Manipulative Therapy (for New Mexico Only)

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Instructions for Use

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Application

This Medical Policy only applies to the state of New Mexico.

Coverage Rationale

Note: Chiropractic services are not covered for Alternative Benefit Package (ABP) members age 21 and over.

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

Manipulative Therapy is unproven and not medically necessary for the following due to insufficient evidence of efficacy:
- Non-Musculoskeletal Disorders (e.g., asthma, otitis media, infantile colic, internal organ disorders, etc.)
- Prevention/maintenance/custodial care
- Craniosacral therapy (cranial manipulation/Upledger technique) or manipulative services that utilize nonstandard techniques including but not limited to applied kinesiology, National Upper Cervical Chiropractic Association (NUCCA), and neural organizational technique
- Musculoskeletal Disorders:
  - Temporomandibular joint (TMJ) disorder
  - Scoliosis

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

Definitions

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

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

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 New Mexico Only) for information regarding CPT code 97140, manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 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 mobilization therapy or “adjustment,” refers to manual therapy employed to soft or osseous tissues for therapeutic purposes. This term encompasses a wide variety of physical manipulations, including rhythmic stretching, deep pressure and traction, and spinal adjustments. Spinal manipulation involves manual and mechanical interventions that may be high or low velocity; short or long lever; high or low amplitude; with or without recoil. Most often, manipulation is performed by applying a controlled force into a joint or joints of the spinal column to reduce or correct a specific derangement. Depending on the provider specialty, a joint derangement may be listed as a subluxation, vertebral subluxation complex, osteopathic lesion, somatic dysfunction, or a mechanical dysfunction.

Craniosacral therapy (CST) is a noninvasive osteopathic technique that involves the therapist touching the individual to detect pulsations and rhythms of flow of cerebrospinal fluid (CSF). The therapist then gently works with the skull and spine, with the goal to effect release of potential restrictions to the flow of CSF, without the use of forceful physical manipulation (Hayes, 2018). It is alleged as a treatment for a variety of conditions, such as multiple sclerosis, asthma, pelvic pain, fibromyalgia, and tension-type and migraine headaches. Many of these disease states are associated with acute and chronic pain.

A variety of non-standard manipulative therapy techniques exist such as applied kinesiology, National Upper Cervical Chiropractic Association (NUCCA), and neural organizational technique (NOT).

Applied kinesiology, also known as muscle strength testing, is a method of diagnosis and treatment based on the belief that various muscles are linked to organs and glands, and that specific muscle weakness can signal distant internal problems such as nerve damage, reduced blood supply, chemical imbalances or other organ or gland problems.

The NUCCA technique is a variation of chiropractic care with the goal to improve structural and sustained postural balance that leads to improved spinal stability along with balanced mobility.

The neural organizational technique attempts to treat the cause, the whole person, and work with what the body communicates is out of balance.

Manipulative treatment may be a primary method of treatment for some medical conditions, and for others it may complement or support medical treatment (Axen et al., 2009).

Clinical Evidence

Musculoskeletal

Spine-Related Disorders

Back

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

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

Trager et al. (2022) conducted a retrospective cohort study to determine whether or not adults receiving chiropractic spinal manipulative therapy (CSMT) for newly diagnosed lumbar disc herniation (LDH) or lumbosacral radiculopathy (LSR) would have reduced odds of lumbar discectomy over 1-year and 2-year follow-up compared with those receiving other care. Adults aged 18-49 with newly diagnosed LDH/LSR (first date of diagnosis) were included. Exclusions were prior lumbar surgery, absolute indications for surgery, trauma, spondylolisthesis, and scoliosis. After matching, there were 5,785 patients per cohort (mean age 36.9 ±8.2). Patients were divided into cohorts according to receipt of CSMT. The ORs (95% CI) for discectomy were reduced in the CSMT cohort compared with the cohort receiving other care over 1-

year [0.69 (0.52 to 0.90), p = 0.006] and 2-year follow-up [0.77 (0.60 to 0.99), p = 0.040]. E-value sensitivity analysis estimated the strength in terms of risk ratio an unmeasured confounding variable would need to account for study results, yielding point estimates for each follow-up (1 year: 2.26; 2 years: 1.92), which no variables in the literature reached. The authors concluded that findings suggest receiving CSMT compared with other care for newly diagnosed LDH/LSR is associated with reduced odds of discectomy over 2-year follow-up. Given socioeconomic variables were unavailable and an observational design precludes inferring causality, the efficacy of CSMT for LDH/LSR should be examined via randomized controlled trial to eliminate residual confounding. The study is limited by its retrospective observations.

In a randomized, sham-controlled group trial, Nguyen et al. (2021) compared the efficacy of standard osteopathic manipulative treatment (OMT) versus sham OMT for reducing low back pain (LBP) in patients with nonspecific subacute and chronic LBP. 394 patients were randomized into two groups with a primary end point of reducing LBP which was measured with the Quebec Back Pain Disability Index (QBPDI). The experimental group received standard OMT; the sham control group received a priori inert procedure which consisted of light touch which stimulated OMT without stimulating physiotherapy or massage. Both groups received therapy for six sessions, two weeks apart. The mean QBPDI score for the standard OMT group was 31.5 at baseline and 25.3 at 3 months; and in the sham OMT group the mean score was 27.2 at baseline and 26.1 at 3 months. At twelve months, both groups experienced a decrease in pain, however, the standard OMT group reported increased pain relief. The authors concluded OMT had a slightly better clinical effect than the sham for patients with LBP. Limitations included a focus on standard OMT only and large loss to follow-up.

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

Rubinstein et al. (2019) conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) to assess the benefits and harms of spinal manipulative therapy (SMT) for the treatment of chronic low back pain. Two reviewers independently selected studies, extracted data, and assessed risk of bias and quality of the evidence. The effect of SMT was compared with recommended therapies, non-recommended therapies, sham (placebo) SMT, and SMT as an adjuvant therapy. Main outcomes were pain and back specific functional status, examined as mean differences and standardized mean differences (SMD), respectively. Outcomes were examined at 1, 6, and 12 months. Forty-seven RCTs including a total of 9,211 participants were identified, who were on average middle aged (35-60 years). Most trials compared SMT with recommended therapies. Moderate quality evidence suggested that SMT has similar effects to other recommended therapies for short term pain relief (mean difference -3.17, 95% confidence interval -7.85 to 1.51) and a small, clinically better improvement in function (SMD -0.25, 95% confidence interval -0.41 to -0.09). High quality evidence suggested that compared with non-recommended therapies SMT results in small, not clinically better effects for short term pain relief (mean difference -7.48, -11.50 to -3.47) and small to moderate clinically better improvement in function (SMD -0.41, -0.67 to -0.15). In general, these results were similar for the intermediate and long-term outcomes as were the effects of SMT as an adjuvant therapy. Evidence for sham SMT was low to very low quality; therefore these effects should be considered uncertain. Statistical heterogeneity could not be explained. About half of the studies examined adverse and serious adverse events, but in most of these it was unclear how and whether these events were registered systematically. Most of the observed adverse events were musculoskeletal related, transient in nature, and of mild to moderate severity. One study with a low risk of selection bias and powered to examine risk (n = 183) found no increased risk of an adverse event (relative risk 1.24, 95% confidence interval 0.85 to 1.81) or duration of the event (1.13, 0.59 to 2.18) compared with sham SMT. In one study, the Data Safety Monitoring Board judged one serious adverse event to be possibly related to SMT. The authors concluded that SMT produces similar effects to recommended therapies for chronic low back pain, whereas SMT seems to be better than non-recommended interventions for improvement in function in the short term. Clinicians should inform their patients of the potential risks of adverse events associated with SMT. The study is limited due to a heterogeneous patient population, and risk of bias. Well designed, adequately powered, prospective, controlled clinical trials of SMT are needed to further describe safety and clinical efficacy. [Authors Ulger et al. (2017) which were previously cited in this policy, are included in this systematic and meta-analysis review].

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

Coulter et al. (2018) conducted a systematic literature review and meta-analysis to determine the efficacy, effectiveness, and safety of various mobilization and manipulation therapies for treatment of chronic low back pain. A total of 64 publications were included in this systematic review. The studies measured self-reported pain, function, health-related quality of life, and adverse events; the most common tool for pain evaluation of measurement was the VAS (26 of 51) and the numeric pain rating scale (12 of 51). The authors concluded a small to moderate effect on pain in favor of manipulation, which increased over time at 3- and 6-months follow-up for reducing pain compared with other active comparators (exercise and physical therapy).

In a systematic review Shekelle, et al. (2017) assessed the effect of manipulative therapy for persons with acute LBP. Treatment with manipulative therapy improved the outcomes of pain and function in patients with acute low back pain. Evidence quality was judged to be moderate, due to heterogeneity (differences between studies in the consistency of effect sizes) of results. The authors found insufficient evidence to arrive at conclusions regarding manipulative therapy and outcomes for patients with low back pain and sciatica.

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

In a systematic review and meta-analysis, Paige et al. (2017) evaluated the effectiveness of spinal manipulative therapy (SMT) for acute (≤ 6 weeks) low back pain. Study quality was assessed using the Cochrane Back and Neck (CBN) Risk of Bias tool. Pain (measured by either the 100 mm visual analog scale, 11 point numeric rating scale, or other numeric pain scale), function [measured by the 24-point Roland Morris Disability Questionnaire or ODI (range, 0-100)], or any harms measured within 6 weeks. Of 26 eligible RCTs identified, 15 RCTs (1,699 patients) provided moderate-quality evidence that SMT has a statistically significant association with improvements in pain [pooled mean improvement in the 100 mm visual analog pain scale, −9.95 (95% CI, −15.6 to −4.3)]. According to the authors, among patients with acute low back pain, spinal manipulative therapy was associated with modest improvements in pain and function at up to 6 weeks, with transient minor musculoskeletal harms. However, heterogeneity in study results was large. Other limitations of this study are that the type of manipulation, study quality, or whether SMT was given alone or as part of a package of therapies was not disclosed.

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

A systematic review performed by De Luca et al. (2016) evaluated the effectiveness and safety of manual therapy interventions on pain and disability in older persons with chronic low back pain (LBP). Four hundred five articles were identified, 38 full-text articles were assessed, and four studies met the inclusion criteria. The main limitation of this review was the lack of randomized controlled trials for review as the eligibility criteria was not met. The older population of participants were excluded from the research if they had existing comorbidities thus the possibility of bias was introduced. A further limitation was the lack of blinding the participants and practitioners due to the nature of the treatment performed. And finally, only one of the studies had a control group. The authors concluded that there is moderate evidence to support the effectiveness of manual therapy (most commonly manipulative therapy) in reducing pain levels in older persons having chronic LBP with or without radiculopathy, however, further investigation is warranted.

Hall et al. (2016) conducted a systematic review and meta-analysis to evaluate effectiveness of manual therapies for managing pregnancy-related low back and pelvic pain. A total of 10 studies with 1,198 pregnant women were included. The therapeutic interventions predominantly involved massage and OMT. Meta-analyses found positive effects for manual therapy on pain intensity when compared to usual care and relaxation but not when compared to sham interventions. One limitation included a trial of pregnant participants that were studied primarily for efficacy of manual therapy for depression but also included back pain in their results; another limitation was the diversity of treatment types and dosage of the manual therapies included in the meta-analysis. And a third limitation was the type of sham control utilized impacting participant blinding. The authors concluded there was limited evidence to support the use of manual therapies including massage and osteopathic manipulative treatment as an option for managing low back and pelvic pain outcomes during pregnancy.

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

Schwerla et al. (2015) conducted a randomized controlled trial on the use of OMT in women with persistent postpartum lower back pain (LBP) greater than 3 months. Women were allocated to an OMT group (n = 40) and a waitlist control group (n = 40) for a period of 8 weeks. OMT was provided four times at intervals of 2 weeks, with a follow-up after 12 weeks. The control group was not allowed any additional pain relief, e.g., medication, physical therapy, during this time. The main outcome measures were pain intensity as measured by a visual analog scale and the effect of LBP on daily activities as assessed by the Oswestry Disability Index (ODI). Based on the results of 8 weeks of therapy, the authors reported that this study provides some evidence that patients with pregnancy- and childbirth-related LBP may be successfully treated with OMT. Limitations included lack of blinding, self-assessments that may have led to overestimation of ratings and the individual judgement of the therapist's techniques for each participant. And finally, the data obtained at follow-up did not fulfill the criteria of a randomized controlled trial because follow-up could only be carried out for the intervention group. Further studies that include prolonged follow-up periods are warranted to corroborate the current findings.

Rubinstein et al. (2012) performed an updated systematic review of an earlier Cochrane review first published in January 2004. The main objective was to examine the effects of spinal manipulative therapy (SMT) for acute low back pain, defined as pain of less than six weeks duration. Randomized controlled trials (RCTs) which examined the effectiveness of spinal manipulation or mobilization in adults with acute low-back pain were included. In addition, studies were included if the pain was predominantly in the lower back, but the study allowed mixed populations, including participants with radiation of pain into the buttocks and legs. Studies which exclusively evaluated sciatica were excluded. No other restrictions were placed on the setting nor the type of pain. The primary outcomes were back pain, back-pain specific functional status, and perceived recovery. Secondary outcomes were return-to-work and quality of life. SMT was defined as any hands-on therapy directed towards the spine, which includes both manipulation and mobilization, and includes studies from chiropractors, manual therapists, and osteopaths. Twenty RCTs (total number of participants = 2,674), 12 (60%) of which were not included in the previous review, were identified. Sample sizes ranged from 36 to 323 [median (IQR) = 108 (61 to 189)]. In total, six trials (30% of all included studies) had a low risk of bias. At most, three RCTs could be identified per comparison, outcome, and time interval; therefore, the amount of data should not be considered robust. In general, for the primary outcomes, there is low to very low-quality evidence suggesting no difference in effect for SMT when compared to inert interventions, sham SMT, or when added to another intervention. There was varying quality of evidence (from very low to moderate) suggesting no difference in effect for SMT when compared with other interventions, with the exception of low quality evidence from one trial demonstrating a significant and moderately clinically relevant short-term effect of SMT on pain relief when compared to inert interventions, as well as low quality evidence demonstrating a significant short-term and moderately clinically relevant effect of SMT on functional status when added to another intervention. In general, side-lying and supine thrust SMT techniques demonstrate a short-term significant difference when compared to non-thrust SMT techniques for the outcomes of pain, functional status, and recovery. The authors concluded that SMT is no more effective in participants with acute low-back pain than inert interventions, sham SMT, or when added to another intervention. SMT also appears to be no better than other recommended therapies. The decision to refer patients for SMT should be based upon costs, preferences of the patients and providers, and relative safety of SMT compared to other treatment options. This review is limited by the small number of studies per comparison, outcome, and time interval. There is no evidence from this review that this information will affect patient management. Further investigation is needed before clinical usefulness of this procedure is proven. [Authors Cleland et al. (2009), which were previously cited in this policy, are included in this systematic review].

Neck

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

In a randomized control trial, Groisman et al. (2020) assessed the effectiveness of OMT combined with stretching and strengthening exercises in the cervical region on patients with non-specific chronic neck pain. This single-blinded trial randomized 90 patients into two groups: either an exercise only group or an exercise group combined with OMT. The study included weekly exercise and/or OMT for 4 weeks. The primary outcomes were pain and disability which were evaluated by the Numeric Pain Rate Scale (NPRS) and Neck Disability Index (NDI). Secondary outcomes included Pressure Pain Threshold (PPT), range of motion, Fear-Avoidance Beliefs Questionnaire (FABQ), and pain-self efficacy. The authors found the group that had received exercise combined with OMT had greater reductions in pain and disability than the group that received exercise only; this was evidenced by the lower NPRS and NDI scores. There were no significant differences in the secondary outcomes. Limitations included lack of long-term effects, difficulty in blinding patients with osteopaths and those that received OMT had increased contact with osteopaths leading to potential placebo effect. Despite this, the authors felt the findings of the study were clinically significant.

In a systematic review, Shekelle et al. (2017) evaluated the benefits of SMT for acute neck pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management. Only five studies were identified of SMT compared to a non-SMT treatment group. Although each study reported favorable results on at least one outcome, in total only 198 patients were included and for neck pain, the authors felt there was simply too few studies to draw firm conclusions; additional RCTs are warranted. The primary limitation of this analysis was the diversity in the results.

In a systematic review, Hidalgo et al. (2017) evaluated the evidence for different forms of manual therapy and exercise for patients with various stages of non-specific neck pain. Only RCTs were included. The authors concluded that combining different forms of manual therapy with exercise resulted in more favorable outcomes than manual therapy or exercise alone, and that mobilization need not be applied at the symptomatic level(s) for improvements of neck pain patients. Limitations included much diversity amongst the different trials, lack of ideal classification of manual therapy techniques, and adjuvant therapy in both intervention and comparison groups which led to difficulty in evaluating objectively.

A randomized controlled trial by Puntumetakul et al. (2015) studied forty-eight patients with chronic mechanical neck pain (CMNP). The patients were randomly allocated to single-level thoracic manipulation (STM) at T6-T7 or multiple-level thoracic manipulation (MTM), or to a control group (prone lying). Cervical range of motion (CROM), visual analog scale (VAS), and the Thai version of the Neck Disability Index (NDI-TH) scores were measured at baseline, and at 24-hour and at 1-week follow-up. At 24-hour and 1-week follow-up, neck disability and pain levels were significantly ($p < 0.05$) improved in the STM and MTM groups compared with the control group. CROM in flexion and left lateral flexion were increased significantly in the STM group when compared with the control group at 1-week follow-up. The CROM in right rotation was increased significantly after MTM compared to the control group at 24-hour follow-up. There were no statistically significant differences in neck disability, pain level at rest, and CROM between the STM and MTM groups. The authors concluded that the results suggest that both single-level and multiple-level thoracic manipulation improve neck disability, pain levels, and CROM at 24-hour and 1-week follow-up in patients with CMNP. Limitations included only post-intervention at 24-hour and 1-week follow-up, thus future studies should examine the long-term effects of STM/MTM in patients with chronic mechanical neck pain and the effects of this clinical intervention in a larger sample size.

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

A prospective, multicenter case series by Rubinstein et al. (2007), evaluated 529 patients with neck pain to assess clinical outcomes and adverse events. Follow-up occurred at 3- and 12-months using questionnaires. Fifty-six percent of patients reported worsening of symptoms or onset of a new symptom during any one of the first three treatments. Only five patients (1%) reported to be much worse at 12 months. No serious adverse events were recorded during the study period. The authors concluded that while adverse events may be common, they are rarely severe in intensity. Most patients report recovery, particularly in the long term. In the authors' opinion, the benefits of chiropractic manipulative therapy for neck pain seem to outweigh the potential risks. Several limitations of the study included lack of a control group, potential response bias to the questionnaires, potential for recall errors, and imaging of the cervical spine was not always performed and only done so at the discretion of the chiropractor.

Extraspinal Disorders

Extremity Disorders

A comprehensive review by Bronfort et al. (2010) evaluated the effectiveness of manual therapies including manipulation for a broad range of extremity disorders. The following had positive results: shoulder girdle pain and dysfunction, adhesive capsulitis, hip osteoarthritis, knee osteoarthritis, patello-femoral syndrome, and plantar fasciitis (when combined with exercise). This determination was made based on the results of the most recent and most updated (spans the last five to ten years) systematic reviews of RCTs, widely accepted evidence-based clinical guidelines and/or technology assessment reports, and all RCTs not yet included in the first three categories. The conclusions regarding effectiveness were based on comparisons with placebo controls (efficacy) or commonly used treatments which may or may not have been shown to be effective (relative effectiveness), as well as comparison to no treatment.

Shoulder

In a randomized control trial, Iqbal et al. (2020) compared the effects of the Spencer muscle energy technique (SMET) and passive stretching on 60 patients with idiopathic frozen shoulder or a stiff painful shoulder joint for at least three months. The participants were randomized into two equal groups. Group 1 contained patients that were treated with a hot pack for 7-10 minutes and then received the SMET; this was repeated 3-5 times with rest intervals over three sessions/week on alternate days for 4 weeks. Group 2 contained patients that were treated with a hot pack for 7-10 minutes and then received specific passive stretching exercises. The shoulder was stretched and rotated for 20 seconds with a ten second rest interval and then repeated ten times over the course of three sessions per week every other day. Shoulder pain was assessed with the numeric pain rating scale (NPRS) which assessed eleven items ranging from zero (no pain) to 10 (worst pain). The authors found that SMET was more effective than passive stretching for decreasing pain shoulder pain and increasing ROM. Limitations included short duration of the study and the lack of appropriate registration with trail registry. It was concluded that future additional long-term RCTs are needed along with long-term follow ups.

Schwerla and colleagues (2020) evaluated the effectiveness of osteopathic treatments in 70 patients suffering from shoulder pain. Participants were randomized into either the intervention group that received osteopathic treatment or a control group (which remained untreated for eight weeks, but later treated with osteopathic treatment upon conclusion of the study). The main outcome was shoulder pain, and this was assessed using the standard VAS for self-pain measurement. Secondary outcomes were specific shoulder pain and disability determined by the should pain and disability index (SPADI) and quality of life assessed by a SF-36 generic questionnaire. Participants in the intervention group received five osteopathic examinations and treatments of 40-60 minutes each delivered every two weeks for eight weeks. Before each visit and two weeks after the last visit, the VAS and SPADI were completed. The SF-36 generic questionnaire was completed at 4 and 10 weeks. The control group was required to fill out the VAS, SPADI and generic questionnaire at their baseline visit and then told they would be placed on the waiting list for osteopathic treatment to be scheduled 8 weeks later. In both groups, on demand pain mediation was allowed. In the control group, 21 patients had no change in their pain and only eight patients showed improvement; in comparison the intervention group had a decrease in pain frequency for 33 patients. Secondary outcome measures had similar findings between the two groups; improvement in quality of life was seen for the intervention group but not the control group. The authors concluded osteopathic treatments over a defined period might be beneficial for patients suffering from shoulder pain, but further studies are needed to validate this finding. Limitations included the control group itself (receiving no treatment until after the study), small sample size and lack of long-term data.

Horst et al. (2017) conducted a randomized controlled study of 66 patients diagnosed with a limited range of motion and pain in the shoulder region (frozen shoulder) to compare the short- and long-term effects of a structural-oriented (manual therapy) with an activity-oriented program. Both groups received 10 days of therapy, 30 minutes each day. The activity-oriented group (n = 33, mean = 44 years, SD = 16 years) included 20 males (61%) and the structural-oriented group (n = 33, mean = 47 years, SD = 17 years) included 21 males (64%). The authors reported that the activity-oriented group revealed significantly greater improvements in the performance of daily life activities and functional and structural tests compared with the group treated with conventional therapy after 10 days of therapy and at the three-month follow-up ($p < 0.05$).

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

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

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

Ho et al. (2009) conducted a systematic review of 14 randomized controlled trials to evaluate the effectiveness of manual therapy (MT) techniques (including massage, joint mobilization, and manipulation) for shoulder disorders. Results were analyzed within diagnostic subgroups [adhesive capsulitis (AC), shoulder impingement syndrome (SIS), non-specific shoulder pain/dysfunction] and a qualitative analysis using levels of evidence to define treatment effectiveness was applied. The authors concluded there was no clear evidence to suggest additional benefits of manual therapy to other interventions for shoulder impingement syndrome. The findings of the higher quality studies, however, favored manual therapy for pain reduction over exercise-alone and conventional physiotherapy-alone. Ranges of motion (ROM) outcomes were equivalent between groups receiving manual therapy and conventional physiotherapy. Studies that measured shoulder function favored the addition of manual therapy to exercises and were more effective than other physiotherapy procedures employed. In contrast, manual therapy was no more effective than other interventions in improving pain, range of motion, and function for the treatment of adhesive capsulitis. For non-specific shoulder pain/dysfunction, manual therapy was effective in reducing pain and short-term active range of motion, when compared to control groups and sham treatment. Perceived recovery favored manual therapy at both short-term and long-term follow-up.

Green et al. (2003) conducted a Cochrane review of 26 trials evaluating physiotherapy interventions for shoulder pain. Of the 26 trials included in the review, only three studies evaluated manual therapy and mobilization with and without exercise. The authors noted that combining mobilization with exercise resulted in additional benefit when compared to exercise alone for rotator cuff disease; however, the same is not true for adhesive capsulitis.

Bergman et al. (2004) conducted a randomized, controlled trial of 150 patients with shoulder symptoms and dysfunction of the shoulder girdle. Patients were evenly allocated to receive manipulative therapy plus usual medical care (n = 79) or usual medical care alone (n = 71). Patients were prescribed oral analgesics or nonsteroidal anti-inflammatory drugs if necessary and if this was not effective, patients could receive up to three corticosteroid injections. Patients were followed for 52 weeks. Outcomes were measured by patient-perceived recovery, severity of the main complaint, shoulder pain, shoulder disability, and general health. During treatment (6 weeks), no significant differences were found between study groups. After completion of treatment (12 weeks), 43% of the intervention group and 21% of the control group reported full recovery. After 52 weeks, approximately the same difference in recovery rate (17 percentage points) was seen between groups. The authors concluded that manipulative therapy for the shoulder girdle in addition to usual medical care accelerates recovery of shoulder symptoms.

Elbow, Wrist, or Hand

Five systematic reviews assessed the efficacy of manipulation or mobilization for elbow lateral epicondyle pain disorders (Heiser et al. 2013; Hoogvliet et al. 2013; Lucado et al. 2018; Piper et al. 2016; Sutton et al. 2016). Collectively, mobilization and manipulation techniques directed at the elbow, as a single intervention or as part of multimodal care, were more beneficial than comparison groups at clinically improving pain in the short term (< 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 quasi-controlled trial to evaluate the effectiveness of OMT in the management of carpal tunnel syndrome. Patients underwent weekly OMT sessions for six consecutive weeks. The main outcome measures were the Boston Carpal Tunnel Syndrome Questionnaire (BCTQ), a sensory symptom diagram (SSD), patient estimate of overall change, electrophysiologic testing of the median nerve (trans-carpal tunnel motor and sensory nerve conduction velocity and amplitude ratio), and carpal tunnel ultrasound imaging of the cross-sectional area of the median nerve and transverse carpal ligament length and bowing. The authors reported that OMT resulted in patient-perceived improvement in symptoms and function associated with CTS. However, median nerve function and morphology at the carpal tunnel did not change, possibly indicating a different mechanism by which OMT acted, such as central nervous system processes. Limitations of this study include unknown patient population and short follow-up period.

Two systematic reviews encompassing a range of physiotherapies for lateral epicondylitis concluded the evidence is insufficient for most physiotherapy interventions including manipulation or mobilization (Bisset et al., 2005; Smidt et al., 2003).

Two systematic reviews that included an assessment of extraspinal manipulation or mobilization for carpal tunnel syndrome reached disparate conclusions. A Cochrane review by O'Connor et al. (2003) of non-surgical treatment (other than steroid injection) for carpal tunnel syndrome concluded, "Current evidence shows significant short-term benefit from oral steroids, splinting, ultrasound, yoga, and carpal bone mobilization. More trials are needed to compare treatments and ascertain the duration of benefit."

Goodyear-Smith and Arroll (2004) also authored a systematic review of nonsurgical treatment options for carpal tunnel syndrome. This review found, "The evidence does not support the use of nonsteroidal anti-inflammatory drugs, diuretics, pyridoxine (vitamin B_6), chiropractic [manipulative] treatment, or magnet treatment."

In a comparative study by Struijs et al. (2003), 31 patients with lateral epicondylitis were randomly assigned to receive either manipulation of the wrist (n = 15) or ultrasound, friction massage, and muscle stretching and strengthening exercises (n = 16). Follow-up was at 3 and 6 weeks with three patients electing to drop out of the study. After 3 and 6 weeks of intervention, no differences in mean improvement in range of motion was found within or between the groups. The authors were unable to definitively conclude the effectiveness of manipulation and recommend further research with randomization, and longer-term follow-up to further evaluate the use of manipulation for lateral epicondylitis.

Hip Osteoarthritis

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

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

In their systematic review and meta-analysis of manual therapy in the treatment of hip OA, Wang et al. (2015) reported that limitations of their systematic review included the paucity of literature and inevitable heterogeneity between included studies and due to this, they were unable to find any evidence that manual therapy benefits the patients at short-, intermediate- or long-term follow-up.

A randomized clinical trial by Hoeksma et al. (2004) evaluated 109 patients with osteoarthritis of the hip to compare the effectiveness of a manual therapy (n = 56) with exercise therapy (n = 53) with a mean age of 72 years. The manual therapy group received therapy including manipulations and vigorous stretching while the control group received standard exercise therapy, which may have included stretching but did not include manipulation. The treatment period was 5 weeks (9 sessions). Outcomes were measured by general perceived improvement after treatment, level of pain, hip function, walking speed, range of motion, and quality of life. No major differences were found on baseline characteristics between groups. Success rates (primary outcome) after 5 weeks were 81% in the manual therapy group and 50% in the exercise group. Furthermore, patients in the manual therapy group had significantly better outcomes on pain, stiffness, hip function, and range of motion with results maintained after 29 weeks. The authors concluded that manual therapy is superior to exercise therapy for patients with OA of the hip.

Knee Osteoarthritis

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

A randomized control trial was performed by Reza et. al. (2021). It contained two-arm parallel-group with a total of (n = 32) individuals with known knee osteoarthritis. Group A received a supervised exercise protocol; and Group B received specified manual therapies in combination with a supervised exercise protocol. Pain intensity and functional disability were primary outcomes and assessed with the numeric pain rating scale (NPRS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The data was collected at baseline, 2 weeks, and 4 weeks post-intervention; all data was collected by the same assessor who was blind to the study. Group A was given specific strengthening exercises that included static quad knee extensions, standing terminal knee extension, seated leg press, partial squats, and step ups; stretching exercises included calf, hamstring and quadricep stretches. Group A performed three sessions every other day for two weeks. Group B received myofascial mobilization technique 10 times/session every other day for two weeks. The outcomes for NPRS and WOMAC demonstrated superiority for group B over group A. The authors concluded group B's interventions were found to be more effective than a group A's for improving the pain intensity and functional status of patients with knee osteoarthritis. Future studies are suggested to study the retention effects of the intervention protocols. Limitations included short intervention time frame, small sample size and no observation for long-term data. The study was limited due to the availability of the intervention protocols and the interventions not able to be carried out for a long period, such as 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-blind, randomized controlled trial (RCT) to compare the efficacy of osteopathic manipulative treatment (OMT) to exercise treatment in knee osteoarthritis (OA). A total of 100 patients (9 males, 76 females; mean age 54.8 ±8.5 years; range, 40 to 70 years) with Stage II-III bilateral knee OA were enrolled in the study and randomized into two groups between January 2015 and June 2015. Group 1 (n = 50) performed exercise and received OMT, and Group 2 (n = 50) performed exercise alone. Clinical parameters with Western Ontario MacMaster Questionnaire (WOMAC) pain score, WOMAC joint stiffness score, WOMAC physical function score, Visual Analog Scale (VAS) and 50-m walking time were evaluated. All patients were assessed at the beginning of the study, just after the treatment, and four weeks after the treatment. Exercises included quadriceps isometric strengthening straight leg lifting, iliotibial band, hamstring stretching, and strengthening abductor and adductor muscle of the hip. Fifteen patients (exercise group = 9), (OMT + exercise = 6), dropped out of the study leaving 85. Results showed no difference between groups in terms of physical examination and clinical assessment parameters before treatment. Upon completion, functional improvement ($p < 0.05$) and pain relief ($p < 0.05$) were higher in the exercise + OMT group. The authors concluded that OMT is beneficial in relieving knee pain when used to complement conventional treatment of OA of the knee. Short terms follow-up did not allow for assessment of intermediate and long-term outcomes. The findings of this study need to be validated by future well-designed studies.

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

Licciardone et al. (2004) conducted a randomized controlled trial of 30 patients who recently underwent surgery for knee osteoarthritis to evaluate the efficacy of osteopathic manipulative treatment (OMT) in the hospital setting. Patients were randomly assigned to receive either OMT or sham treatment. Patients receiving OMT for knee osteoarthritis had longer length of stays, decrease efficiency in rehabilitation and vitality. The authors concluded that osteopathic manipulative treatment does not appear to be efficacious in this hospital rehabilitation population.

Ankle and Foot

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

Brantingham et al. (2012) performed an updated literature review for manipulative therapy (MT) for lower extremity conditions. 142 abstracts were reviewed which included RCTs, case series and case reports. Of the 142 studies, eight pertained to conditions effecting the knee, four regarding the hip, five regarding the ankle, and two regarding the foot. The authors found insufficient evidence for MT of the ankle and/or foot combined with multimodal or exercise therapy for hallux abducto valgus. Further research is needed with inclusion of larger randomized, controlled trials and improved methodology.

Cleland et al. (2009) conducted a multicenter randomized clinical trial of 60 patients with plantar heel pain to compare the effectiveness of electrophysical agents and exercise (EPAX) which included iontophoresis with dexamethasone and stretching of the gastrocnemius muscle and/or plantar fascia or a manual physical therapy and exercise (MTEX) which included aggressive soft tissue mobilization directed at the triceps surae and the insertion of the plantar fascia at the medial calcaneal tubercle. Patients were equally split between the control and treatment groups and followed for 6 months. Outcomes were measured utilizing several patient self-report questionnaires, including the Lower Extremity Functional Scale (LEFS), the Foot and Ankle Ability Measure (FAAM), and the Numeric Pain Rating Scale (NPRS). The primary aim (effects of treatment on pain and disability) was examined with a mixed-model analysis of variance (ANOVA). Both groups demonstrated a significant improvement over time; however, the patients receiving in the MTEX group experienced greater clinical benefits in terms of function and pain than the patients in the EPAX group.

A randomized trial by du Plessis et al. (2011) compared manual and manipulative therapy (MMT) with standard care of a night splint(s) for symptomatic mild to moderate hallux abducto valgus (HAV). Thirty patients were equally assigned to each group. The control group used a night splint(s) while the experimental group (MMT) received 4 MMT 4 treatments over a 2-week period. Outcomes were measured with visual analogue scale, foot function index and hallux dorsiflexion. Outcome measure scores in the control group (night splint) regressed between the 1-week follow-up and 1-month follow-up when patients 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 manual and manipulative therapy is equivalent to standard care of a night splint(s) for symptomatic mild to moderate HAV in the short term.

Headache

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

Rist et al. (2019) performed a systematic review and meta-analysis of published randomized clinical trials (RCTs) to evaluate the evidence regarding spinal manipulation as an alternative therapy in reducing migraine pain and disability. The search identified six RCTs with a total of 677 participants eligible for meta-analysis. Outcomes included measures of migraine days, migraine pain/intensity, and migraine disability. Methodological quality varied across the studies. For example, some studies received high or unclear bias scores for methodological features such as compliance, blinding, and completeness of outcome data. Heterogeneity across the studies was low. The authors observed that spinal manipulation may be an effective therapeutic technique in reducing migraine days and pain/intensity. The results are preliminary and future rigorous, large-scale RCTs are warranted to further evaluate spinal manipulation as a treatment for migraine. [Author Chaibi 2017a/b, which was previously cited in this policy, is included in the Rist et al. (2019) and Rani et al. (2019) meta-analysis].

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

The effectiveness of mobilization and manipulation was compared to other conservative treatments on reducing pain intensity, frequency, and disability in patients with cervicogenic and tension-type headaches in a systematic review and meta-analysis (Coelho et al., 2019). Nine RCTs totaling 793 participants were included in the systematic review. Of these, only three trials were judged to have a low risk of bias. Manipulation/mobilization was found to be equally as effective as other conservative treatments in reducing pain, disability, and frequency of headache in individuals with cervicogenic headache. Manipulation/mobilization was found to be more effective than comparative conservative care over the short-term (up to 4 weeks) and like other interventions at 3 months follow-up for individuals with tension-type headache.

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

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

Temporomandibular Joint (TMJ) Disorders (TMD)

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

Asquini et al. (2022) performed a systematic review to evaluate the effectiveness of manual therapy applied to the craniomandibular structures [Cranio-Mandibular Manual Therapy (CMMT)] on pain and maximum mouth opening in people with temporomandibular disorders (TMD). Randomized controlled trials (RCTs) comparing the effect of CMMT on pain and maximum mouth opening versus other types of treatment in TMDs were included from inception until October 2020. Two reviewers independently screened articles for inclusion, extracted data, assessed risk of bias with the revised Cochrane risk of bias tool for randomized trials and evaluated the overall quality of evidence with the Grading of Recommendations, Assessment, Development and Evaluations. A total of 2,720 records were screened, of which only 6 (293 participants) satisfied the inclusion criteria. All studies showed improvement in pain and maximum mouth opening for CMMT from baseline in the mid-term, but only two showed superiorities compared to other interventions. A quantitative synthesis was not performed. The authors concluded there is a need for future high methodology research investigating different manual therapy techniques applied to different regions and different populations (e.g., chronic versus acute TMD) to determine what is most effective for pain and maximum mouth opening in patients with TMDs. This study was limited by its heterogeneous patient population, risk of bias, and small sample sizes. Further research is needed to determine the clinical relevance of these findings. [Authors Brochado et al. (2018), which were previously cited in this policy, are included in this systematic review].

Detoni et al. (2022) conducted a randomized, controlled, double-blinded study to assess the effect of osteopathic manipulative treatment (OMT) of the temporomandibular joint (TMJ) and the orthostatic posture using the molar shim (MS) as a postural adjustment factor. Twenty individuals classified with temporomandibular disorder (TMD) were randomly assigned to a treated group (TG, n = 10) and placebo (PG, n = 10). The independent variables were MS and OMT of the TMJ. The dependent variables were DC-TMD data; local pressure pain using algometry; and orthostatic posture assessed by the distribution of plantar pressures (baropodometry), in the evaluation periods before and immediately after the interventions. Pain did not show a statistically significant difference after the interventions. However, when comparing the Effect Size (ES) between the groups in the post-intervention moment, a moderate relationship was observed for the left trapezius muscle (0.51) and right and left TMJ (0.41 and 0.54 respectively). When correlating the pain and percentage of anteroposterior postural dislocation variables, a moderate inverse correlation was observed in the post-intervention moment. The results of the MS pointed to a decrease ($p \leq 0.05$) of the average peak pressure (Medium P) during the use of the MS (503.4 ±44.1 kgf/cm^2) and after performing the OMT (516.5 ±49.6 kgf/cm^2), both for the TG compared to the pre intervention moment (519.3 ±42.9 kgf/cm^2). The authors concluded that there is a correlation between TMJ and orthostatic posture. OMT of the TMJ influences orthostatic posture. The MS can be added to the evaluative context of TMD. Study limitations included the following: the dysfunctional side of the TMJ was not addressed, and ROMs and masticatory predominance were not part of the pre- and post-intervention comparison. In addition, the feet were not evaluated, which prevented the foot correlation in relation to the baropodometric variables. Long-term evaluations of the results and prospective randomized studies are still needed.

Two systematic reviews evaluated the effectiveness of manual therapy in the treatment of pain related to temporomandibular joint disorder (TMD). The systematic review by Herrera Valenci et al. (2020) found six RCTs; two studies were of low quality and the other four were considered high quality. While the analysis concluded that manual therapy was an effective treatment for TMD, the positive effect seems to decrease over time unless paired with therapeutic exercise (TE) which seem to favor long term effects on decreasing pain. The de Melo et al. (2020) systematic review consisted of five studies which found manual therapy to be effective for pain relief, however, there was a high risk of bias. Both studies concluded due to the low number of studies and the variability within each, the conclusion was further research is needed on the topic to validate the efficacy and long-term effects of manual therapy for TMD.

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

A systematic literature search identified two other systematic reviews with meta-analysis (Martins, 2016; Armijo-Olivo, 2016), an additional three systematic reviews (Adelizzi, 2016; Calixtre, 2015; De Castro 2018), and two RCTs (Corum, 2018; Brochado, 2018) that were not included in any evidence synthesis.

The individual studies investigated the treatment of participants with different temporomandibular dysfunction (TMD) diagnostic classifications (arthrogenous, myogenous, mixed) using a range of manual therapy (MT) interventions including manipulation of the jaw and cervical spine, with or without exercise, in comparison to passive and active interventions. The reviews and one of two RCTs reported results favoring manipulative therapy for the outcomes of pain intensity, maximal mouth opening (MMO) and pressure pain threshold (PPT), typically over the short-term (< 3 months follow-up). Most of the individual studies were judged to have a high or unclear risk of bias (RoB). Most studies did not satisfy critical indicators of methodological risk of bias (likely to over-estimate beneficial treatment effects) such as randomization, allocation concealment, blinding and intention-to-treat analyses. Additionally, it was uncertain if sample size was adequate for most of the included studies and clinical significance was not routinely described. Therefore, the data in the reviews should be interpreted carefully.

Four of the systematic reviews had one or more critical flaws along with other methodologic weaknesses and could not be relied on to provide an accurate and comprehensive summary of the available studies. Adelizzi et al. (2016) was rated as being of critically low quality due to limitations in reporting the research questions and inclusion criteria for the review, uncertainty about the comprehensiveness of the literature search strategy, and methods used to assess RoB in non-randomized studies of interventions (NRSI). Calixtre et al. (2015) was judged to be of low quality due to a critical flaw regarding the accuracy of the results. The analysis (Tables 4 and 5) reported absolute changes incorrectly, as effect sizes, and further compounded the error by interpreting the magnitude of results using Cohen's d criteria. Non-critical weaknesses were identified increasing the risk of selection and funding bias. The systematic review authored by De Castro et al. (2018) contained several critical methodologic flaws relating to the development of the review, the approach used to identify and extract study data, and the failure to incorporate the role of study bias into the analysis. A systematic review with meta-analysis (Martins et al; 2016) was deemed to be of critically low quality. There were critical flaws pertaining to the literature search strategy and the statistical methods used to interpret the meta-analytic results, which likely over-estimated the effects of manipulative therapy for pain intensity and MMO.

The systematic review and meta-analysis conducted by Armijo-Olivo et al. (2016), was rated as moderate overall quality. A detailed assessment of the review showed that for pain intensity MT interventions including manipulative therapy, when used as a monotherapy, did not achieve clinically relevant outcomes. Further, it was not possible to distinguish the effects on pain intensity of MT when combined with exercise interventions. Over the short-term, MT demonstrated potentially clinically meaningful benefit concerning MMO. MT-alone (6 RCTs) showed mixed results for individuals diagnosed as having mixed (arthrogenous and myogenous) TMD.

A RCT conducted by Corum et al. (2018) was not included in any of the evidence syntheses. As with previous trials on the topic, the study had a high RoB due to significant flaws concerning treatment allocation, blinding and failure to include all participants in the analysis. Also, there were concerns about the potential for bias due to compliance with the intervention and avoidance of co-interventions. Further, the treatment arms did not permit conclusions about the discreet effects of MT on pain and MMO. Additionally, the statistical approach did not allow for judgments about clinical relevance and precision.

Another RCT that was not assessed in the included reviews was performed by Brochado et al. (2018). The authors investigated the comparative effectiveness of photobiomodulation (laser therapy) and MT, alone or combined. Outcomes measured included pain intensity, MMO, psychosocial aspects, and anxiety symptoms of TMD patients. While all groups improved across the measured outcomes, the change in mean scores did not differ significantly between groups during the 90-day evaluation time.

In summary, the current body of evidence regarding the efficacy of MT for TMD consists of generally promising results across patient-important outcomes. However, confidence in the estimates of effect is limited by the low quality of evidence, uncertainty about clinical relevance, and durability of outcomes.

Prevention Manipulative Treatment Care

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

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

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

Eklund et al. (2018) conducted a pragmatic randomized controlled trial to investigate the effectiveness of chiropractic maintenance care (MC) versus symptom-guided treatment for recurrent and persistent low back pain (LBP) who had an early favorable response to chiropractic care. After an initial course of treatment, eligible subjects were randomized to either MC (n = 166) or control (symptom-guided treatment) (n = 161). The primary outcome was total number of days with bothersome LBP during 52 weeks collected weekly with text-messages and estimated by a GEE model. Of the subjects who were eligible after the first visit, 32% were lost and of the subjects who were eligible at the fourth visit, 25% were lost. During the 12-month study period, the MC group (n = 163, 3 dropouts) reported 12.8 (95% CI = 10.1, 15.5; p = < 0.001) fewer days in total with bothersome LBP compared to the control group (n = 158, 4 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 patients with recurrent or persistent non-specific LBP who respond well to an initial course of chiropractic care, MC should be considered an option for tertiary prevention. Further research is likely to have an important impact on confidence in estimate of effect of MC and may change the estimate. Limitation included lack of a sham intervention and possibility of social desirability in participants' report of symptoms.

Brumm et al. (2012) conducted a prospective cohort study to apply a preventive OMT protocol for cross-country athletes to reduce the incidence of stress fractures. Examinations of cross-country athletes at an NCAA (National Collegiate Athletic Association) Division I university were performed over successive academic years. More than 1,800 participant examinations were performed on 124 male and female participants over the course of five consecutive academic years. Data from these academic years were compared with data from the previous eight academic years. The intervention included osteopathic structural examination and OMT that focused on somatic dysfunction identified in the pelvis, sacrum, and lower extremities. According to the authors, the results demonstrated a statistically significant decrease in the cumulative annual incidence of stress fractures in male, but not female, cross-country athletes after receiving OMT. The study is limited by the lack of a contemporary comparison group. Further research with randomized controlled trials is needed to validate these findings.

Martel et al. (2011) conducted a randomized controlled trial to compare the efficacy of preventive spinal manipulative therapy (SMT) to no treatment in 108 patients with non-specific chronic neck pain. The trial was divided into two phases. The first was the non-randomized, symptomatic phase during which all eligible participants received a short course of SMT. Ten patients dropped out of the study following the symptomatic phase. After completing the symptomatic phase, the remaining 98 participants were randomly assigned to 1 of 3 parallel groups (no treatment (n = 29), a SMT group (n = 36) or a SMT plus exercise group (n = 33)). The second preventive phase lasted 10 months. Outcomes were measured using visual analog scale (VAS), active cervical ranges of motion (cROM), the neck disability index (NDI) and the Bournemouth questionnaire (BQ). Patients were also asked to keep an exercise diary. Mean adherence to the home exercise program was 48.8%. In the preventive phase, all three groups showed outcomes scores like those obtain following the non-randomized, symptomatic phase. Overall spinal manipulation or spinal manipulation combined with exercises did not have any significant advantages when compared to the no treatment strategy. The authors found that preventive therapy was no more effective than no treatment at all for patients with non-specific chronic neck pain. Limitations included small sample size and absence of blinding.

A randomized controlled trial by Senna and Machaly (2011) investigated the effects of maintenance spinal manipulation therapy for chronic non-specific low back pain. Subjects were randomized into three groups and followed for 10 months. Group 1 (n = 40) received sham manipulation during the first month and no treatment over the subsequent 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 subjects declined follow-up. Five withdrew in the first phase before treatment began. Of the remaining 88 subjects, 80 were evaluated at 4 months, 71 at 7 months and 60 at 10 months. Subjects in groups 2 and 3 experienced significantly lower pain and disability scores compared to the control group after the initial 1-month treatment period. At the end of 10 months, group 3 reported significantly lower pain and disability scores compared to Group 2. The authors concluded that spinal manipulation is an effective treatment for chronic non-specific low back pain. While Group 3 reported better outcomes, the basis of this improvement could not be determined as to whether it was the manipulation or the placebo effect of continued visits. The study is further limited by serious methodological flaws e.g., 35% drop-out rate; incomplete outcome data; lack of blinding; and uncertainty about allocation concealment, use of co-interventions, and compliance across groups.

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

The long-term safety and effectiveness of the use of chiropractic management and manual therapies in the treatment of non-neuromusculoskeletal conditions, including but not limited to hypertension, asthma, colic, and otitis media have not been proven in the medical literature through quality research, such as long-term, randomized, controlled clinical trials.

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

Franke et al. (2022) conducted a systematic review to determine the effectiveness of osteopathic manipulative treatment (OMT) for all pediatric complaints. Forty-seven RCTs examining 37 pediatric conditions were reviewed. These conditions included musculoskeletal, visceral, ear, respiratory, cerebral palsy, and learning difficulties. Twenty-three studies reported favorable outcomes for OMT relative to the control intervention, and 14 additional studies reported non-significant outcomes, which suggested potential favorable effects of OMT. Fifteen of the studies were judged to have a low risk of bias (RoB), 12 had high risk, and the remainder had indeterminate RoB. There was moderate evidence for the effectiveness of OMT for 13 of the 43 comparisons, particularly for length of hospital stay for preterm infants, but no high-quality evidence for any condition. The authors concluded that although a number of studies indicated positive results with 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 confirm this hypothesis. [Authors Castejón-Castejón et al. (2019) which were previously cited in this policy, are included in this systematic review].

Rehman et al. (2022) conducted a systematic review to evaluate the safety and effectiveness of osteopathic manipulative therapy (OMT) and comparable techniques in the treatment of dizziness. From inception to March 2021, there were 3,375 studies identified and screened, with only 12 meeting inclusion criteria for data extraction. Moderate-quality evidence showed that articular OMT techniques were associated with decreases (all $p < 0.01$) in disability associated with dizziness [n = 141, mean difference (MD) = -11, 95% confidence interval (CI) = -16.2 to -5.9], dizziness severity (n = 158, MD = -1.6, 95% CI = -2.4 to -0.7), and dizziness frequency (n = 136, MD = -0.6, 95% CI = -1.1 to -0.2). Low-quality evidence showed that articular OMT was not associated with all case dropouts (ACD) rates [odds ratio (OR) = 2.2, 95% CI = 0.5 to 10.2, p = 0.31]. When data were pooled for any type of OMT technique, findings were similar; however, disability associated with dizziness and ACD rates had high heterogeneity (I^2 = 59 and 46%). No studies met all of the criteria for risk of bias. The authors concluded the current review found moderate-quality evidence that treatment with articular OMT techniques was associated with decreased disability associated with dizziness, dizziness severity, and dizziness frequency. Limitations include a small sample size (11 RCTs, 1 observational study, n = 367 participants) and high risk of bias. Further research is needed to determine the clinical relevance of these findings.

The global summit on the efficacy and effectiveness of spinal manipulative therapy (SMT) for the prevention and treatment of non-musculoskeletal disorders conducted a systematic review of the literature and found no evidence that SMT has a positive effect for management of non-musculoskeletal disorders including infantile colic, childhood asthma and migraines (Côté, et al. 2021).

An interventional study by Jones et al. (2021) was performed to evaluate the change in same-day pulmonary function testing in pediatric patients receiving osteopathic manipulative treatment (OMT) compared to those receiving usual care. The study population included 58 patients: 31 (53.4%) were assigned to the OMT group and 27 (46.6%) were assigned to the standard of care group. The selected patients were: 1) ages 7-18 years, 2) a diagnosis of asthma, 3) patients receiving care at a primary care-based asthma clinic, and 4) those patients who had baseline spirometry. Selected patients were then randomized to either an OMT or a control group. Patients who were experiencing an acute asthma exacerbation were excluded. Patients 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 patients received standard care only. A second PFT was performed on both groups at the end of the visit. OMT was performed by multiple osteopathic pediatric residents who were specifically trained for the purposes of this study. Change in spirometry results (FVC, FEV1, FVC/FEV1, and FEF 25-75%) were then compared. Patients who received OMT had greater improvement in all spirometry values compared to 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 asthma patients remain unclear. Further investigation in a larger cohort is necessary to recommend broad scale application of these techniques in clinical practice.

Numerous systematic literature reviews have investigated manipulative therapies for a range of non-musculoskeletal disorders. Relevant systematic reviews address the treatment of respiratory disorders such as asthma (Alcantara et al., 2012; Hondras et al., 2005, Kaminsky et al., 2010; Pepino et al., 2013) cystic fibrosis, bronchiolitis, recurrent infections (Pepino et al., 2013); and chronic pulmonary obstructive disease (Heneghan et al., 2013).

Four systematic reviews examined the use of manipulation for the management of gastrointestinal disorders affecting infants e.g., infantile colic (Alcantara et al., 2011; Carnes et al., 2018; Dobson et al., 2012), adults for irritable bowel syndrome (Müller et al., 2013), gastroesophageal reflux and duodenal ulcers (Ernst, 2011).

Three systematic reviews reported on the efficacy of manual therapy for the treatment of otitis media (Carr and Nahata, 2006; Leighton, 2009; Pohlman, 2012).

Systematic reviews of manipulation as part of manual therapy interventions were identified for the treatment of attention deficit hyperactivity disorder (ADHD) (Karpouzis et al., 2010), hypertension (Mangum et al., 2012), nocturnal enuresis (Huang et al., 2011), insomnia (Kingston et al., 2010), and lower urinary tract symptoms (LUTS) (Franke and Hoesele, 2013).

Collectively, the direction of outcomes favored subjects receiving manual therapy interventions. However, the limited number of studies and the quality of research evidence (designs, methodologies, sample sizes, variation of interventions, and outcomes measured) do not permit confident judgments about the effectiveness and safety of manual therapy interventions including manipulation for the treatment of non-musculoskeletal disorders.

Additional systematic reviews that included a wide range of non-musculoskeletal disorders found the evidence lacking, inconclusive or unproven in assessing the effectiveness of manual therapy interventions including manipulative therapy for the treatment of non-musculoskeletal disorders (Clar et al., 2014; Posadzki et al., 2013; Gleberzon et al., 2012; Gotlib and Rupert, 2008; Ferrance and Miller, 2010).

Neuroimmunoendocrine Effects

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

Visceral Disorders

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

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

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 ADHD, autism, asthma, infantile colic, constipation, otitis media, scoliosis, and torticollis. Of the fifty studies found, 32 were RCTs and 18 were observational; 23 studies were specific to OMT, 17 used chiropractic manipulative therapy and 10 with mobilization. While some pediatric conditions such as low back pain and pulled elbow had a positive outcome with implementation of osteopathic treatment, the authors found the overall results as inconclusive. It was determined that additional research investigating osteopathic treatment on pediatric conditions is needed.

Silva et al. (2018) conducted a randomized, double-blind, placebo-controlled pilot study to evaluate the effect of osteopathic visceral manipulation (OVM) on pain, cervical range of motion, and upper trapezius (UT) muscle activity in patients with chronic nonspecific neck pain (NS-NP) and functional dyspepsia. Twenty-eight NS-NP patients 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 electromyographic activity of the UT muscle. Significant effects were confirmed for both groups immediately after treatment (OVMG and PVMG) for numeric rating scale scores ($p < 0.001$) and pain area ($p < 0.001$). Significant increases in EMG amplitude were identified immediately and 7 days after treatment for the OVMG ($p < 0.001$). No differences were identified between the OVMG and the PVMG for cervical range of motion ($p > 0.05$). The authors' concluded that this study demonstrated that a single visceral mobilization session for the stomach and liver reduces cervical pain and increases the amplitude of the EMG signal of the UT muscle immediately and 7 days after treatment in patients with nonspecific neck pain and functional dyspepsia. Limitations of this study include small sample size, lack of blinding, and short follow-up period. These findings need to be independently reproduced with focus on group difference rather than before-after changes.

In a randomized, placebo-controlled trial, Panagopoulos et al. (2015) investigated whether the addition of visceral manipulation, to a standard physiotherapy algorithm, improved outcomes in patients with low back pain. Sixty-four patients with low back pain who presented for treatment at a private physiotherapy clinic were randomized to one of two groups: standard physiotherapy plus visceral manipulation (n = 32) or standard physiotherapy plus placebo visceral manipulation (n = 32). The primary outcome was pain (measured with the 0-10 Numerical Pain Rating Scale) at 6 weeks. 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 or 52 weeks. The group receiving addition of visceral manipulation had less pain than the placebo group at 52 weeks (mean 1.57, 95% CI = 0.32 to 2.82). The results suggest that visceral manipulation in addition to standard care is not effective in changing short-term outcomes but may produce clinically worthwhile improvements in pain at 1 year.

Scoliosis

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

Pu Chu et al. (2020) conducted a retrospective chart review to investigate the role of chiropractic intervention for patients with adolescent idiopathic scoliosis (AIS). Ten cases of patients with AIS, mean age 13.3 years, undergoing chiropractic adjustment were retrospectively evaluated. 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 post-treatment radiographs revealed that Cobb angle reduced from average 29.7° down to average 23.4° (average 21.2% correction). Improvements in spinal morphologies were observed in most curves (64%, n = 9/14) and curve stabilization in the rest (36%, n = 5/14). A better correction was obtained in cases of mild and moderate AIS. In terms of stabilizing progression (≤ 5° curve progression) or correcting curvatures (≥ 6° reduction), radiological changes were observed in all patients. This study was limited by 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.

Langensiepen et al. (2017) conducted a randomized controlled trial (RCT) to evaluate the effect of scoliosis specific exercises (SSE) on a side-alternating whole body vibration platform (sWBV) as a home-training program in girls with adolescent idiopathic scoliosis (AIS). Forty female AIS patients (10-17 years) wearing a brace were randomly assigned to two groups. The intervention was a six month, home-based, SSE program on a sWBV platform five times per week. Exercises included standing, sitting, and kneeling. The control group received regular SSE (treatment as usual). The Cobb angle was measured at start and after six months. Onset of menarche was documented for sub-group analysis. The major curve in the sWBV group decreased by -2.3° (SD ±3.8) (95% CI -4.1 to -0.5; p = 0.014) compared to the difference in the control group of 0.3° (SD ±3.7) (95% CI -1.5 to 2.2; p = 0.682) (p = 0.035). In the sWBV group 20% (n = 4) improved, 75% (n = 15) stabilized and 5% (n = 1) deteriorated by ≥ 5°. In the control group 0% (n = 0) improved, 89% (n = 16) stabilized and 11% (n = 2) deteriorated. The clinically largest change was observed in the 'before-menarche' sub-group. The authors concluded that home-based SSE combined with sWBV for six months counteracts the progression of scoliosis in girls with AIS; the results were more obvious before the onset of the menarche. This RCT is limited by its small study population, endpoints such as quality of life were not assessed, and progression of the Cobb angle in AIS was not stratified by Risser sign. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes.

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

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

Czaprowski (2016) conducted a systematic review to assess the efficacy of non-specific manual therapy (manual therapy, chiropractic, osteopathy) used in the treatment of children and adolescents with IS. Results of these studies are contradictory, ranging from Cobb angle reduction to no treatment effects whatsoever. The papers analyzed are characterized by poor methodological quality, small group sizes, incomplete descriptions of the study groups, and no follow-up or control groups.

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.

Craniosacral Therapy (CST)

CST is considered unproven as there is insufficient evidence to support its role in manipulative therapy; additional robust, high quality studies are needed to support its safety and efficacy.

Castejón-Castejón et al. (2022) conducted a randomized controlled trial (RCT) to evaluate the number of craniosacral therapy sessions that can be helpful to obtain a resolution of the symptoms of infantile colic. And in addition, to observe if there are any differences in the evolution obtained by the groups that received a different number of craniosacral therapy sessions at 24 days of treatment, compared with the control group which did not receive any treatment. A total of 58 infants with colic were randomized into two groups of which 29 babies in the control group received no treatment, and those in the experimental group received 1-3 sessions of craniosacral therapy (CST) until symptoms were resolved. Evaluations were performed until day 24 of the study. In this RCT, crying hours served as primary outcome. The secondary outcome were the hours of sleep and the severity, measured by an Infantile Colic Severity Questionnaire (ICSQ). Differences were observed in favor of experimental group compared to the control group on day 24 in crying hours (mean difference = 2.94, at 95% CI = 2.30-3.58; $p < 0.001$) primary outcome, and also in hours of sleep (mean difference = 2.80; at 95% CI = - 3.85 to - 1.73; $p < 0.001$) and colic severity (mean difference = 17.24; at 95% CI = 14.42-20.05; $p < 0.001$) secondary outcomes. Also, the differences between the groups ≤ 2 CST sessions (n = 19), 3 CST sessions (n = 10) and control (n = 25) were statistically noteworthy on day 24 of the treatment for crying, sleep, and colic severity outcomes ($p < 0.001$). The authors concluded that babies with infantile colic may obtain a complete resolution of symptoms on day 24 by receiving 2 or 3 CST sessions compared to the control group, which did not receive any treatment. This RCT is a small, unblinded study. Further investigation is needed before clinical usefulness of this procedure is proven.

Muñoz-Gómez et al. (2022) conducted a randomized controlled trial (RCT) to evaluate the effectiveness of a craniosacral therapy protocol on different features in migraine patients. Fifty individuals with migraine were randomly divided into two groups (n = 25 per group): (i) craniosacral therapy group (CTG), following a craniosacral therapy protocol, and (ii) sham control group (SCG), with a sham treatment. The analyzed variables were pain, migraine severity and frequency of episodes, functional, emotional, and overall disability, medication intake, and self-reported perceived changes, at baseline, after a 4-week intervention, and at 8-week follow-up. After the intervention, the CTG reduced pain ($p = 0.01$), frequency of episodes ($p = 0.001$), functional ($p = 0.001$) and overall disability ($p = 0.02$), and medication intake ($p = 0.01$), as well as led to a higher self-reported perception of change ($p = 0.01$), when compared to SCG. In addition, the results were maintained at follow-up evaluation in all variables. The authors concluded that a protocol based on craniosacral therapy is effective in improving pain, frequency of episodes, functional and overall disability, and medication intake in migraineurs. This protocol may be considered as a therapeutic approach in migraine patients. Limitations include a small sample size which makes it difficult to decide whether these conclusions can be generalized to a larger population, and a lack of follow-up did not allow for assessment of intermediate and long-term outcomes. The findings of this study need to be validated by well-designed studies.

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

The effectiveness and safety of craniosacral therapy for chronic pain conditions was investigated by Haller et al (2020). Ten RCTs of 681 patients with neck and back pain, migraine, headache, fibromyalgia, epicondylitis, and pelvic girdle pain were included. Craniosacral therapy showed small/moderate greater post intervention effects on pain intensity and disability compared to treatment as usual care, sham, and active manual treatments. Effects were maintained through 6-months follow-up. The implications of the findings were viewed by the authors as preliminary due to the small number of studies included in the meta-analysis. Most individual analyses included only two studies with a median pooled sample of 138 (range 119-230) participants, which produced imprecise results across primary and secondary outcomes. It is likely that additional studies will change the estimates of effect. Confidence in the reported estimates of effect was also reduced due to the frequent unclear risk of bias profile of the included RCTs. Many RCTs did not report allocation concealment, blinding of outcome assessment, and alternative methods of decreasing the risk of performance bias. Additionally, the study does not allow for making conclusions about the effectiveness of craniosacral therapy for specific pain conditions. [Author Haller et al. (2016) which was previously cited in this policy, is included in the Haller et al. (2020) meta-analysis].

Castejón-Castejón et al. (2019) conducted a small RCT (n = 58) to assess the effectiveness of craniosacral therapy in the treatment of infantile colic. The authors reported clinically significant benefits for crying time (hours), colic severity and sleep duration favoring craniosacral therapy at 7, 14, and 24 days follow up assessments. Confidence in the conclusions was limited due to a high risk of detection, performance, and attrition bias. In addition to methodologic limitations, the results are likely not generalizable as the study was conducted at a single site by one clinician.

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

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

Manipulative Therapy with Non-Standard Techniques

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

Clinical Practice Guidelines

American Osteopathic Association (AOA)

In a systematic review on the use of osteopathic manipulative treatment (OMT) in patients with low back pain (LBP), the AOA's updated clinical guideline (2016) concludes that this therapy significantly reduces pain and improves functional status in patients, including pregnant and postpartum women, with nonspecific acute and chronic LBP. The AOA recommends that larger randomized controlled trials with robust comparison groups 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.

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

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

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

U.S. Food and Drug Administration (FDA)

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

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

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Policy History/Revision Information

Date	Summary of Changes
07/01/2024	• New Medical Policy

Instructions for Use

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

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