Manipulative Therapy (for Louisiana Only)

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Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

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, etc.)
- Prevention/maintenance/custodial care
- Internal organ disorders (e.g., gallbladder, spleen, intestinal, kidney, or lung disorders)
- Temporomandibular joint (TMJ) disorder
- Scoliosis
- 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

Manipulative therapy is unproven and not medically necessary when any of the following apply:
- The member's condition has returned to the pre-symptom state
- Little or no improvement is demonstrated within 30 days of the initial visit despite modification of the treatment plan
- Concurrent manipulative therapy, for the same or similar condition, provided by another health professional whether or not the healthcare professional is in the same professional discipline

Definitions

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).

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.

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

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 considered 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.

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 particular 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 Disorders

Back

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 in particular. 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 (1699 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, 5 examined OMT for LBP in pregnancy and 3 for postpartum LBP. Moderate-quality evidence suggested 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. This review suggests OMT produces clinically relevant benefits for pregnant or postpartum women with LBP. Further research may change estimates of effect, and larger, high-quality RCTs with robust comparison groups are recommended.

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 1198 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. Considering the lack of effect compared to sham interventions, further high-quality research is needed to determine causal effects, the influence of the therapist on the perceived effectiveness of treatments, and adequate dose-response of complementary manual therapies on low back and pelvic pain outcomes during pregnancy.

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 4 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. Further studies that include prolonged follow-up periods are warranted to corroborate the current findings.

A 2014 cohort study by Leeman et al. evaluated 148 patents between the ages of 18 and 65 with low back and leg pain due to MRI confirmed herniated disc, who were being treated with high velocity and low amplitude spinal manipulation in terms of their short-, medium-, and long-term outcomes of self-reported global impression of change and pain levels at various time points up to 1 year and to determine if outcomes differ between acute and chronic patients using a prospective, cohort design. The type of manipulation was dependent upon whether the disc herniation was intraforaminal or paramedian as seen on the magnetic resonance images and was performed by a doctor of chiropractic. Outcomes included the patient's global impression of change scale for overall improvement, the NRS for LBP, leg pain, and the Oswestry questionnaire at 2 weeks, 1, 3, and 6 months, and 1 year after the first treatment. The proportion of patients reporting "improvement" on the patient's global impression of change scale was calculated for all patients and acute vs. chronic patients. At the conclusion of the study a large percentage of acute and importantly chronic lumbar disc herniation patients treated with chiropractic spinal manipulation reported clinically relevant improvement.

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.

In a systematic review and meta-analysis of 15 trials with 18 comparison groups and 1502 participants, Franke et al. (2014) assessed OMT for the treatment of non-specific low back pain. The authors concluded that clinically relevant effects of OMT were found for reducing pain and improving functional status in patients with acute and chronic nonspecific LBP (moderate quality evidence) and for LBP in pregnant (low quality evidence) and postpartum women at 3 months post-treatment (moderate quality evidence). Given the small sample sizes, different comparison groups in different studies, heterogeneity, and lack of long-term measurement, larger, high-quality RCTs with robust comparison groups are needed to provide firm conclusions regarding the effectiveness of OMT for LBP.

Dagenais et al. (2010) conducted a systematic review to evaluate spinal manipulation therapy for low back pain. Of 699 studies, 14 (n=2,027 patients) were included for review. Spinal manipulation therapy was most commonly compared to physical modalities, education, medication, exercise, mobilization, or sham therapy. The authors found that the results from most studies suggest that 5 to 10 sessions of spinal manipulation therapy administered over 2 to 4 weeks achieve equivalent or superior improvement in pain and function when compared with other commonly used interventions for short, intermediate, and long-term follow-up.

A 2011 Cochrane review by Rubinstein et al. (2011) evaluated 26 randomized controlled trials that assessed the effects of spinal manipulative therapy (SMT) in 6070 patients with chronic low-back pain. They concluded that SMT appears to be as effective as other common therapies prescribed for chronic low-back pain, such as, exercise therapy, standard medical care or physiotherapy. However, it is less clear how it compares to no treatment or sham (placebo) treatment.

In a 2010 Cochrane review by Walker et al., 12 studies involving 2887 participants were evaluated to assess the various combinations of chiropractic care for low-back pain. The review showed that while combined chiropractic interventions slightly improved pain and disability in the short term and pain in the medium term for acute and subacute low-back pain, there is currently no evidence to support or refute that combined chiropractic interventions provide a clinically meaningful advantage over other treatments for pain or disability in people with low-back pain.

A meta-analysis by Chou et al. (2007) evaluated non-pharmacologic therapies for acute and chronic low back pain and found that there is good evidence spinal manipulation is moderately effective for subacute and chronic low back pain; and fair evidence for small to moderate benefits for acute low back pain.

A systematic review by Licciardone et al. (2005) of 6 osteopathic manipulative treatment (OMT) clinical trials were evaluated to assess the efficacy of OMT as a complementary treatment for low back pain. A total of 525 subjects with low back pain were randomized in the eligible trials. Overall, OMT significantly reduced low back pain (effect size, -0.30; 95% confidence interval, -

0.47 - -0.13; P = .001). Stratified analyses demonstrated significant pain reductions in trials of OMT vs. active treatment or placebo control and OMT vs. no treatment control. The authors concluded that OMT significantly reduces low back pain and the level of pain reduction was greater than expected from placebo effects alone. This review was limited by the various study designs such as the methodology, trial setting, subject characteristics, OMT and control treatment interventions, and pain measures.

Neck

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 5 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.

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.

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.

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 4 treatments of either neck manipulation (n=91) or mobilization (n=91) over 2 weeks. Outcomes were measured by the number of days taken to recover from the episode of neck pain. 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 prospective, multicenter study 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 3 treatments. Only 5 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.

Headache

Chaibi et al. (2017a) investigated the efficacy of chiropractic SMT versus placebo (sham manipulation) and control (continued usual but non-manual management) for cervicogenic headache in a prospective 3-armed single-blinded, placebo, RCT of 17 months' duration. Nineteen participants were randomized into the three groups, and 12 participants completed the RCT. Headache frequency improved at all time points in the chiropractic SMT and the placebo group. Headache index improved in the chiropractic SMT group at all time points, while it improved at 6 and 12 months' follow-up in the placebo group. The control group remained unchanged during the whole study period. Adverse events were few, mild and transient. Blinding was concealed throughout the RCT. In the authors' opinion, the results suggest that manual-therapy might be a safe treatment option for participants with cervicogenic headache, but data need to be confirmed in a randomized controlled trial with sufficient sample size and statistical power. Larger RCTs with longer outcomes are needed to validate these findings.

In a three-armed, single-blinded, placebo RCT, Chaibi et al. (2017b) investigated the efficacy of chiropractic spinal manipulative therapy (CSMT) in migraine headache (n=104). Inclusion criteria consisted of one migraine per month. Active treatment consisted of CSMT, whereas placebo was a sham push maneuver of the lateral edge of the scapula and/or the gluteal region. The control group continued their usual pharmacological management. The RCT consisted of a 1-month run-in, 3 months intervention and outcome measures at the end of the intervention and at 3, 6 and 12 months follow-up. The primary end-point was the number of migraine days per month, whereas secondary end-points were migraine duration, migraine intensity and headache index, and medicine consumption. Migraine days were significantly reduced within all three groups from baseline to post-treatment ($P < 0.001$). The effect continued in the CSMT and placebo group at all follow-up time points, whereas the control group returned to baseline. The reduction in migraine days was not significantly different between the groups ($P > 0.025$ for interaction). Migraine duration and headache index were reduced significantly more in the CSMT than the control group towards the end of follow-up ($P = 0.02$ and $P = 0.04$ for interaction, respectively). Adverse events were few, mild and transient. The authors concluded that the results were most likely due to a placebo effect.

Seffinger and Tang (2017) evaluated spinal manipulation and mobilization therapy for cervicogenic headache through a systematic review of 10 RCTs. The authors concluded that cervical spine manipulation and mobilization are more beneficial than traditional physical therapy modalities and placebo interventions in lessening the intensity and frequency of symptoms in patients with cervicogenic headache. However, the authors note that it is difficult to draw general conclusions because the studies varied in terms of the spinal manipulative therapy techniques used, the intervention or placebo used in control groups, the diagnostic criteria for CEH, and primary outcome measures. Well-conducted RCTs are needed to assess the effectiveness of OMT in treating patients with cervicogenic 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.

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

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); pneumonia (Yang et al., 2013); and chronic pulmonary obstructive disease (Heneghan et al., 2013).

Four systematic reviews examined the use of manipulation for the management of gastro-intestinal disorders affecting infants e.g., infantile colic (Alcantara et al., 2011; 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 manual therapy for the treatment of otitis media. (Carr and Nahata, 2006; Leighton, 2009; Pohlman, 2012)

Single 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; Cole and Reed, 2010).

Prevention Manipulative Treatment Care

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.

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 2 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 3 groups showed outcomes scores similar to 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.

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 3 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 phrase 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.

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 1800 participant examinations were performed on 124 male and female participants over the course of 5 consecutive academic years. Data from these academic years were compared with data from the previous 8 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. Further research with randomized controlled trials is needed to validate these findings.

Internal Organ Disorders

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 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.

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.

Temporomandibular Joint (TMJ) Disorders (TMD)

A systematic literature search identified two systematic reviews with meta-analysis (Martins, 2016; Armijo-Olivo, 2016), an additional three systematic reviews (Adelizzi, 2016; Calixtre, 2016; 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). In particular, 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. (2016) 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.

Scoliosis

Théroux et al. (2017) conducted a systematic review of 4 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.

Morningstar et al. (2017a) conducted a retrospective chart review of 60 adolescent patients who received chiropractic care for treatment of idiopathic scoliosis (IS). All patients participated in a short-term chiropractic rehabilitation program which included external postural weights, motorized repetitive traction, and supine positional traction for a total of 25 hours per week. The majority of patients received an average of 1-3 manipulations over the 1-2 weeks of therapy. A home exercise program was also prescribed. According to outcomes reporting measures from the Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) and the Scoliosis Research Society (SRS) Non-Operative Management Committee, 90% of patients who participated in a chiropractic rehabilitation treatment for adolescent idiopathic scoliosis, and were followed through at least the end of growth, achieved a curve correction or stabilization. Study limitations include inconsistent application of chiropractic manipulations, and non-quantification of home exercise compliance. Future randomized controlled studies with longer follow-up periods are needed to evaluate chiropractic care in the treatment of IS in adolescents.

In a systematic review to evaluate the current body of literature on chiropractic treatment of IS, Morningstar et al. (2017b) identified 15 case reports, 10 case series, 1 prospective cohort, and 1 RCT. Of the 27 studies, only 2 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, 2 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 of 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.

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.

In a systematic review of 6 randomized controlled trials identified to have a low risk of bias, Sutton et al. (2016) evaluated the effectiveness of multimodal care for the management of musculoskeletal disorders of the elbow, forearm, wrist and hand on self-rated recovery, functional recovery or clinical outcomes in adults or children. Therapeutic modalities included a combination of: manual therapy (manipulation, mobilization, traction), soft-tissue therapies (e.g., massage, muscle energy technique), acupuncture, education, exercise, passive physical modalities (e.g., heat application, cryotherapy, ultrasound, splints, braces), prescribed medication (e.g., acetaminophen, non-steroidal anti-inflammatory drugs), psychological interventions (e.g., relaxation, biofeedback). Based on the outcome of their review, the authors reported that there may be a role for multimodal care in the management of patients with persistent lateral epicondylitis, specifically including manual therapy. The evidence did not support the use of multimodal care for the management of carpal tunnel syndrome. This systematic review highlights the need for further high quality studies to determine the effectiveness of multimodal care for musculoskeletal disorders of the elbow, forearm, wrist and hand.

Shoulder

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 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 or not they would alter the conclusions of their review.

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 3 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 3 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.

A prospective study by Mintken et al. (2010) utilized 5 prognostic factors associated with shoulder pain in 80 individuals to determine if cervical and thoracic spine manipulation would improve pain and disability. Participants underwent a standardized examination and then a series of thrust and non-thrust manipulations directed toward the cervicothoracic spine. Outcomes were measured using a 15-point Global Rating of Change (GROC) scale as well as outcomes from the prognostic variables. The GROC scale ranges from -7 ("a very great deal worse") to 0 ("about the same") to +7 ("a very great deal better"). Patients who rated their score as +4 or better were categorized as having a successful outcome. A total of 49 patients (61%) experienced a successful outcome. Mean Shoulder Pain and Disability Index (SPADI) scores decreased by more than 50% (from 38.1 to 18.4) in the successful group compared to 18% (from 37.9 to 30.4) in the non-successful group. Numeric pain rating scale (NPRS) scores also showed greater improvements in the successful group compared to the non-successful group. The participants' ability to flex the shoulder without pain improved significantly in both groups. The authors found that if 3 of the 5 variables were present, the chance of achieving a successful outcome improved from 61% to 89%. The study is limited by small sample size, lack of a control group and no long term follow-up.

Elbow, Wrist or Hand

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 6 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 Arrol (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 B6), 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 3 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

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.

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.

Knee Osteoarthritis

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.

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 a number of 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; 4 of which were felt to have a low risk for bias and high treatment fidelity.

Ankle and Foot

Plaza-Manzano et al. (2016) conducted a randomized single-blind controlled clinical trial to analyze the effects of proprioceptive strengthening exercises versus the same exercises and manual therapy in the management of recurrent ankle sprains (n=56). The control group performed 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.

Cleland et al. (2009) conducted a multicenter randomized clinical trial of 60 patients with plantar heel pain to compare the effectiveness of electro physical 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 a number of 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.

Craniosacral Therapy (CST)

Haller et al. (2016) conducted a randomized controlled clinical trial with a parallel-group design and 3 months of follow-up observation to investigate the efficacy of CST in chronic nonspecific neck pain in comparison with a manual sham control intervention. Patients (n=54) were randomized into either the CST group or an active attention-control group receiving light-touch sham treatment. Outcome measures were collected at week 8 after randomization (after intervention) and week 20 after randomization (3-month follow-up). The primary outcome was the average pain intensity during the last 7 days, recorded on a 100-mm VAS at week 8. Secondary outcomes were pain on movement, pressure pain sensitivity, neck pain-related disability, health-related quality of life, well-being, anxiety and depression, stress perception, pain acceptance, body awareness, patients' global impression of improvement, and safety. Based on the outcomes, the authors concluded that CST was both specifically effective and safe in reducing neck pain intensity and may improve functional disability and the quality of life up to 3 months after intervention. Limitations to this study include concurrent analgesic use, small sample size, short follow-up period, and primarily subjective outcome measures.

A systematic review to evaluate the benefits of CST identified the scarcity of CST research in patients with different clinical pathologies (Jäkel and von Hauenschild, 2012). In the authors' opinion, CST assessment is feasible in randomized controlled trials and has the potential of providing valuable outcomes to further support clinical decision making. However, due to the current moderate methodological quality of the included studies, further research is needed. The conclusion was based on 7 studies which met the inclusion criteria, of which three studies were RCTs and four were of observational study design. Positive clinical outcomes were reported for pain reduction and improvement in general well-being 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 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).

Professional Societies

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)

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 a number of other nonpharmacological therapies, (Chou et al., 2007).

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
04/01/2021	Template Update • Removed *Related Policies* and *CMS* sections • Updated *Instructions for Use*; replaced reference to "MCG™ Care Guidelines" with "InterQual® criteria"
02/01/2021	Template Update • Reformatted policy; transferred content to new template
06/01/2020	• Created state-specific policy version for Louisiana (no change to guidelines)
05/01/2019	• Simplified coverage rationale (no change to guidelines) • Added definition of "Musculoskeletal Disorders" • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references • Archived previous policy version CS076.H

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.