenic headache: a single-blinded, placebo, randomized controlled trial. BMC Res Notes. 2017a Jul 24;10(1):310.

Chou R, Deyo R, Friedly J, et al. Noninvasive treatments for low back pain. Comparative effectiveness review no. 169. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014I.) AHRQ Publication. Rockville, MD: Agency for Healthcare Research and Quality; February 2016.

Chou R, Deyo R, Friedly J, et al. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. Ann Intern Med. 2017 Apr 4;166(7):493-505.

Chow N, Hogg-Johnson S, Mior S, et al. Assessment of studies evaluating spinal manipulative therapy and infectious disease and immune system outcomes: a systematic review. JAMA Netw Open. 2021;4(4):e215493.

Cleland JA, Abbott JH, Kidd MO, et al. Manual physical therapy and exercise versus electrophysical agents and exercise in the management of plantar heel pain: a multicenter randomized clinical trial. J Orthop Sports Phys Ther. 2009 Aug;39(8):573-85.

Coelho M, Ela N, Garvin A, et al. The effectiveness of manipulation and mobilization on pain and disability in individuals with cervicogenic and tension-type headaches: a systematic review and meta-analysis, Physical Therapy Reviews 2019;24(1-2):29-43.

Cook AC, Egli AE, Cohen NE, et al. The neurophysiological effects of craniosacral treatment on heart rate variability: A systematic review of literature and meta-analysis. Cureus. 2024 Jul 18;16(7):e64807.

Côté P, Hartvigsen J, Axén I, et al. The global summit on the efficacy and effectiveness of spinal manipulative therapy for the prevention and treatment of non-musculoskeletal disorders: A systematic review of the literature. Chiropr Man Therap. 2021 Feb 17;29(1):8.

Coulter ID, Crawford C, Hurwitz EL, et al. Manipulation and mobilization for treating chronic low back pain: a systematic review and meta-analysis. The Spine Journal 2018;18(5):866-79.

Czaprowski D. Manual therapy in the treatment of idiopathic scoliosis. analysis of current knowledge. Ortop Traumatol Rehabil. 2016 Oct 28;18(5):409-424.

Dal Farra F, Buffone F, Risio RG, et al. Effectiveness of osteopathic interventions in patients with non-specific neck pain: a systematic review and meta-analysis. Complement Ther Clin Pract. 2022 Nov;49:101655.

de Melo LA, Bezerra de Medeiros AK, Campos MFTP, et al. Manual therapy in the treatment of myofascial pain related to temporomandibular disorders: a systematic review. J Oral Facial Pain Headache. 2020 Spring;34(2):141-148.

Detoni R, Hartz CS, Fusatto EL, et al. Relationship between osteopathic manipulative treatment of the temporomandibular joint, molar shim and the orthostatic position: a randomized, controlled and double blinded study. J Bodyw Mov Ther. 2022 Jan;29:187-197.

Dunning J, Butts R, Bliton P, et al. Dry needling and upper cervical spinal manipulation in patients with temporomandibular disorder: A multi-center randomized clinical trial. Cranio. 2024 Nov;42(6):809-822.

du Plessis M, Zipfel B, Brantingham JW, et al. Manual and manipulative therapy compared to night splint for symptomatic hallux abducto valgus: An exploratory randomized clinical trial. Foot (Edinb). 2011 Jan 13.

Eguaras N, Rodríguez-López ES, Lopez-Dicastillo O, et al. Effects of osteopathic visceral treatment in patients with gastroesophageal reflux: a randomized controlled trial. J Clin Med. 2019 Oct 19;8(10):1738.

El-Tallawy SN, Nalamasu R, Salem GI, et al. Management of musculoskeletal pain: an update with emphasis on chronic musculoskeletal pain. Pain Ther. 2021 Jun;10(1):181-209.

Everett CR, Patel RK. A systematic literature review of nonsurgical treatment in adult scoliosis. Spine. 2007; 32(19 Suppl):S130-S134.

Franke H, Franke JD, Belz S, et al. Osteopathic manipulative treatment for low back and pelvic girdle pain during and after pregnancy: a systematic review and meta-analysis. J Bodyw Mov Ther. 2017 Oct;21(4):752-762.

Franke H, Franke JD, Fryer G. Osteopathic manipulative treatment for nonspecific low back pain: a systematic review and meta-analysis. BMC Musculoskeletal Disord. 2014 Aug 30;15:286.

Groisman S, Malysz T, de Souza da Silva L, et al. Osteopathic manipulative treatment combined with exercise improves pain and disability in individuals with non-specific chronic neck pain: A pragmatic randomized controlled trial. J Bodyw Mov Ther. 2020 Apr;24(2):189-195.

Gross AR, Olson KA, Pool J, Basson A, Clewley D, Dice JL, Milne N. Spinal manipulation and mobilisation in paediatrics - an international evidence-based position statement for physiotherapists. J Man Manip Ther. 2024 Jun;32(3):211-233.

Guillaud A, Darbois N, Monvoisin R, Pinsault N. Reliability of diagnosis and clinical efficacy of cranial osteopathy: a systematic review. PLoS ONE 2016;11(12):e0167823.

Haller H, Dobos G, Cramer H. The use and benefits of craniosacral therapy in primary health care: a prospective cohort study. Complement Ther Med. 2021 May;58:102702.

Haller H, Lauche R, Cramer H, et al. Craniosacral therapy for the treatment of chronic neck pain: a randomized sham-controlled trial. Clin J Pain. 2016 May;32(5):441-9.

Haller H, Lauche R, Sundberg T, et al. Craniosacral therapy for chronic pain: a systematic review and meta-analysis of randomized controlled trials. BMC Musculoskeletal Disorders. 2020;21(1):1-4.

Hayes Inc. Health Technology Assessment. Craniosacral Therapy. Lansdale, PA: Hayes Inc.; May 2014. Updated April 2018.

Heiser R, O'Brien VH, Schwartz DA. The use of joint mobilization to improve clinical outcomes in hand therapy: a systematic review of the literature. Journal of Hand Therapy 2013;26(4):297-311.

Herrera-Valencia A, Ruiz-Muñoz M, Martin-Martin J, et al. Efficacy of manual therapy in temporomandibular joint disorders and its medium-and long-term effects on pain and maximum mouth opening: A systematic review and meta-analysis. J Clin Med. 2020 Oct 23;9(11):3404.

Ho CYC, Sole G, Munn J. The effectiveness of manual therapy in the management of musculoskeletal disorders of the shoulder: a systematic review. Man Ther. 2009 Oct;14(5):463-74.

Hoeksma HL, Dekker J, Ronday HK, et al. Comparison of manual therapy and exercise therapy in osteoarthritis of the hip: a randomized clinical trial. Arthritis Rheum. 2004 Oct 15; 51(5):722-9.

Hoogvliet P, Randsdorp MS, Dingemanse R, et al. Does effectiveness of exercise therapy and mobilisation techniques offer guidance for the treatment of lateral and medial epicondylitis? A systematic review. British Journal of Sports Medicine 2013;47(17):1112-1119.

Hope-Bell J, Draper-Rodi J, Edwards DJ. Applying an osteopathic intervention to improve mild to moderate mental health symptoms: A mixed-methods feasibility randomised trial. Chiropr Man Therap. 2024 Nov 6;32(1):32.

Idaho Medicaid Provider Handbook. Chiropractor. 5.44. Available at: https://www.idmedicaid.com/Provider%20Guidelines/Chiropractor.pdf. Accessed March 18, 2025.

Iqbal M, Riaz H, Ghous M, et al. Comparison of Spencer muscle energy technique and passive stretching in adhesive capsulitis: A single blind randomized control trial. J Pak Med Assoc. 2020 Dec;70(12(A)):2113-2118.

Kawchuk G, Goertz C, Axén I, et al. The Effect of Spinal Adjustment/Manipulation on Immunity and the Immune System: A Rapid Review of Relevant Literature. World Federation of Chiropractic 2020 (March). Available at: https://www.wfc.org/website/images/wfc/Latest_News_and_Features/Spinal_Manipulation_Immunity_Review_2020_03_19.pdf. Accessed February 5, 2025.

Lam AC, Liddle LJ, MacLellan CL. The Effect of Upper cervical mobilization/manipulation on temporomandibular joint pain, maximal mouth opening, and pressure pain thresholds: a systematic review and meta-analysis. Arch Rehabil Res Clin Transl. 2022 Nov 2;5(1):100242.

Langensiepen S, Stark C, Sobottke R, et al. Home-based vibration assisted exercise as a new treatment option for scoliosis - a randomised controlled trial. J Musculoskelet Neuronal Interact. 2017 Dec 1;17(4):259-267.

Leaver AM, Maher CG, Herbert RD, et al. A randomized controlled trial comparing manipulation with mobilization for recent onset neck pain. Arch Phys Med Rehabil. 2010 Sep;91(9):1313-8.

Liu Z, Shi J, Huang Y, et al. A systematic review and meta-analysis of randomized controlled trials of manipulative therapy for patients with chronic neck pain. Complement Ther Clin Pract. 2023 Aug;52:101751.

Lucado AM, Dale RB, Vincent J, et al. Do joint mobilizations assist in the recovery of lateral elbow tendinopathy? A systematic review and meta-analysis. Journal of Hand Therapy. 2018 (in press).

Maistrello LF, Rafanelli M, Turolla A. Manual therapy and quality of life in people with headache: systematic review and meta-analysis of randomized controlled trials. Current Pain and Headache Reports 2019;23(10):78.

Martins WR, Blasczyk JC, de Oliveira MA, et al. Efficacy of musculoskeletal manual approach in the treatment of temporomandibular joint disorder: A systematic review with meta-analysis. Manual Therapy 2016;21:10-7.

Muñoz-Gómez E, Inglés M, Aguilar-Rodríguez M, et al. Effect of a craniosacral therapy protocol in people with migraine: a randomized controlled trial. J Clin Med. 2022 Jan 30;11(3):759.

Nagata K, Hori S, Mizuhashi R, et al. Efficacy of mandibular manipulation technique for temporomandibular disorders patients with mouth opening limitation: a randomized controlled trial for comparison with improved multimodal therapy. J Prosthodont Res. 2019 Apr;63(2):202-209.

National Cancer Institute (NCI), National Institutes of Health. Complementary and alternative medicine (CAM). U.S. Department of Health and Human Services, 21 Mar 2022. Available at: https://www.cancer.gov/about-cancer/treatment/cam. Accessed February 22, 2023.

Nguyen C, Boutron I, Zegarra-Parodi R, et al. Effect of osteopathic manipulative treatment vs sham treatment on activity limitations in patients with nonspecific subacute and chronic low back pain: A randomized clinical trial. JAMA Intern Med. 2021 Mar 15:e210005.

Noten S, Meeus M, Stassijns G, et al. Efficacy of different types of mobilization techniques in patients with primary adhesive capsulitis of the shoulder: a systematic review. Archives of Physical Medicine and Rehabilitation 2016;97(5):815-825.

Núñez-Cabaleiro P, Leirós-Rodríguez R. Effectiveness of manual therapy in the treatment of cervicogenic headache: a systematic review. Headache. 2022 Mar;62(3):271-283.

Page MJ, Green S, McBain B, et al. Manual therapy and exercise for rotator cuff disease. Cochrane Database Syst Rev. 2016 Jun 10;(6):CD012224.

Paige NM, Miake-Lye IM, Booth MS, et al. Association of spinal manipulative therapy with clinical benefit and harm for acute low back pain systematic review and meta-analysis. JAMA. 2017;317(14):1451-1460.

Pala ÖO, Çıtaker S, Güney E, et al. Effectiveness of osteopathic manipulative applications on hypothalamic-pituitary-adrenal (HPA) axis in youth with major depressive disorder: A randomized double-blind, placebo-controlled trial. J Osteopath Med. 2024 Feb 29;124(6):267-275.

Panagopoulos J, Hancock MJ, Ferreira P, et al. Does the addition of visceral manipulation alter outcomes for patients with low back pain? A randomized placebo controlled trial. Eur J Pain. 2015 Aug;19(7):899-907.

Piper S, Shearer HM, Côté P, et al. The effectiveness of soft-tissue therapy for the management of musculoskeletal disorders and injuries of the upper and lower extremities: a systematic review by the Ontario Protocol for Traffic Injury management (OPTIMa) collaboration. Manual Therapy 2016;21:18-34.

Plaza-Manzano G, Vergara-Vila M, Val-Otero S, et al. Manual therapy in joint and nerve structures combined with exercises in the treatment of recurrent ankle sprains: A randomized, controlled trial. Man Ther. 2016 Dec;26:141-149.

Popovich JM Jr, Cholewicki J, Reeves NP, et al. The effects of osteopathic manipulative treatment on pain and disability in patients with chronic low back pain: A single-blinded randomized controlled trial. J Osteopath Med. 2024 Jan 11;124(5):219-230.

Puntumetakul R, Pithak R, Namwongsa S, et al. The effect of massage technique plus thoracic manipulation versus thoracic manipulation on pain and neural tension in mechanical neck pain: a randomized controlled trial. *J Phys Ther Sci*. 2019;31(2):195-201.

Qaseem A, Wilt TJ, McLean RM, Forciea MA. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. Annals of Internal Medicine 2017;166(7):514-30.

Rani M, Kulandaivelan S, Bansal A, et al. Physical therapy intervention for cervicogenic headache: an overview of systematic reviews. European Journal of Physiotherapy. 2019; 21 (4): 217-223.

Rehman Y, Kirsch J, Wang MY, et al. Impact of osteopathic manipulative techniques on the management of dizziness caused by neuro-otologic disorders: systematic review and meta-analysis. J Osteopath Med. 2022 Oct 12.

Reza MK, Shaphe MA, Qasheesh M, et al. Efficacy of specified manual therapies in combination with a supervised exercise protocol for managing pain intensity and functional disability in patients with knee osteoarthritis. J Pain Res. 2021 Jan 26;14:127-138.

Rist PM, Hernandez A, Bernstein C, et al. The impact of spinal manipulation on migraine pain and disability: a systematic review and meta-analysis. Headache: The Journal of Head and Face Pain 2019;59(4):532-542.

Romano M, Negrini S. Manual therapy as a conservative treatment for adolescent idiopathic scoliosis: a systematic review. Scoliosis. 2008 Jan 22; 3:2.

Rubinstein SM, Terwee CB, Assendelft WJ, et al. Spinal manipulative therapy for acute low-back pain. Cochrane Database Syst Rev. 2012 Sep 12;2012(9):CD008880. doi: 10.1002/14651858.CD008880.pub2. PMID: 22972127; PMCID: PMC6885055.

Salamh P, Cook C, Reiman MP, et al. Treatment effectiveness and fidelity of manual therapy to the knee: A systematic review and meta-analysis. Musculoskeletal Care. 2017 Sep;15(3):238-248.

Sampath KK, Mani R, Miyamori T, et al. The effects of manual therapy or exercise therapy or both in people with hip osteoarthritis: a systematic review and meta-analysis. Clin Rehabil. 2016 Dec;30(12):1141-1155.

Santos TS, Oliveira KKB, Martins LV, et al. Effects of manual therapy on body posture: systematic review and meta-analysis. Gait Posture. 2022 Jul;96:280-294.

Schwerla F, Hinse T, Klosterkamp M, et al. Osteopathic treatment of patients with shoulder pain. A pragmatic randomized controlled trial. J Bodyw Mov Ther. 2020 Jul;24(3):21-28.

Schulz C, Evans R, Maiers M, et al. Spinal manipulative therapy and exercise for older adults with chronic low back pain: a randomized clinical trial. Chiropr Man Therap. 2019 May 15;27:21.

Senna MK, Machaly SA. Does maintained spinal manipulation therapy for chronic non-specific low back pain result in better long term outcome? Spine. 2011 Aug 15;36(18):1427-37.

Silva ACO, Biasotto-Gonzalez DA, Oliveira FHM, et al. Effect of osteopathic visceral manipulation on pain, cervical range of motion, and upper trapezius muscle activity in patients with chronic nonspecific neck pain and functional dyspepsia: a randomized, double-blind, placebo-controlled pilot study. Evid Based Complement Alternat Med. 2018 Nov 11;2018:4929271.

Skelly AC, Chou R, Dettori JR, et al. Noninvasive nonpharmacological treatment for chronic pain: a systematic review update. Comparative Effectiveness Review No. 227. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No. 20-EHC009. Rockville, MD: Agency for Healthcare Research and Quality; April 2020.

Steuri R, Sattelmayer M, Elsig S, et al. Effectiveness of conservative interventions including exercise, manual therapy and medical management in adults with shoulder impingement: a systematic review and meta-analysis of RCTs. British Journal of Sports Medicine 2017;51(18):1340-1347.

Sutton D, Gross DP, Côté P, et al. Multimodal care for the management of musculoskeletal disorders of the elbow, forearm, wrist and hand: a systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. Chiropr Man Therap. 2016; 24: 8.

Terrell ZT, Moudy SC, Hensel KL, et al. Effects of osteopathic manipulative treatment vs. osteopathic cranial manipulative medicine on Parkinsonian gait. J Osteopath Med. 2022 Feb 14;122(5):243-251.

Théroux J, Stomski N, Losco CD, et al. Spinal manipulative therapy for adolescent idiopathic scoliosis: a systematic review. J Manipulative Physiol Ther. 2017 Jul-Aug;40(6):452-458.

Ulger O, Demirel A, Oz M, et al. The effect of manual therapy and exercise in patients with chronic low back pain: double blind randomized controlled trial. J Back Musculoskelet Rehabil. 2017 Nov 6;30(6):1303-1309.

Upledger, J. Discover craniosacral therapy and somatoemotional release. Upledger Institute International. 1978, Available at: https://www.upledger.com/therapies/index.php. Accessed March 4, 2025.

Wenxia Z, Yuelong L, Zhou Z, et al. The efficacy of combined physiotherapeutic scoliosis-specific exercises and manual therapy in adolescent idiopathic scoliosis. BMC Musculoskelet Disord. 2024 Oct 31;25(1):874.

Zhou Y, Chin J, Evangelista A, et al. Inhibiting the musculoskeletal pathological processes in post-knee replacement surgery with osteopathic manipulative treatment: a systematic review. Cureus. 2022 Jan 25;14(1):e21599.

Policy History/Revision Information

Date	Summary of Changes

10/01/2025	**Related Policies**
	• Removed reference link to the Medical Policy titled:
	  ○ *Diagnostic Spinal Ultrasonography (for Idaho Only)* (retired Oct. 1, 2025)
	  ○ *Neuropsychological Testing Under the Medical Benefit (for Idaho Only)* (retired Oct. 1, 2025)

08/01/2025	**Coverage Rationale** ***State-Specific Criteria*** • Added instruction to refer to the *Idaho Medicaid Provider Handbook, Chiropractor* for medical necessity clinical coverage criteria for chiropractic Manipulative Therapy

Date	Summary of Changes

	Non State-Specific Criteria
	• Replaced language indicating:
	  ○ "Manipulative Therapy is proven and medically necessary for treating Musculoskeletal Disorders, except as noted [in the policy as unproven and not medically necessary]" with "*osteopathic* Manipulative Therapy is proven and medically necessary for treating Musculoskeletal Disorders, except as noted [in the policy as unproven and not medically necessary]"
	  ○ "Manipulative Therapy is unproven and not medically necessary for all other indications [not listed in the policy as proven and medically necessary] due to insufficient evidence of efficacy" with "*osteopathic* Manipulative Therapy is unproven and not medically necessary for all other indications [not listed in the policy as proven and medically necessary] due to insufficient evidence of efficacy"
	Definitions
	• Added definition of "Upledger Technique"
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version CS076ID.A

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.