

# Manipulative Therapy (for Nebraska Only)

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[Instructions for Use](#)

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## Related Policies

- [Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation \(for Nebraska Only\)](#)
- [Home Traction Therapy \(for Nebraska Only\)](#)
- [Manipulation Under Anesthesia \(for Nebraska Only\)](#)
- [Motorized Spinal Traction \(for Nebraska Only\)](#)
- [Treatment of Temporomandibular Joint Disorders \(for Nebraska Only\)](#)

## Application

This Medical Policy only applies to the State of Nebraska.

## Coverage Rationale

### State-Specific Criteria

#### *Chiropractic Manipulative Therapy*

For medical necessity clinical coverage criteria for chiropractic [Manipulative Therapy](#), refer to the [Nebraska Department of Health and Human Services, Code § 471-5-003.02: Chiropractic Services](#).

### Non–State-Specific Criteria

#### *Osteopathic Manipulative Therapies*

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, including but not limited to the following:**

- Nonmusculoskeletal disorders (e.g., asthma, otitis media, infantile colic, internal organ disorders)
- Prevention/maintenance/custodial care
- Craniosacral therapy (cranial manipulation/upledger technique)
- Temporomandibular joint disorder
- Scoliosis
- Manipulative services that use nonstandard techniques (e.g., applied kinesiology, including the neural organizational technique and the National Upper Cervical Chiropractic Association process)

This policy does not address manipulation under anesthesia; refer to the Medical policy titled [Manipulation Under Anesthesia \(for Nebraska Only\)](#).

## Definitions

Refer to the federal, state, or contractual definitions that supersede the definitions below.

**Manipulative Therapy:** Manipulative Therapy, osteopathic manipulative treatment, osteopathic manipulative medicine, 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 individual's body to achieve and maintain the individual's 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. (American Association of Colleges of Osteopathic Medicine, 2023; National Cancer Institute, 2022)

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

## 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 \(Occupational, Physical, and Speech\) \(for Nebraska Only\)](#) 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

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

## Description of Services

Manipulative Treatment, also known as osteopathic manipulative treatment or Manipulative Therapy, is a treatment typically used by Doctor of Osteopathic Medicine to diagnose, treat, and prevent illnesses and injuries. Practitioners move individuals' 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 (American Osteopathic Association). 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 is a noninvasive osteopathic technique that involves touch detecting pulsations and rhythms of flow of cerebrospinal fluid. The therapist then gently works with the skull and spine, with the goal to affect release of potential restrictions to the flow of cerebrospinal fluid, 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 nonstandard Manipulative Therapy techniques exist such as applied kinesiology, which includes the neural organizational technique that claims to organize the central nervous system the National Upper Cervical Chiropractic Association technique that specifically aligns the head and neck to improve spinal stability and balanced mobility.

## Clinical Evidence

### Musculoskeletal

#### *Back*

The aim of this interventional, prospective, randomized, and blinded study by Hartz et al. (2025) was to evaluate the effect of osteopathic manipulative treatment (OMT) on pain intensity, flexibility, autonomic nervous system function, energetic status, and thermal profile in participants with chronic low back pain (LBP). Overall, 28 participants were randomly placed into two groups, the OMT group and the placebo group, and both groups underwent three treatment sessions, with reassessments immediately following the initial session and occurring 1 week after the final session. The OMT group sessions were based on osteopathic evaluation, and the placebo group had transcutaneous electrical nerve stimulation electrodes placed without electrical current. A significant interaction between group and time was observed for flexibility ( $F = 7.5$ ;  $p = 0.001$ ), visual analog scale (VAS) pain scores ( $F = 2.8$ ;  $p = 0.05$ ), low frequency (LF;  $F = 3.5$ ;  $p = 0.04$ ), LF/high frequency (HF) ratio ( $F = 3.6$ ;  $p = 0.04$ ), and total energy ( $F = 4.4$ ;  $p = 0.01$ ). The OMT group had significant improvements in flexibility, VAS scores, L3 algometry, and total energy post intervention. Additionally, significant reductions in LF and LF/HF ratios were noted following OMT. The authors concluded that the three sessions of OMT resulted in significant reductions in pain, increased posterior chain flexibility, enhanced parasympathetic activity, and elevated total energy in participants with chronic LBP. These improvements were more pronounced after the full course of treatment than after a single session, suggesting increased efficacy with multiple interventions in this population. Limitations, according to the authors, included the modest sample size, absence of an active treatment comparison group, limited long-term follow-up, and pragmatic nature of the intervention, which may impact standardization and replicability. According to the authors, future studies should incorporate larger samples, active comparators, and extended follow-up to enhance the interpretability of results.

The aim of this study by Lisi et al. (2025) was to assess the effect of chiropractic care on the likelihood of receiving an opioid prescription within 1 year following an initial primary care physician (PCP) visit for LBP among opioid-naive veterans receiving care in the Veterans Health Administration (VHA) system. The research used a cross-sectional analysis with longitudinal follow-up. Eligible individuals were veterans who had an LBP visit with a VHA PCP between October 1, 2015, and September 30, 2020; had no VHA LBP visit in the previous 18 months; and completed at least two additional VHA LBP visits within the subsequent 12 months. The study used VHA electronic health record data, including information on outpatient visits, prescriptions, and comorbid diagnoses. A total of 128,377 veterans met the study criteria, with 7,327 (5.71%) receiving chiropractic care and 121,050 (94.29%) not receiving chiropractic care. The primary outcome was the occurrence of an opioid prescription filled within 365 days of the index PCP visit. The study also measured the time from the index visit to receipt of an opioid prescription for rate estimation. Due to the inclusion criteria, all individuals were opioid naive, defined as having no opioid prescription in the 180 days preceding the index visit. Any opioid prescription, regardless of quantity or dosage, was considered, and prescriptions could have been for acute or chronic painful conditions. Throughout the 1-year follow-up period, veterans who received chiropractic care had a lower cumulative incidence of opioid prescription fills than those who did not. Specifically, 13.2% of chiropractic care users filled an opioid prescription vs 17.1% of nonusers, resulting in a number needed to treat of 26. In the full sample, the unadjusted hazard ratio for receiving an opioid prescription among chiropractic care users was 0.74 (95% CI, 0.70-0.80), indicating a reduced risk. In the propensity-matched sample, the cumulative incidence of opioid prescriptions was 13.0% for chiropractic care users and 16.8% for nonusers, with a number needed to treat of 27. When adjusting for propensity score, the hazard ratio for opioid prescription fills among chiropractic care users compared with nonusers was 0.77 (95% CI, 0.71-0.83), showing a consistently lower risk over time. This study indicated several limitations and potential sources of bias. First, the findings were limited to a veteran population, which may not be generalizable to other groups. Additionally, the analysis did not evaluate the specific content or quality of chiropractic care provided. Individual and provider preferences regarding opioid prescribing and chiropractic treatment were not examined, as these details are not captured in VHA electronic health record data. Lastly, it was not possible to link opioid prescriptions to diagnoses for either group. The authors concluded that the findings from this study demonstrate that nonpharmacological chiropractic care may play a valuable role in strategies aimed at reducing opioid prescriptions for veterans with LBP.

Bagagiolo et al. (2022) performed an overview of systematic reviews and meta-analyses to summarize the available clinical evidence on the efficacy and safety of OMT for various conditions. The literature search revealed nine systematic reviews or meta-analyses conducted between 2013 and 2020, with 55 primary trials involving 3,740 individuals. The systematic reviews reported a wide range of conditions, including acute and chronic nonspecific LBP (four systematic reviews), chronic nonspecific neck pain (one systematic review), chronic noncancer pain (one systematic review),

pediatric conditions (one systematic review), neurological conditions (primary headache; one systematic review), and irritable bowel syndrome (IBS; one systematic review). Although with a different effect size and quality of evidence, meta-analyses reported that OMT is more effective than comparators in reducing pain and improving functional status in acute/chronic nonspecific LBP, chronic nonspecific neck pain, and chronic noncancer pain. No adverse events were reported in most systematic reviews. According to AMSTAR 2, the methodological quality of the included systematic reviews was rated low or critically low. The authors concluded that based on the currently available systematic reviews and meta-analyses, 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 the small sample size, presence of conflicting results, and high heterogeneity, questionable evidence exists for 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. (Posadzki et al., 2013, Müller et al., 2014, and Franke et al., 2014, 2017, 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 manual therapy causes postural changes. In March 2022, the authors performed a search in the PubMed, CINAHL (Cumulative Index to Nursing and Allied Health), Embase, PEDro, and Cochrane Central databases that yielded 6,627 articles, of which 38, including 1,597 individuals, 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 was rated through the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) system. The clinical trials included in this review used different doses of manual therapy sessions, ranging from one to 18 sessions. When compared with no intervention or sham, in the short and medium term, manual therapy reduced the forward head posture (14 studies; 584 individuals; 95% CI, 0.38-1.06), reduced thoracic kyphosis (five studies; 217 individuals; 95% CI, 0.37-0.94), improved lateral pelvic tilt (five studies; 211 individuals; 95% CI, 0.11-0.67) and pelvic torsion (two studies; 120 individuals; 95% CI, 0.44-1.19), and increased plantar area (three studies; 134 individuals; 95% CI, 0.04-0.74). With moderate certainty, there was no significant effect on shoulder protrusion (five studies; 176 individuals; 95% CI, -0.11 to 0.61), shoulder alignment in the frontal plane (three studies; 160 individuals; 95% CI, -0.15 to 0.52), scoliosis (two studies; 26 individuals; 95% CI, -1.57 to 2.19), and pelvic anteversion (five studies; 233 individuals; 95% CI, -0.02 to 0.51). With low certainty, manual therapy had no effect on scapular upward rotation (two studies; 74 individuals; 95% CI, -0.76 to 2.17). With low to very low certainty, it is possible to conclude that manual therapy was not superior to other interventions in the short or medium term regarding the improvement of forward head posture (five studies; 170 individuals; 95% CI, -1.39 to 0.67) and shoulder protrusion (three studies; 94 individuals; 95% CI, -4.04 to 0.97). The authors concluded that manual therapy 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. Manual therapy 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 OMT vs that of sham OMT for reducing LBP in participants with nonspecific subacute and chronic LBP. Overall, 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. The experimental group received standard OMT; the sham control group received a priori inert procedure that consisted of light touch, which stimulated OMT without stimulating physiotherapy or massage. Both groups received therapy for six sessions, 2 weeks apart. The mean Quebec Back Pain Disability Index score in the standard OMT group was 31.5 at baseline and 25.3 at 3 months; in the sham OMT group, the mean score was 27.2 at baseline and 26.1 at 3 months. At 12 months, both groups experienced a decrease in pain; however, the standard OMT group reported increased pain relief. The authors concluded that OMT had a slightly better clinical effect than the sham in participants with LBP. Limitations include 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 aged 65 years or older with subacute or chronic LBP. Overall, 550 participants 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 and HEP; or (3) SMT and HEP. The HEPs and supervised exercise programs were delivered by nine exercise therapists and two chiropractors, and the SMT was delivered by 11 licensed chiropractors. Outcomes were measured by participant self-report questionnaires, blind objective assessment, and in-person and telephone interviews. Participant self-report questionnaires were collected at baseline and 4, 12, 26, and 52 weeks post randomization. The authors concluded that 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. However, it did enhance satisfaction with care. While the trial had several strengths, including an adequate sample size and rigorous design, the limitations include the blinding of participants and providers; absence of measuring outcomes specific to the age of the participants; and inability to control contextual effects, which may explain differences in participant satisfaction.

Rubinstein et al. (2019) conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) to assess the benefits and harms of SMT for the treatment of chronic LBP. Two reviewers independently selected studies, extracted data, and assessed the risk of bias and quality of the evidence. The effect of SMT was compared with that of recommended therapies, nonrecommended therapies, sham (placebo) SMT, and SMT as an adjuvant therapy. The main outcomes were pain and back-specific functional status, examined as mean differences (MDs) and standardized MDs (SMDs), respectively. The outcomes were examined at 1, 6, and 12 months. Overall, 47 RCTs, including a total of 9,211 individuals, were identified; on average, the individuals were middle aged (35-60 years). Most trials compared SMT with recommended therapies. Moderate-quality evidence suggests that SMT has similar effects to other recommended therapies for short-term pain relief (MD, -3.17; 95% CI, -7.85 to 1.51) and a small, clinically better improvement in function (SMD, -0.25; 95% CI, -0.41 to -0.09). High-quality evidence suggests that compared with nonrecommended therapies, SMT results in small, not clinically better effects for short-term pain relief (MD, -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. Approximately 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 that was powered to examine risk ( $n = 183$ ) found no increased risk of an adverse event (relative risk, 1.24; 95% CI, 0.85-1.81) or duration of the event (1.13; 0.59-2.18) 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 LBP, whereas SMT seems to be better than nonrecommended interventions for improvement in function in the short term. Clinicians should inform individuals of the potential risks of adverse events associated with SMT. The study is limited due to a heterogeneous population of individuals and risk of bias. Well-designed, adequately powered, prospective, controlled clinical trials of SMT are needed to further describe safety and clinical efficacy. (Ulger et al., 2017, previously cited in this policy, is 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, 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 LBP. No serious adverse events or withdrawals due to adverse events were reported. Nonserious 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 the treatment of chronic LBP. 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 and measurement was the VAS (26 of 51) and the numeric pain rating scale (NPRS; 12 of 51). The authors concluded that there was a small to moderate effect on pain in favor of manipulation, which increased over time at 3 and 6 months of follow-up, for reducing pain compared with other active comparators (exercise and physical therapy).

Ulger et al. (2017) conducted an RCT to determine the effects of spinal stabilization exercises (SSEs) and manual therapy methods on pain, function, and quality-of-life levels in participants with chronic LBP. A total of 113 participants diagnosed with chronic LBP were enrolled in the study and allocated into the spinal stabilization group or manual therapy group randomly. While SSEs were performed in the spinal stabilization group, soft tissue mobilizations, muscle energy techniques, joint mobilizations, and manipulations were performed in the manual therapy group. While the severity of pain was assessed with the VAS, Oswestry Disability Index (ODI), and 36-Item Short Form Health Survey (SF-36), assessments were performed to evaluate functional status and quality of life. 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 quality of life, while manual treatment is more effective on the pain and functional parameters. Additional RCTs, with longer-term outcomes, are needed to evaluate manual therapies in the treatment of chronic LBP.

In a systematic review and meta-analysis, Paige et al. (2017) evaluated the effectiveness of SMT for acute ( $\leq 6$  weeks) LBP. The study quality was assessed using the Cochrane Back and Neck risk-of-bias tool. Pain [measured by either the 100-mm VAS, 11-point numeric rating scale (NRS), or other numeric pain scale], function [measured by the 24-point Roland Morris Disability Questionnaire or ODI (range, 0-100)], or any harms were measured within 6 weeks. Of 26 eligible RCTs identified, 15 RCTs (1,699 individuals) provided moderate-quality evidence that SMT has a statistically significant association with improvements in pain (pooled mean improvement in the 100-mm VAS pain, -9.95; 95% CI, -15.6 to -4.3).

According to the authors, among individuals with acute LBP, SMT was associated with modest improvements in pain and function at up to 6 weeks, with transient minor musculoskeletal harms. However, heterogeneity in the study results was large. Another limitation of this study is 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 LBP and pelvic girdle pain during and after pregnancy. Of 102 studies, five examined OMT for LBP during pregnancy, and three examined OMT postpartum. The authors found moderate-quality evidence suggesting that 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 suggests that 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 the treatment of pregnancy-related or postpartum LBP, the authors' findings included small sample sizes, mixed studies of different designs, duplicate data, the lack of long-term follow-up, and use of both OMT and non-osteopathic manual therapies, 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, 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 LBP, there is limited evidence that spinal manipulation is associated with some beneficial effects vs 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 LBP. The assessment and reporting of harms for nonpharmacological 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 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 an RCT to investigate the impact of combined physiotherapeutic scoliosis-specific exercises (PSSEs) and manual therapy on trunk deformity, spinal function, mobility, and mental health in participants with adolescent idiopathic scoliosis (AIS). Overall, 31 participants who were diagnosed with AIS and had a Cobb angle between 10° and 45° were enrolled in the study. Participants in the intervention group received 50 minutes of PSSE combined with 10 minutes of manual therapy, while the control group performed 50 minutes of PSSE as their HEP. Both treatments were implemented three times a week for 4 weeks. Cobb angle, spinal mobility, trunk morphology (vertebral rotation angle, apical deviation, and pelvic obliquity distance and angle), movement capability, and quality of life were assessed at baseline and post intervention. The treatment effects between the intervention and control groups were analyzed using a two-way repeated measures analysis of variance (ANOVA). Following a 4-week treatment period, the Cobb angle was reduced from 21.58° to 18.58° in the 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 with baseline ( $p < 0.05$ ). Improvements were higher in the intervention group than in the control group. The authors concluded that combining PSSE and manual therapy shows potential benefits in alleviating AIS symptoms and improving quality of life. Further studies to substantiate these findings are warranted. The results of the present study should be interpreted with caution due to the limitations. The absence of a control group, comprising either a general exercise group or individual PSSE and manual therapy training groups, limits the direct comparisons, which hinders the interpretation of 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.

Pu Chu et al. (2020) conducted a retrospective chart review to investigate the role of chiropractic intervention in patients with AIS. Ten patients with AIS, with a mean age of 13.3 years, who were undergoing chiropractic adjustment were retrospectively evaluated. A chart review was performed to extract age, medical history, and treatment intervention. The magnitude of scoliosis was quantified using the Cobb method on standing radiographs. A comparison of the measurements from pre- and posttreatment radiographs revealed that the Cobb angle reduced from an average of 29.7° down to an average of 23.4° (average 21.2% correction). Improvements in spinal morphologies were observed in most curves (64%;  $n = 9/14$ ), and curve stabilization was observed in the rest (36%;  $n = 5/14$ ). A better correction was obtained in cases of mild and moderate AIS. In terms of stabilizing progression ( $\leq 5^\circ$  curve progression) or correcting curvatures ( $\geq 6^\circ$  reduction), radiological changes were observed in all patients. This study was limited by a small sample size, retrospective design, and absence of a control or sham treatment group. In addition, all radiographs were measured by

one of the authors, and no interobserver performance in Cobb angle measures was obtained. These risks of bias can threaten the validity of results and affect conclusions.

In a systematic review to evaluate the current body of literature on the chiropractic treatment of idiopathic scoliosis, Morningstar et al. (2017) identified 15 case reports, 10 case series, one prospective cohort study, and one RCT. Of the 27 studies, only two described their outcomes, as recommended in a 2014 SOSORT (Society on Scoliosis Orthopedic and Rehabilitation Treatment) and the SRS Non-Operative Management Committee consensus paper. The consensus paper details the format and types of outcomes that they collectively believe are the most important and relevant to the individual. Among the chiropractic studies located in this review, two described outcomes consistent with how SOSORT recommends that they be reported. Given that the 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 methodological 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**

Studies of SMT have shown improvement in chronic neck pain, but there are limited data to support its effect on acute neck pain (ANP). In this systematic review and meta-analysis of eight RCTs, with 965 individuals, Diao et al. (2025) investigated the efficacy and safety of SMT for the treatment of ANP. MDs with 95% CIs were computed to evaluate outcomes, including pain intensity, cervical range of motion (ROM), and disability. Methodological quality and evidence strength were assessed using the PEDro scale, with scores ranging from 4 to 9 (mean, 6.38; SD, 1.25), and the GRADE framework. A study analysis indicated that SMT outperformed the control group in reducing pain (MD, -1.53; 95% CI, -2.22 to -0.83), improved all aspects of cervical ROM, and significantly lowered disability scores (MD, -6.20; 95% CI, -9.81 to -2.59). The authors concluded that while this study has shown SMT for ANP to be a promising treatment option, additional studies, with improved standardization of interventions, larger sample sizes, longer follow-up periods, and blind assessments, are needed.

In a 2023 systematic review and meta-analysis of RCTs, Liu et al. sought to determine the effectiveness of manipulative therapy for chronic neck pain. Overall, 17 articles, comprising 1,190 individuals with chronic neck pain for more than 3 months and in whom manipulative therapy was the primary treatment, were included. The results showed that for the overall effects of pain intensity, manipulative therapy resulted in significantly decreased pain intensity and disability compared with exercise and control groups, with no significant differences in adverse events reported. The authors concluded that despite the high heterogeneity in treatment outcomes, manipulative therapy is effective in relieving chronic neck pain and disability. Future research should include the impact of the selection of individuals 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 individuals with nonspecific neck pain. Five articles were included in the review, and none of these were completely judged to be at a low risk of bias. Four of these were included in the meta-analysis. Osteopathic interventions, compared with no intervention/sham treatment, showed statistically noteworthy results for pain levels (effect size, -1.57; -2.50 to -0.65;  $p = 0.0008$ ) and functional status (effect size, -1.71; -3.12 to -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 nonspecific neck pain. However, these findings are affected by a very low quality of evidence. Further research, with RCTs, is needed to validate these findings. (Haller et al., 2016, and Groisman et al., 2020, previously cited in this policy, are included in this systematic and meta-analysis review.)

In an RCT, Groisman et al. (2020) assessed the effectiveness of OMT combined with stretching and strengthening exercises in the cervical region in participants with nonspecific chronic neck pain. This single-blinded trial randomized 90 participants into two groups: either an exercise-only group or an exercise combined with OMT group. The study included weekly exercise and/or OMT for 4 weeks. The primary outcomes were pain and disability, which were evaluated by the NPRS and Neck Disability Index. The secondary outcomes included pressure pain threshold (PPT), ROM, Fear-Avoidance Beliefs Questionnaire, and Pain Self-Efficacy. The authors found that 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 Neck Disability Index scores. There were no significant differences in the secondary outcomes. Limitations include the lack of long-term effects and difficulty in blinding participants with osteopaths; additionally, those who received OMT had increased contact with osteopaths, leading to a potential placebo effect.

Leaver et al. (2010) conducted an RCT comparing manipulation with mobilization for the 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 2 weeks. Outcomes were measured by the number of days taken to recover from the episode of neck pain. The median days to recovery was 47 for the manipulation group and 43 for the mobilization group. The authors concluded that manipulation was no more effective than mobilization in treating the recent onset of neck pain. A potential limitation of this study is the inability to blind practitioners and participants to treatment allocation.

## **Extremity Disorders**

### ***Shoulder***

In an RCT, Iqbal et al. (2020) compared the effects of the Spencer muscle energy technique (SMET) and passive stretching in 60 participants with idiopathic frozen shoulder or a stiff painful shoulder joint for at least 3 months. The participants were randomized into two equal groups. Group 1 contained participants who were treated with a hot pack for 7 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 4 weeks. Group 2 contained participants who were treated with a hot pack for 7 to 10 minutes and then received specific passive stretching exercises. The shoulder was stretched and rotated for 20 seconds, with a 10-second rest interval; this was then repeated 10 times over the course of three sessions per week, every other day. Shoulder pain was assessed with the NPRS, which assessed 11 items ranging from 0 (no pain) to 10 (worst pain). The authors found that the SMET was more effective than passive stretching for decreasing shoulder pain and increasing ROM. Limitations include the short duration of the study and lack of appropriate registration with trial 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 with shoulder pain. Participants were randomized into either the intervention group that received osteopathic treatment or a control group (which remained untreated for 8 weeks but was later treated with osteopathic treatment on conclusion of the study). The main outcome was shoulder pain, and this was assessed using the standard VAS for self-pain measurement. The secondary outcomes were specific shoulder pain and disability, determined by the Shoulder Pain and Disability Index (SPADI), and quality of life, assessed by an SF-36 generic questionnaire. Participants in the intervention group received five osteopathic examinations and treatments of 40 to 60 minutes each delivered every 2 weeks for 8 weeks. Before each visit and 2 weeks after the last visit, the VAS and SPADI were completed. The SF-36 generic questionnaire was completed at 4 and 10 weeks. The control group was required to fill out the VAS, SPADI, and generic questionnaire at their baseline visit and was then told that they would be placed on the waiting list for osteopathic treatment to be scheduled 8 weeks later. In both groups, on-demand pain medication was allowed. In the control group, 21 participants had no change in their pain, and only eight participants had improvement; in comparison, the intervention group had a decrease in pain frequency in 33 participants. The secondary outcome measures had similar findings between the two groups; improvement in quality of life was seen in the intervention group but not the control group. The authors concluded that osteopathic treatments over a defined period might be beneficial for individuals with shoulder pain, but further studies are needed to validate this finding. Limitations include 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 ROM in adults with shoulder impingement syndrome. For pain, exercise was superior to nonexercise control interventions, but when manual therapy was combined with exercise, it was superior to just exercise alone. Limitations include broad clinical diversity, the lack of control groups, varying length of follow-up, heterogeneity, and trials with a high risk of bias. Even though the authors found that the quality of evidence is low, exercise should be considered for individuals 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 with that of placebo, no intervention, or other therapies, Page et al. (2016) did not identify any clinically important differences between groups in any outcome. The authors recommended 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 on a strong rationale and consideration of whether they would alter the conclusions of their review.

### ***Elbow, Wrist, and 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 (< 3 months) and intermediate term (up to 6 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 quasiconrolled trial to evaluate the effectiveness of OMT in the management of carpal tunnel syndrome. Participants underwent weekly OMT sessions for 6 consecutive weeks. The main outcome measures were the Boston Carpal Tunnel Syndrome Questionnaire, a sensory symptom diagram, a participant estimate of overall change, electrophysiological testing of the median nerve (transcarpal 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 carpal tunnel syndrome. 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 an unknown participant population and short follow-up period.

## ***Hip Osteoarthritis***

Terrell et al. (2022) conducted a two-group RCT to determine whether a single session of OMT or OMT plus osteopathic cranial manipulative medicine (OCMM) can improve the gait of participants with Parkinson disease (PD) by addressing joint restrictions in the sagittal plane and by increasing ROM in the lower limb. A total of 90 participants, participants with PD (n = 45) and age-matched healthy control participants (n = 45), were included in this RCT. Participants with PD were included if they were otherwise healthy, able to stand and walk independently, had not received OMT or physical therapy within 30 days of data collection, and had idiopathic PD in Hoehn and Yahr stages 1.0 to 3.0. Participants with PD were randomly assigned to one of three experimental treatment protocols: a whole-body OMT (OMT-WB) protocol, which included OMT and OCMM techniques; a neck-down OMT protocol, including only OMT techniques; and a sham treatment protocol. Control participants were age matched to a participant with PD and were provided with the same OMT experimental protocol. An 18-camera motion analysis system was used to capture three-dimensional 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, which is a type of waveform analysis. Participants with PD had reduced hip and knee extension in the stance phase compared with controls (32.9%-71.2% and 32.4%-56.0% of the gait cycle, respectively). Participants 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, neck-down OMT, or sham treatment protocols. The authors concluded that 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 plus 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). The 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.

An RCT by Hoeksma et al. (2004) evaluated 109 participants with OA of the hip to compare the effectiveness of manual therapy (n = 56) with that of exercise therapy (n = 53), with a mean participant 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 5 weeks (nine sessions). The outcomes were measured by general perceived improvement after treatment, level of pain, hip function, walking speed, ROM, and quality of life. No major differences were found in baseline characteristics between groups. Success rates (primary outcome) after 5 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 for pain, stiffness, hip function, and ROM, with results maintained after 29 weeks. The authors concluded that manual therapy is superior to exercise therapy for individuals with OA of the hip.

## ***Knee Osteoarthritis***

Zhou et al. (2022) conducted a systematic review to highlight the therapeutic benefits that OMT can have in the postoperative management of total knee arthroplasty with respect to ROM, 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. Overall, 18 studies met the inclusion criteria and encompassed a wide variety, with the majority of studies performed being prospective studies (10), followed by case reports (three), cross-sectional studies (two), literature reviews (two), and case-control studies (one). Among the prospective studies, the sample sizes ranged from 43 individuals to 621 individuals. Two cohort studies were used, with a sample size of 8,325 individuals. 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, and mobility. The authors concluded that the use of OMT would positively influence ROM by manipulation of localized musculature and that it can result in decreased demand for analgesics. This can, in turn, shorten hospital stay and return the ability of individuals 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. (Licciardone et al., 2004, previously cited in this policy, is included in this systematic and meta-analysis review.)

An RCT was performed by Reza et al. (2021). It had a two-arm, parallel-group design, with a total of 32 participants with known knee OA. Group A received a supervised exercise protocol; group B received specified manual therapies in combination with a supervised exercise protocol. Pain intensity and functional disability were the primary outcomes and were assessed with the NPRS and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The data were collected at baseline, 2 weeks, and 4 weeks post intervention; all data were collected by the same assessor who was blinded 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 2 weeks. Group B received a myofascial mobilization technique 10 times/session every other day for 2 weeks. The outcomes for NPRS and the WOMAC demonstrated superiority for group B over group A. The authors concluded that group B's interventions were found to be more effective than group A's for improving the pain intensity and functional status in participants with knee OA. Future studies are suggested to study the retention effects of the intervention protocols. Limitations include the short intervention time frame, small sample size, and lack of observation for long-term data. The study was limited due to the availability of the intervention protocols, and the interventions could not be carried out for a long period, such as 4 to 8 weeks. Future research is recommended to include studies that measure long-term effects and retention effects.

Altinbilek et al. (2018) conducted a single-blinded RCT to compare the efficacy of OMT with that of exercise treatment in knee OA. A total of 100 participants (nine male; 76 female; mean age, 54.8 ±8.5 years; range, 40-70 years) with stage II to 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 WOMAC pain score, WOMAC joint stiffness score, WOMAC physical function score, the VAS, and 50-m walking time were evaluated. All participants were assessed at the beginning of the study, just after the treatment, and 4 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. Overall, 15 participants (exercise group: nine; OMT plus exercise: six) dropped out of the study, leaving 85. Results showed no difference between groups in terms of physical examination and clinical assessment parameters before treatment. On completion, functional improvement (p < 0.05) and pain relief (p < 0.05) were higher in the exercise plus 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-term 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 vs several different comparators for improvement in self-reported knee function. As lesser support is present for pain reduction, the authors could not 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 of bias and high treatment fidelity.

## ***Ankle and Foot***

Plaza-Manzano et al. (2016) conducted a randomized, single-blinded, controlled clinical trial to analyze the effects of proprioceptive strengthening exercises vs those of the same exercises and manual therapy in the management of recurrent ankle sprains (n = 56). The control group performed 4 weeks of proprioceptive strengthening exercises; the experimental group performed 4 weeks of the same exercises combined with manual therapy (mobilizations to influence joint and nerve structures). Pain, self-reported functional ankle instability, PPT, ankle muscle strength, and active ROM were evaluated in the ankle joint before, just after, and 1 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 than 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 night splints for symptomatic mild to moderate hallux abductor valgus. Overall, 30 participants were equally assigned to each group. The control group used night splints, while the experimental group (MMT) received four MMT treatments over a 2-week period. The outcomes were measured with the VAS, Foot Function Index, and hallux dorsiflexion. Outcome measure scores in the control group (night splint) regressed between the 1-week follow-up and 1-month follow-up when participants did not use the night splint, while the scores in the experimental group (MMT) were sustained up to the 1-month follow-up. The authors concluded that a structured protocol of MMT is equivalent to standard care of night splints for symptomatic mild to moderate hallux abductor valgus in the short term.

Cleland et al. (2009) conducted a multicenter randomized clinical trial in 60 participants with plantar heel pain to compare the effectiveness of electrophysical agents and exercise, which included iontophoresis, with dexamethasone and stretching of the gastrocnemius muscle and/or plantar fascia or a manual physical therapy and exercise, 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 up for 6 months. The outcomes were measured using several participant self-report questionnaires, including the Lower Extremity Functional Scale, Foot and Ankle Ability Measure, and the NPRS. The primary aim (effects of treatment on pain and disability) was examined with a mixed-model ANOVA. Both groups had a significant improvement over time; however, the participants in the manual physical therapy and exercise group experienced greater clinical benefits in terms of function and pain than the participants in the electrophysical agents and exercise group.

## **Headache**

Posadzki et al. (2024) performed a systematic review and meta-analysis of six randomized clinical trials to evaluate the effectiveness of SMT as a treatment for migraine headaches. The trials included 645 individuals who had migraine attacks. The outcomes included migraine duration, quality of life, pain intensity/severity, number of migraine days, disability, and adverse effects at 12-month follow-ups. According to the review, the GRADE approach was used, and all outcomes were judged to be an extremely low quality of evidence. The authors found that SMT has no effect on migraine intensity/severity, migraine duration, or emotional quality of life compared with controls such as usual care, drug therapy, and placebo. Limitations of the review include uncertainty regarding the comprehensiveness of the literature search, small study groups, limited follow-up, and significant statistical heterogeneity in migraine severity and intensity outcomes that is attributable to methodological and clinical differences across study populations and interventions. The authors concluded that the treatment of migraine attacks with SMT is not supported by evidence-based research; additionally, future studies, with larger RCTs, more rigorous methodology, and comparisons to established headache treatments such as lifestyle changes, physical therapy, cognitive behavior therapy, or pharmacotherapy, are needed. Chaibi et al. (2017b), which was previously cited in this policy, is included in Núñez-Cabaleiro and Leirós-Rodríguez (2022) and Rist (2019).

Núñez-Cabaleiro and Leirós-Rodríguez (2022) conducted a systematic review to identify the manual therapy methods and techniques that have been evaluated for the treatment of cervicogenic headache and their effectiveness. Two reviewers independently screened 365 articles for demographic information, characteristics of the 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 RCTs, and three were quasiexperimental studies published from 2015 to the present that studied interventions with manual therapy techniques in individuals with cervicogenic headache. The techniques studied were SMT, Mulligan 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 SMT to the treatment can maintain long-term results. The authors concluded that manual therapy techniques could be effective in the treatment of individuals with cervicogenic headache. The combined use of manual therapy techniques improved the results compared with using them separately. This review has methodological limitations, such as the inclusion of quasiexperimental studies and studies with small sample sizes that reduced the generalizability of the results obtained. Further investigation is needed before the clinical usefulness of this procedure is proven. (Chaibi et al., 2017, previously cited in this policy, is included in this systematic review.)

Rist et al. (2019) performed a systematic review and meta-analysis of published 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 individuals eligible for meta-analysis. The outcomes included measures of migraine days, migraine pain/intensity, and migraine disability. The methodological quality varied across the studies. For example, some studies received high or unclear bias scores for methodological features such as adherence, 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. (Chaibi et al., 2017a/b, previously cited in this policy, is included in the Rist et al., 2019, and Rani et al., 2019, meta-analyses.)

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 individuals with cervicogenic headache.

The effectiveness of mobilization and manipulation was compared with that of other conservative treatments on reducing pain intensity, frequency, and disability in individuals with cervicogenic and tension-type headaches in a systematic review and meta-analysis (Coelho et al., 2019). Nine RCTs, totaling 793 individuals, 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 in the short term (up to 4 weeks) and like other interventions at 3 months of follow-up in 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 individuals with tension-type headache, migraine, or cervicogenic headache (Maistrello et al., 2019). Manual therapy obtained more favorable, clinically significant effects than usual care and placebo in terms of quality of life in individuals 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 in the most influential studies. In individuals 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."

## **Temporomandibular Joint Disorders**

The available evidence for the use of manual therapy in the treatment of temporomandibular joint (TMJ) disorders is insufficient to consider the procedure safe and effective; additional quality, long-term RCTs 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. Multiple treatments for this condition were evaluated and included the results for manual therapy compared with conservative treatments. Overall, 202 individuals with disc displacement with reduction included in three RCTs, with follow-up time ranging from 2 weeks to 4 months, were included. The results showed that individuals who received manual therapy experienced a significantly greater reduction in TMJ pain than those who received conservative therapy. This meta-analysis was limited by the small numbers of individuals in the included RCTs, and research with larger numbers is needed to validate these findings.

Dunning et al. (2024) conducted a multicenter RCT to compare the effects of dry needling and upper cervical spinal manipulation with those of interocclusal splint therapy, diclofenac, and TMJ mobilization in participants with temporomandibular disorder (TMD). Overall, 120 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 7 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 3-month follow-up. The authors concluded that dry needling plus upper cervical spinal manipulation was more effective than interocclusal splint therapy, diclofenac, and TMJ mobilization in participants 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 postgraduate 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 for others, which may have caused some variability in the comparison group. The findings of this study need to be validated by well-designed studies. Further investigation is needed before the 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 in the reduction of pain, PPTs, and increase in maximal mouth opening (MMO) compared with that of sham or other interventions in adults with TMD. Eight RCTs, with 437 individuals, evaluating manual therapy vs sham and manual therapy vs other interventions were included. The results for manual therapy compared with sham intervention were included in two trials and showed that manual therapy reduced pain intensity; results of three trials showed that manual therapy significantly increased MMO but did not significantly reduce PPTs. Compared with other interventions, which did not specify the type of mobilization or manipulation performed, manual therapy reduced pain and improved MMO, with no significant improvement in the PPTs. The authors concluded that manual therapy of the upper cervical spine does not significantly reduce symptoms of TMD compared with 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 [craniomandibular manual therapy (CMMT)] on pain and MMO in people with TMDs. RCTs, from inception until October 2020, comparing the effect of CMMT on pain and MMO vs other types of treatment in TMDs were included. 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 GRADE. A total of 2,720 records were screened, of which only six (293 individuals) satisfied the inclusion criteria. All studies showed improvement in pain and MMO for CMMT from baseline in the mid-term, but only two showed superiorities compared with other interventions. A quantitative synthesis was not performed. The authors concluded that there is a need for future high-methodology research investigating different manual therapy techniques applied to different regions and different populations (e.g., chronic vs acute TMD) to determine what is most effective for pain and MMO in individuals with TMDs. This study was limited by its heterogeneous population of individuals, risk of bias, and small sample sizes. Further research is needed to determine the clinical relevance of these findings. (Brochado et al., 2018, previously cited in this policy, is included in this systematic review.)

Detoni et al. (2022) conducted a randomized controlled, double-blinded study to assess the effect of OMT of the TMJ and the orthostatic posture, using the molar shim (MS) as a postural adjustment factor. Overall, 20 participants diagnosed with TMD were randomly assigned to a treated group (n = 10) and placebo (n = 10). The independent variables were MS and OMT of the TMJ. The dependent variables were data on TMD diagnostic criteria; 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 between the groups in the postintervention 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 postintervention moment. The results of the MS pointed to a decrease ( $p \leq 0.05$ ) in the average peak pressure (medium P) during the use of the MS ( $503.4 \pm 44.1$  kgf/cm<sup>2</sup>) and after performing the OMT ( $516.5 \pm 49.6$  kgf/cm<sup>2</sup>), both for the treated group compared with the preintervention moment ( $519.3 \pm 42.9$  kgf/cm<sup>2</sup>). 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 include that the dysfunctional side of the TMJ was not addressed and that ROMs and masticatory predominance were not part of the pre- and postintervention 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 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 seemed to decrease over time, unless manual therapy was paired with therapeutic exercise, which seemed 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 that due to the low number of studies and the variability in each, 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 an RCT to evaluate the efficacy of mandibular manipulation therapy used for the treatment of participants with TMDs and mouth-opening limitations. Overall, 61 participants with TMD who had a mouth-opening limitation (upper and lower middle incisor distance of 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 behavior therapy for bruxism and education. Mouth-opening limitation, orofacial pain, and TMJ sounds were recorded from baseline to 18 weeks after baseline. These parameters were statistically compared between the two treatment groups by using ANOVA and the Scheffe test to assess mouth-opening distance and pain; TMJ sounds were compared using the 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 and manual therapy, alone or combined, on pain intensity, mandibular movement, psychosocial aspects, and anxiety in participants with TMDs. Overall, 51 participants were randomized; 18 received photobiomodulation, 16 received manual therapy, 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 that 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 SMT and its efficacy and effectiveness in preventing or improving the immune system and infectious disease outcomes. The analysis included 529 individuals from eight high-quality articles. While SMT has been associated with immediate changes in the levels of selected immunologic biomarkers, the duration of these changes and their clinical significance are unknown. The authors concluded that the evidence analyzed neither supported nor refuted the effectiveness of SMT and its association with lymphocyte levels among individuals with LBP; further studies of high-quality RCTs are warranted. Limitations include that only English-published studies were included and that study screening was performed by only one investigator rather than two.

Eklund et al. (2019) conducted a pragmatic, multicenter, randomized trial to investigate whether participants in specific psychological subgroups had different responses to maintenance care (MC) regarding the total number of days with bothersome pain and the number of treatments. A total of 328 participants, who were aged 18 to 65 years between 2012 and 2016 and from chiropractic clinics in Sweden, were recruited. Participants with recurrent and persistent LBP seeking chiropractic care, with a good effect of the initial treatment, were included and analyzed using a generalized estimating equation linear regression framework. Eligible participants were randomized to either MC (n = 166) or to the control intervention of symptom-guided care (n = 162). Participants were then categorized and placed into the adaptive copier, interpersonally distressed, and dysfunctional subgroups. The primary outcome of the trial was the total number of days with bothersome LBP, which was collected weekly for 12 months using an automated SMS (text message) system. Data used to classify participants according to psychological subgroups, defined by the West Haven-Yale Multidimensional Pain Inventory, were collected at the screening visit. Participants in the dysfunctional subgroup who received MC reported fewer days with pain (-30.0; 95% CI, -36.6 to -23.4) and an equal number of treatments compared with the control intervention. In the adaptive copier subgroup, participants who received MC reported more days with pain (10.7; 95% CI, 4.0-17.5) and more treatments (3.9; 95% CI, 3.5-4.2). Participants in the interpersonally distressed subgroup reported an equal number of days with pain (-0.3; 95% CI, -8.7 to 8.1) and more treatments (1.5; 95% CI, 0.9-2.1) with MC. The authors concluded that psychological and behavioral characteristics modify the effect of MC and should be considered when recommending long-term preventive management in individuals with recurrent and persistent LBP. Limitations include physicians who were unblinded to the treatment assignment. Even though the physicians were instructed to behave the same toward all participants, this may have resulted in different behaviors and procedures in each of the two treatment arms. In addition, the trial was not primarily designed for the subgroup analysis, which may have resulted in a theoretically underpowered design that was subject to bias from random error. As a result, secondary analyses are generally considered to be hypothesis generating rather than confirming, given the limitations regarding statistical power and design. The findings of this trial need to be validated by well-designed studies. Further investigation is needed before the clinical usefulness of MC is proven.

Eklund et al. (2018) conducted a pragmatic RCT to investigate the effectiveness of chiropractic MC vs that of symptom-guided treatment in participants with recurrent and persistent LBP who had an early favorable response to chiropractic care. After an initial course of treatment, eligible participants were randomized to either MC (n = 166) or control (symptom-guided treatment; n = 161). The primary outcome was the total number of days with bothersome LBP during 52 weeks, collected weekly with text messages and estimated by a generalized estimating equation model. Of the participants who were eligible after the first visit, 32% were lost, and of the participants who were eligible at the fourth visit, 25% were lost. During the 12-month study period, the MC group (n = 163; three dropouts) reported 12.8 (95% CI, 10.1-15.5 days; p < 0.001) fewer days in total with bothersome LBP compared with the control group (n = 158; four dropouts) and received 1.7

(95% CI, 1.8-2.1;  $p < 0.001$ ) more treatments. The 12.8% reduction from MC did not meet the prespecified clinically meaningful difference of 20% for acute LBP and 30% for chronic LBP. The authors concluded that for selected individuals with recurrent or persistent nonspecific LBP who respond well to an initial course of chiropractic care, MC should be considered as an option for tertiary prevention. Further research is likely to have an important impact on the confidence in the estimate of effect of MC and may change the estimate. Limitations include the lack of a sham intervention and possibility of social desirability in the participants' reports of symptoms.

An RCT by Senna and Machaly (2011) investigated the effects of maintenance SMT for chronic nonspecific LBP. Participants were randomized into three groups and followed up for 10 months. Group 1 ( $n = 40$ ) received sham manipulation during the first month and no treatment over the subsequent 9 months. Group 2 ( $n = 27$ ) received manipulation during the first month but no treatment during the following 9 months. Group 3 ( $n = 26$ ) received manipulation during the first month and maintenance manipulation every 2 weeks for an additional 9 months. At the end of 10 months, 33 participants declined follow-up. Five withdrew in the first phase before treatment began. Of the remaining 88 participants, 80 were evaluated at 4 months, 71 at 7 months, and 60 at 10 months. Participants in groups 2 and 3 experienced significantly lower pain and disability scores than the control group after the initial 1-month treatment period. At the end of 10 months, group 3 reported significantly lower pain and disability scores than group 2. The authors concluded that spinal manipulation is an effective treatment for chronic nonspecific LBP. 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 such as the 35% dropout rate; incomplete outcome data; lack of blinding; and uncertainty about allocation concealment, use of cointerventions, and adherence across groups.

### **Nonmusculoskeletal Disorders (e.g., Asthma, Otitis Media, Infantile Colic)**

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 individuals receiving manual therapy interventions, additional high-quality research, such as long-term RCTs and comparative studies, is needed to validate these findings.

This scoping review by Tedeschi and Giorgi (2025) explored the evidence on manual therapy interventions for infantile colic. The research question focused on delineating the scope and nature of RCT evidence regarding hands-on therapies for infants under 6 months of age who were diagnosed with colic. The inclusion criteria required individuals to be otherwise healthy infants aged 0 to 6 months, with colic confirmed by the Wessel rule of threes or Rome IV criteria. Eligible studies evaluated manual therapy interventions delivered in health care or home settings, specifically assessing abdominal massage, pediatric tuina, craniosacral therapy (CST), chiropractic manipulation, osteopathic light touch, reflexology, and acupressure. Seven RCTs were included, collectively measuring outcomes such as crying duration and frequency, sleep duration, parent-reported improvement, and safety/adverse events. The findings indicate that low-force manual therapies may provide modest short-term relief of colic symptoms and enhance parental experience. However, the certainty of these effects is constrained by methodological variability, small sample sizes, and inconsistent reporting across studies. Limitations of the evidence base include the absence of meta-analysis, potential recall bias in parent-reported outcomes, inadequate blinding, and overall limited sample sizes. These factors restrict the generalizability and strength of conclusions drawn. Clinical implications suggest that while the current evidence offers cautious but valuable insights into manual therapy for infantile colic, the overall quality remains limited. The review recommends that future research prioritize standardized intervention protocols, objective outcome measures, and robust adverse event surveillance to enhance reliability and clinical relevance. The authors concluded that manual therapy interventions for infantile colic represent a growing area of interest, but further high-quality research is needed to establish efficacy and safety with greater confidence.

Rowane et al. (2025) conducted a prospective single-blinded study to assess the immediate and sustained relief of chronic rhinosinusitis (CRS) symptoms with the implementation of OMT focused on lymphatic drainage of cranial structures. The study was conducted at a single facility and included 43 participants with CRS who did not respond to conventional medical therapy and who had prior OMT. Overall, 22 participants were assigned to the OMT group that underwent sequential treatments, while a structural examination involving light touch was applied to the 21 control group participants. Both groups were assessed using a four-item, 5-point Likert scale survey. A paired t test was used to statistically compare pre- and postintervention survey responses. The investigators reported that all participants (100%) completed the surveys administered immediately before and after the intervention; however, only 60.5% of participants completed the follow-up survey conducted 10 days post intervention. Pre- and immediate postsurvey results in the OMT group showed a statistically significant decrease in the severity of facial or sinus pain or pressure ( $p = 0.0004$ ), nasal congestion ( $p = 0.001$ ), and postnasal drainage ( $p = 0.002$ ) vs the control group, with no statistically significant difference (average  $p = 0.32$ ). The comparison of pre- vs 10-day postsurvey results for both groups revealed no evidence of a statistically significant difference (OMT average  $p = 0.28$  and control group average  $p = 0.22$ ). The authors concluded that

while the study did show that OMT may improve immediate CRS symptoms, additional studies that address long-term outcomes are needed. Limitations, according to the authors, were the location, limited racial diversity, lack of a standardized scale, high rate of attrition, and duration variability of each encounter.

Hope-Bell et al. (2024) conducted a mixed-methods feasibility RCT evaluating the efficacy of four osteopathic interventions on psychophysiological and mental health outcomes. A mixed-methods feasibility study that had an explanatory sequential design was implemented. The quantitative phase involved randomizing 42 participants into four intervention groups: (1) high-velocity and articulation techniques, (2) soft tissue massage, (3) CST, and (4) a combination approach. The primary outcome measures encompassed recruitment rate, assessment duration, questionnaire completion, intervention attrition, and adverse events. The secondary outcomes included validated assessments of depression, anxiety, stress, psychological flexibility, heart rate variability (HRV), and interoception, administered prior to and post intervention. ANOVA was used to evaluate pre-post intervention changes. The qualitative phase comprised semistructured 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 1-hour time frame, with full questionnaire completion. The attrition rate was 21%. No adverse events were reported. A 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 HRV, 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-term follow-up did not allow for assessment of intermediate- and long-term outcomes. Further research, with RCTs, is needed to validate these findings.

Pala et al. (2024) conducted a randomized, double-blinded, placebo-controlled trial to evaluate the effectiveness of the osteopathic sympathetic harmonization (OSH) on the sympathetic nervous system and hypothalamic-pituitary-adrenal axis in youth with major depressive disorder. The study included 39 youths aged 15 to 21 years who were diagnosed with major depressive disorder. The participants were randomly assigned to 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, State Anxiety Inventory, and Trait Anxiety Inventory before the application. Blood pressure and pulse measurements were made, and saliva samples were taken before, immediately after, and 20 minutes after application. The baseline Beck Depression Inventory ( $p = 0.617$ ) and Trait Anxiety Inventory ( $p = 0.322$ ) scores were similar in both groups. Although the State Anxiety Inventory scores decreased in both groups post intervention, no statistical difference was found between the two groups. Participants who received OSH had a decrease in  $\alpha$ -amylase level ( $p = 0.028$ ) and an increase in cortisol level ( $p = 0.009$ ) 20 minutes after the procedure. The authors concluded that following OSH application in youths with depression, sympathetic nervous system activity may decrease, whereas hypothalamic-pituitary-adrenal axis activity may increase. Future studies may examine the therapeutic efficacy of repeated OSH applications in individuals with depression. This study has limitations. The first limitation is that mechanoreceptors sensitive to touch and pressure were stimulated, creating the same input to the cortex, in both groups. The second limitation is that any intervention to the ribs may have affected 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 a 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 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 RCTs and retrospective studies with OMT compared with any kind of control in term or preterm infants to improve gastrointestinal disorders. Nine articles met the eligibility criteria, investigating OMT compared with no intervention, with five involving term infants; the remaining studies treated preterm infants. Five studies showed a 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 (effect size, -2.46; -3.05 to -1.87;  $p < 0.00001$ ). The 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 a lack of high-quality replication studies prevent generalization. This systematic review and meta-analysis is limited by its heterogeneous population of individuals. Further research, with RCTs, is needed to validate these findings. (Castejón-Castejón et al., 2019, previously cited in this policy, is included in this systematic and meta-analysis review.)

Franke et al. (2022) conducted a systematic review to determine the effectiveness of OMT for all pediatric concerns. Overall, 47 RCTs, examining 37 pediatric conditions, were reviewed. These conditions included musculoskeletal, visceral, ear, and respiratory conditions as well as cerebral palsy and learning difficulties. Overall, 23 studies reported favorable outcomes with OMT relative to the control intervention, and 14 additional studies reported nonsignificant outcomes, which suggested potential favorable effects of OMT. Overall, 15 of the studies were judged to have a low risk of bias, 12 had high risk, and the remainder had indeterminate risk of bias. There was moderate evidence for the effectiveness of OMT for 13 of the 43 comparisons, particularly for length of hospital stay in preterm infants, but no high-quality evidence was found for any condition. The authors concluded that although a number of studies indicated positive results with the use of OMT, few pediatric conditions have been investigated in more than one study, which results in no high-quality evidence for any condition. Additional research may change estimates of effect, and larger, high-quality RCTs focusing on a smaller range of conditions are recommended. However, further research is needed that confirms this hypothesis. (Castejón-Castejón et al., 2019, previously cited in this policy, is included in this systematic review.)

Rehman et al. (2022) conducted a systematic review to evaluate the safety and effectiveness of 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 the 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 ( $n = 141$ ; MD, -11; 95% 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 dropout rates (odds ratio, 2.2; 95% CI, 0.5-10.2;  $p = 0.31$ ). When data were pooled for any type of OMT technique, the findings were similar; however, disability associated with dizziness and all case dropout rates had high heterogeneity ( $I^2 = 59$  and 46%). No studies met all the criteria for risk of bias. The authors concluded that 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;  $n = 367$ ) 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 SMT for the primary, secondary, and tertiary prevention of nonmusculoskeletal disorders. The global summit took place on September 14 to 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, CINAHL, 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 nonmusculoskeletal disorders. Eligible for review were RCTs published in English. The methodological quality of eligible studies was assessed independently by reviewers using the Scottish Intercollegiate Guidelines Network criteria for RCTs. The authors synthesized the evidence from articles with high or acceptable methodological quality according to the Synthesis Without Meta-Analysis 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 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 nonmusculoskeletal disorders. A 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 nonmusculoskeletal 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 nonmusculoskeletal disorders. The authors found no evidence of an effect of SMT for the management of nonmusculoskeletal 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 nonmusculoskeletal disorders. This systematic review and meta-analysis has 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 RCTs with a low risk of bias included in this review showed that SMT is not effective for the management of nonmusculoskeletal disorders. The authors recommended that their systematic review be updated every 2 to 3 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 the authors' findings and conclusions are based on a limited number of high- and

acceptable-quality trials and only single trials for all but one condition. Therefore, future trials can potentially alter the findings and conclusions.

An interventional study by Jones et al. (2021) was performed to evaluate the change in same-day pulmonary function testing in pediatric participants receiving OMT compared with those receiving usual care. The study population included 58 participants: 31 (53.4%) were assigned to the OMT group, and 27 (46.6%) were assigned to the standard-of-care group. The selected participants were (1) aged 7 to 18 years, (2) were diagnosed with asthma, (3) were receiving care at a primary care-based asthma clinic, and (4) had baseline spirometry. Selected participants were then randomized to either an OMT or a control group. Participants who were experiencing an acute asthma exacerbation were excluded. Participants in the OMT group were treated with rib raising and suboccipital release, with a goal of normalizing autonomic tone, in addition to standard asthma care, while control group participants received standard care only. A second pulmonary function test was performed in both groups at the end of the visit. OMT was performed by multiple residents who were focusing on osteopathic pediatrics and specifically trained for the purposes of this study. Change in spirometry results (forced vital capacity; forced expiratory volume in 1 second; forced vital capacity/forced expiratory volume in 1 second; and forced expiratory flow 25%-75%) was then compared. Participants who received OMT had greater improvement in all spirometry values compared with the usual group; however, these changes were not statistically significant. The authors concluded that the benefits of OMT on short-term spirometry results in pediatric individuals with asthma remain unclear. Further investigation in a larger cohort is necessary to recommend broad-scale application of these techniques in clinical practice.

### ***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 individuals. The authors concluded that no credible, scientific evidence of effectiveness for conferring or enhancing immunity through spinal manipulation exists. 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.

This clinical study by Wójcik M et al. (2025) assessed the effects of visceral manipulation on quality of life and postural stability in women diagnosed with endometriosis and pelvic organ prolapse. The study consisted of 60 women who were split into two groups: 30 with endometriosis and 30 with pelvic organ prolapse. Both groups followed a standardized visceral manipulation protocol, and the outcome measures included validated quality-of-life questionnaires and objective postural stability assessments performed at baseline and after completion of therapy. The application of visceral manipulation was associated with a statistically significant improvement in quality of life among women in both study groups. Specifically, the pelvic organ prolapse group had a p value of 0.0093, and the endometriosis group had a p value of 0.0001. However, measurements of postural stability, including anterior-posterior and lateral-medial tilt, area, and pivoting, with eyes open revealed no effect of visceral manipulation in either study group. Although the authors found that this study suggests that visceral manipulation may contribute to improved quality of life in women with endometriosis and pelvic organ prolapse, the study's limitations include a relatively small sample size and the absence of a control group, which may restrict the generalizability of the results. The authors concluded that further research, with larger RCTs, is warranted to confirm these preliminary findings and establish broader clinical recommendations.

In a 2023 RCT, Boas Fernandes et al. investigated the effect of osteopathic visceral manipulation (OVM) on functional constipation and chronic nonspecific LBP. Overall, 70 participants were included and randomized 1:1. Assessors and participants were blinded. The primary clinical outcome was pain intensity, which was measured using an NRS, and disability, which was measured using the ODI. The secondary outcomes were electromyographic (EMG) signals measured during the flexion-extension cycle, the finger-to-floor distance during complete flexion of the trunk, and the Fear-Avoidance Beliefs Questionnaire. All outcomes were measured after 6 weeks of treatment and at 3 months. Treatment was provided in 15-minute sessions once a week for 6 weeks. The results showed that the treatment group reported a reduction in pain and an improved ODI after 6 weeks and at follow-up. The sham group did not report pain reduction at 6 weeks but did report it at the 3-month follow-up. The secondary outcomes assessed showed statistically significant improvement in EMG activity. The authors concluded that OVM improved outcomes in these participants, statistically. However, the ODI change was not clinically relevant to participants. Future research should include adding OVM to other treatments in this population.

A randomized, double-blinded, placebo-controlled trial was conducted by Eguaras et al. (2019) to evaluate the effects of osteopathic visceral treatment in participants with gastroesophageal reflux disease. Overall, 60 participants were recruited and randomized into two groups, each receiving two sessions of treatment with a week-long 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. Neither pressure nor any actual osteopathic treatment was applied. The scores of the GerdQ test showed that the application of the osteopathic manual treatment produced a significant improvement in symptoms in the experimental group compared with the sham group. The authors concluded that the osteopathic visceral technique may be useful in individuals for improvement in their gastroesophageal reflux disease symptoms. Limitations include the lack of long-term follow-up, restriction to one technique for only two sessions, and absence of practitioner blinding.

Parnell Prevost et al. (2019) conducted a systematic review, which evaluated the use of osteopathic treatment for clinical conditions in the pediatric population. Examples of clinical conditions consisted of attention-deficit/hyperactivity disorder, autism spectrum disorder, asthma, infantile colic, constipation, otitis media, scoliosis, and torticollis. Of the 50 studies found, 32 were RCTs, and 18 were observational; 23 studies were specific to OMT, 17 used chiropractic manipulative therapy, and 10 included mobilization. While some pediatric conditions such as LBP and pulled elbow had a positive outcome with implementation of osteopathic treatment, the authors found the overall results to be inconclusive. It was determined that additional research investigating osteopathic treatment in pediatric conditions is needed.

Silva et al. (2018) conducted a randomized, double-blinded, placebo-controlled pilot study to evaluate the effect of OVM on pain, cervical ROM, and upper trapezius (UT) muscle activity in participants with chronic nonspecific neck pain and functional dyspepsia. Overall, 28 participants with nonspecific neck pain 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 7 days after treatment through pain, cervical range, and EMG activity of the UT muscle. Significant effects were confirmed in both groups immediately after treatment (OVMG and PVMG) for NRS scores ( $p < 0.001$ ) and pain area ( $p < 0.001$ ). Significant increases in EMG amplitude were identified immediately and 7 days after treatment in the OVMG ( $p < 0.001$ ). No differences were identified between the OVMG and the PVMG in cervical ROM ( $p > 0.05$ ). The authors concluded that this study demonstrates 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 7 days after treatment in individuals with nonspecific neck pain and functional dyspepsia. Limitations of this study include the small sample size, lack of blinding, and short follow-up period. These findings need to be independently reproduced, with a 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 participants with LBP. Overall, 64 participants with LBP 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 NPRS) at 6 weeks. The secondary outcomes were pain at 2 and 52 weeks; disability (measured with the Roland Morris Disability Questionnaire) at 2, 6, and 52 weeks; and function (measured with the Patient-Specific Functional Scale) at 2, 6, and 52 weeks. The addition of visceral manipulation did not affect the primary outcome of pain at 6 weeks (-0.12; 95% CI, -1.45 to 1.21). There were no significant between-group differences for the secondary outcomes of pain at 2 weeks or disability and function at 2, 6, and 52 weeks. The group receiving the addition of visceral manipulation had less pain than the placebo group at 52 weeks (mean, 1.57; 95% CI, 0.32-2.82). 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 1 year.

## Craniosacral Therapy

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 RCTs to assess the clinical effectiveness of CST compared with that of standard care, sham treatment, or no treatment in adults and children. All RCTs using 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, and disagreements were settled by consensus. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 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 G value (SMD) and aggregated using random-effects models. The GRADE system was used to assess the quality of evidence. The primary study outcome was the effectiveness of CST for selected outcomes, as applied to nonhealthy adults or children and

measured by SMD effect size. Overall, 24 RCTs were included in the final meta-analysis, with a total of 1,613 individuals. 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 to 2.05), and pain, (chronic somatic;  $g = 0.34$ ; 95% CI, 0.18-0.50; prediction interval, -0.41 to 1.09) showed a 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 individuals' 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, although likely in the positive direction. Additionally, many included papers had poor blinding, poor randomization, and incomplete results 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 CST in the management of any conditions. Two independent reviewers searched PubMed, PEDro, the Cochrane Library, Web of Science, and the Osteopathic Medicine Digital Library and extracted data from 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. A quantitative synthesis was carried out with RevMan 5.4 software using random-effects models. Overall, 15 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 individuals with headache disorders, neck pain, LBP, pelvic girdle pain, or fibromyalgia. For nonmusculoskeletal 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 suggested that CST produces no benefits in any of the musculoskeletal or nonmusculoskeletal 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 has several limitations. First, even though the literature searches were thorough, the authors stated that 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 HRV as a measure of cardiovascular stress and autonomic system activity proposed as a tool to evaluate the neurophysiological effects of CST. HRV can be analyzed in two different bands: HF and LF power associated with a parasympathetic and sympathetic response. In this meta-analysis, the authors provided a brief introduction to CST, analyzed three primary studies, and summarized the therapeutic benefits and pitfalls of this alternative treatment on the autonomic nervous system. A significant negative HF SMD after CST was observed; the SMD was -0.46 (95% CI, -0.79 to -0.14). No significant effect on LF power was observed. The authors concluded that CST does provide a moderate short-term increase in parasympathetic activity. These findings suggest that CST may be used to treat individuals 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 be derived from the placebo effect of receiving a treatment rather than the facilitation of the cranial rhythmic impulse itself. Further, the small number of studies included in the meta-analysis and the variation in treatment protocols and populations of individuals 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 that there may be an acute benefit of CST in individuals with an unbalanced, overactive sympathetic state. However, further research using 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 an RCT to (1) evaluate the number of CST sessions that can be helpful to obtain a resolution of the symptoms of infantile colic and to (2) observe if there are any differences in the evolution obtained by the groups that received a different number of CST 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; 29 infants in the control group received no treatment, and those in the experimental group received one to three sessions of CST until symptoms were resolved. Evaluations were performed until day 24 of the study. In this RCT, crying hours served as the primary outcome. The secondary outcome was the hours of sleep and the severity, measured by the Infantile Colic Severity Questionnaire. Differences were observed in favor of the experimental group compared with the control group on day 24 in the crying hours (MD, 2.94; 95% CI, 2.30-3.58;  $p < 0.001$ ) primary outcome and also in the hours of sleep (MD, 2.80; 95% CI, -3.85 to -1.73;  $p < 0.001$ ) and colic severity (MD, 17.24; 95% CI, 14.42-20.05;  $p < 0.001$ ) secondary outcomes. Also, the differences between the groups that received two or less CST sessions ( $n = 19$ ) or three CST sessions ( $n = 10$ ) and the 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 infants with infantile colic may obtain complete resolution of symptoms on day 24 by receiving two or three CST sessions compared with the control group, which did not receive any treatment. This RCT is a small, unblinded study. Further investigation is needed before the clinical usefulness of this procedure is proven.

Muñoz-Gómez et al. (2022) conducted an RCT to evaluate the effectiveness of a CST protocol on different features in participants with migraine. Overall, 50 participants with migraine were randomly divided into two groups ( $n = 25$  per group): (1) the CST group, following a CST protocol, and (2) the sham control group, which received 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 4-week intervention, and at the 8-week follow-up. After the intervention, the CST group had 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 a higher self-reported perception of change ( $p = 0.01$ ) than the sham control group. In addition, the results were maintained at the follow-up evaluation in all variables. The authors concluded that a protocol based on CST 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 individuals 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 that 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 CST in primary health care. Consecutive outpatient participants using 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 NRS version of the Measure Yourself Medical Outcome Profile. CST therapists submitted 220 participant records (71.4% female), including 15.5% infants and toddlers, 7.7% children, and 76.8% adolescents and adults. Participants received, on average,  $7.0 \pm 7.3$  CST sessions to treat 114 different acute and chronic conditions. Symptom intensity decreased by -4.38 NRS (95% CI, -4.69 to -4.07) and disability by -4.41 NRS (95% CI, -4.78 to -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 Measure Yourself Medical Outcome Profile score included participants' expectations ( $p = 0.001$ ) and therapists' CST experience ( $p = 0.013$ ), and negative predictors were symptom duration ( $p < 0.002$ ) and participant age ( $p = 0.021$ ); a final categorical predictor was CST type ( $p = 0.023$ ). Minor adverse events but no serious adverse events occurred. The authors concluded that the use of CST may provide a promising additional treatment option for primary care individuals 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 populations of individuals.

The effectiveness and safety of CST for chronic pain conditions were investigated by Haller et al. (2020). Ten RCTs, including 681 participants with neck and back pain, migraine, headache, fibromyalgia, epicondylitis, and pelvic girdle pain, were included. CST showed small/moderate greater postintervention effects on pain intensity and disability than treatment-as-usual care, sham, and active manual treatments. Effects were maintained through 6 months of 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 did not allow for making conclusions about the effectiveness of CST for specific pain conditions. (Haller et al., 2016, 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 CST in the treatment of infantile colic. The authors reported clinically significant benefits for crying time (hours), colic severity, and sleep duration,

which favored CST at the 7-, 14-, and 24-day follow-up assessments. Confidence in the conclusions was limited due to a high risk of detection, performance, and attrition bias. In addition to methodological 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 the reliability of diagnosis and the clinical efficacy of cranial osteopathy techniques. The systematic review included nine studies concerning the reliability of diagnosis and 14 RCTs that described the efficacy of cranial osteopathy techniques for a range of musculoskeletal and nonmusculoskeletal conditions. The authors found no evidence to support the reliability of diagnoses made using cranial osteopathy techniques. Most studies were vulnerable to a high risk of bias and failed to demonstrate any reliability for the selected outcomes. The authors also concluded that there were very few well-conducted trials demonstrating the clinical efficacy of the techniques and therapeutic strategies used in cranial osteopathy techniques. 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 nonspecific effects of treatments. The authors concluded that there is insufficient evidence to support cranial osteopathy techniques as being relevant for the diagnosis or treatment of individuals.

## **Manipulative Therapy With Nonstandard Techniques**

Published peer-reviewed literature was not identified for nonstandard manipulative therapy techniques such as applied kinesiology, the National Upper Cervical Chiropractic Association technique, and the neural organizational technique.

## **Clinical Practice Guidelines**

### ***American Osteopathic Association (AOA)***

In an updated review on the use of OMT in patients with 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 RCTs, 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)

### ***International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT)/International Organisation of Physiotherapists in Paediatrics (IOPTP)***

Clinical guidelines published jointly by the IFOMPT and IOPTP for the diagnosis and treatment of musculoskeletal conditions, including spinal mobility impairments associated with neck-back pain and neck pain with headache, state that it may be appropriate to treat using spinal mobilization and manipulation in adolescents, spinal mobilization in children, and thoracic manipulation in children for neck-back pain only. It is not recommended to perform spinal manipulation and mobilization in infants, cervical and lumbar spine manipulation in children, and spinal manipulation and mobilization in infants, children, and adolescents for nonmusculoskeletal pediatric conditions, including asthma, attention-deficit/hyperactivity disorder, autism spectrum disorder, breastfeeding difficulties, cerebral palsy, infantile colic, nocturnal enuresis, and otitis media. (Gross et al., 2024)

## **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.

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## Policy History/Revision Information

Date	Summary of Changes
06/01/2026	<p><b>Coverage Rationale</b></p> <p><b>State-Specific Criteria</b></p> <p><b>Chiropractic Manipulative Therapy</b></p> <ul style="list-style-type: none"> <li>Replaced instruction to “refer to the Nebraska Department of Health and Human Services, Code § 471-5-003.02: Chiropractic Services for chiropractic <i>treatment</i>” with “refer to the Nebraska Department of Health and Human Services, Code § 471-5-003.02: Chiropractic Services for <i>medical necessity clinical coverage criteria</i> for chiropractic <i>Manipulative Therapy</i>”</li> </ul> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Removed definition of “Upledger Technique”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information</li> <li>Archived previous policy version CS076NE.N</li> </ul>

## 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, 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.

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