

# UnitedHealthcare® Medicare Advantage Medical Policy

# **Osteopathic Manipulations (OMT)**

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Instructions for Use

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# **Coverage Rationale**

#### **Overview**

Osteopathic manipulative treatment (OMT) is a treatment employed, primarily by osteopathic physicians, to facilitate a patient's recovery from somatic dysfunction, and is defined under the Glossary of Osteopathic Terminology as impaired or altered function of related components of the somatic (body framework) system; skeletal, arthroidal and myofascial structures, and related vascular, lymphatic, and neuro elements. The positional and motion aspects of somatic dysfunction are best described using at least one of three parameters:

- 1. The position of a body part as determined by palpation and reference to its adjacent defined structure;
- The direction in which motion is freer: and
- 3. The direction in which motion is restricted.

The diagnosis of somatic dysfunction is made by determining the presence of one or more findings, described by the acronym TART (tenderness, asymmetry, restriction of motion, and tissue abnormality). Osteopathic manipulative treatment includes muscle energy, high velocity-low amplitude, counterstrain, myofascial release, visceral, and craniosacral. The chosen treatment will vary depending on patient's age and clinical condition.

Somatic dysfunction in one region can create compensatory somatic dysfunction in other regions. Osteopathic manipulative treatment is also utilized to treat the somatic component of visceral diseases. This component can manifest as changes in the skeletal, arthrodial, and myofascial tissues.

#### CMS National Coverage Determinations (NCDs)

Medicare does not have an NCD for osteopathic manipulations (OMT).

## CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Osteopathic Manipulative Treatment.

Osteopathic manipulative treatment is covered when medically necessary and performed by a qualified physician, in patients whose history and physical examination indicate the presence of somatic dysfunction of one or more regions.

**Note**: Osteopathic manipulative treatment specifically encompasses only the procedure itself. Evaluation and management (E&M) services are covered, as a separate and distinct service when medically necessary and appropriately documented.

#### Limitations

Osteopathic manipulative treatment is not covered when the indication of coverage is not met, and conventional documentation of somatic dysfunction is not present in the patient's medical record.

**Note**: No E&M service is warranted for previously planned follow-up OMT treatments unless a new condition occurs or the patient's condition has changed substantially, necessitating an overall reassessment.

# **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; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document 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

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<b>Diagnosis Code</b>	Description
M99.00	Segmental and somatic dysfunction of head region
M99.01	Segmental and somatic dysfunction of cervical region
M99.02	Segmental and somatic dysfunction of thoracic region
M99.03	Segmental and somatic dysfunction of lumbar region
M99.04	Segmental and somatic dysfunction of sacral region
M99.05	Segmental and somatic dysfunction of pelvic region
M99.06	Segmental and somatic dysfunction of lower extremity
M99.07	Segmental and somatic dysfunction of upper extremity
M99.08	Segmental and somatic dysfunction of rib cage
M99.09	Segmental and somatic dysfunction of abdomen and other regions

## **Definitions**

Glossary of Osteopathic Terminology: The Glossary of Osteopathic Terminology is developed and revised by the Educational Council on Osteopathic Principles (ECOP) of the American Association of Colleges of Osteopathic Medicine (AACOM). The purpose of this osteopathic glossary is to present important and frequently used words, terms, and phrases that are unique or with special significance to the osteopathic profession. It is not meant to replace a dictionary. The glossary offers the consensus of a large segment of the osteopathic profession and serves to standardize terminology. The ECOP Glossary Review Committee specifically seeks to include those definitions that are uniquely osteopathic in their origin or common usage, distinctive in the osteopathic usage of a common word, and/or important in describing OPP/OMT. (American Association of Colleges of Osteopathic Medicine, 2019)

# Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the <u>Medicare Coverage Database</u>, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the <u>Coverage Rationale</u> section above.

NCD	LCD	LCA	Contractor Type	<b>Contractor Name</b>	
Osteopathic Manip	Osteopathic Manipulative Treatment				
N/A	N/A	A52435 Billing and Coding: Osteopathic Manipulative Treatment	Part A and B MAC	CGS	
	L33616 Osteopathic Manipulative Treatment	A56954 Billing and Coding: Osteopathic Manipulative Treatment	Part A and B MAC	NGS	

MAC Name (Abbreviation)	States/Territories
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DE, LA, MD, MS, NJ, NM, OK, PA, TX, DC
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE

#### **CMS Benefit Policy Manual**

Chapter 15; § 30.5 Chiropractor's Services, § 40.4 Definition of Physician/Practitioner, § 240 Chiropractic Services - General

## **CMS Claims Processing Manual**

Chapter 12; § 10 General, § 220 Chiropractic Services

## **Clinical Evidence**

# Musculoskeletal Back

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

Santos et al. (2022) conducted a systematic review and meta-analysis to determine whether or not manual therapy (MT) causes postural changes. In March 2022, the authors performed a search in the PUBMED, Cinahl, Embase, PEDro, and

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

In a randomized, sham-controlled group trial, Nguyen et al. (2021) compared the efficacy of standard osteopathic manipulative treatment (OMT) versus sham OMT for reducing low back pain (LBP) in 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.

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 3 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 (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 during pregnancy and 3 for postpartum. The authors found moderate-quality evidence suggesting OMT had a significant medium-sized effect on decreasing pain (MD, -16.65) and increasing functional status (SMD, -0.50) in pregnant women with LBP; low-quality evidence suggested OMT had a significant moderate-sized effect on decreasing pain (MD, -38.00) and increasing functional status (SMD, -2.12) in postpartum women with LBP. While there is growing evidence that OMT may be beneficial for treatment of pregnancy related or postpartum LBP, the author's findings included small sample sizes, mixed studies of different designs, duplicate data, lack of long-term follow-up and both OMT and non-osteopathic manual therapies utilized so the conclusions should be reviewed with caution. Further research may change estimates of effect, and larger, high-quality RCTs with robust comparison groups are recommended.

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

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. 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.

#### Neck

In a 2023 systematic review and meta-analysis of randomized controlled trials, Liu et al., sought to determine the effectiveness of manipulative therapy for chronic neck pain. Seventeen articles comprised of 1190 participants with patients with chronic neck pain for more than 3 months in which manipulative therapy was the primary treatment were included. The results showed for overall effects of pain intensity, manipulative therapy resulted in significantly decreased pain intensity and disability when compared to exercise and control groups with no significant differences in adverse events reported. The authors concluded that despite high heterogeneity in treatment outcomes, manipulative therapy is effective in relieving chronic neck pain and disability. Future research should include the impact of patient selection and type of treatment on the heterogeneity of the treatment effects.

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

In a randomized control trial, Groisman et al. (2020) assessed the effectiveness of OMT combined with stretching and strengthening exercises in the cervical region on patients with non-specific chronic neck pain. This single-blinded trial randomized 90 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.

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 potential limitation of this study was the inability to blind practitioners or participants to treatment allocation.

#### **Extremity Disorders**

#### Shoulder

In a randomized control trial, Iqbal et al. (2020) compared the effects of the Spencer muscle energy technique (SMET) and passive stretching on 60 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 3 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 3 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 8 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.

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 7 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.

#### 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 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.

#### 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 18camera motion analysis system was utilized to capture 3-dimensional (3D) position data in a treadmill walking trial before and after the assigned treatment protocol. Pretreatment and posttreatment hip, knee, and ankle ROM were compared with paired t-tests, and joint angle waveforms during the gait cycle were analyzed with statistical parametric mapping (SPM), which is a type of waveform analysis. Individuals with PD had reduced hip and knee extension in the stance phase compared to controls (32.9-71.2% and 32.4-56.0% of the gait cycle, respectively). Individuals with PD experienced an increase in total sagittal hip ROM (p = 0.038) following a single session of the standardized OMT-WB treatment protocol. However, waveform analysis found no differences in sagittal hip, knee, or ankle angles at individual points of the gait cycle following OMT-WB, OMT-ND, or sham treatment protocols. The authors concluded the increase in hip ROM observed following a single session of OMT-WB suggests that OCMM in conjunction with OMT may be useful for improving gait kinematics in individuals with PD. Limitations include assessing the effects of only a single session of OMT and OCMM on Parkinsonian gait, and no follow-up. To determine the clinical relevance of these findings, longitudinal studies over multiple visits are needed to determine the long-term effect of regular OMT and OMT+OCMM treatments on Parkinsonian gait characteristics.

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

A randomized clinical trial by Hoeksma et al. (2004) evaluated 109 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 3 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; 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 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.

# Clinical Practice Guidelines American Osteopathic Association (AOA)

The Glossary of Osteopathic Terminology defines Osteopathic manipulative treatment (OMT) as, "the therapeutic application of manually guided forces by an osteopathic physician (U.S. Usage) to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction. OMT employs a variety of techniques." The glossary defines somatic dysfunction as, "impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial and myofascial structures, and their related vascular, lymphatic, and neural elements. Somatic dysfunction is treatable using osteopathic manipulative treatment." 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).

# References

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

American Association of Colleges of Osteopathic Medicine (AACOM). Osteopathic manipulative medicine explained. AACOM 2023. Available at: <a href="https://www.aacom.org/become-a-doctor/about-osteopathic-medicine/omm-explained">https://www.aacom.org/become-a-doctor/about-osteopathic-medicine/omm-explained</a>. Accessed January 31, 2024.

American Association of Colleges of Osteopathic Medicine (AACOM). Glossary of Osteopathic Terminology (Third Edition). Available <a href="https://www.aacom.org/docs/default-source/publications/glossary2017.pdf">https://www.aacom.org/docs/default-source/publications/glossary2017.pdf</a><a href="https://www.aacom.org/news-reports/news/2019/08/09/glossary-of-osteopathic-terminology-(third-edition">https://www.aacom.org/news-reports/news/2019/08/09/glossary-of-osteopathic-terminology-(third-edition)</a>. Accessed April 3, 2024.

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

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

Bergman G, Winters J, Groenter K, et al. Manipulative therapy in addition to usual medical care for patients with shoulder dysfunction and pain. Annals of Internal Medicine 2004; 141:432-439.

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

Bronfort G, Haas M, Evans R, et al. Effectiveness of manual therapies: the UK evidence report. Chiropr Osteopat. 2010; 18:3.

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

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

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

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

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

Clar C, Tsertsvadze A, Court R, et al. Clinical effectiveness of manual therapy for the management of musculoskeletal and nonmusculoskeletal conditions: systematic review and update of UK evidence report. Chiropr Man Therap. 2014 Mar 28;22(1):12.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Licciardone JC, Stoll ST, Cardarelli KM, et al. A randomized controlled trial of osteopathic manipulative treatment following knee or hip arthroplasty. J Am Osteopath Assoc. 2004 May;104(5):193-202.

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

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

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

Müller A, Franke H, Resch KL, et al. Effectiveness of osteopathic manipulative therapy for managing symptoms of irritable bowel syndrome: a systematic review. J Am Osteopath Assoc. 2014; 114:470–479.

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

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

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

Posadzki P, Lee MS, Ernst E. Osteopathic manipulative treatment for pediatric conditions a systematic review. Pediatrics 2013; 132:140–152.

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

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

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

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

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

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

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

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

Rubinstein SM, de Zoete A, van Middelkoop M, et al. Benefits and harms of spinal manipulative therapy for the treatment of chronic low back pain: systematic review and meta-analysis of randomised controlled trials. BMJ. 2019 Mar 13;364:1689.

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

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

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

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

Schwerla F, Rother K, Rother D, et al. Osteopathic manipulative therapy in women with postpartum low back pain and disability: a pragmatic randomized controlled trial. J Am Osteopath Assoc. July 2015, Vol. 115, 416-425.

Shekelle PG, Paige NM, Miake-Lye IM, et al. The effectiveness and harms of spinal manipulative therapy for the treatment of acute neck and lower back pain: a systematic review. Washington (DC): Department of Veterans Affairs (US); 2017 Apr.

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

Skelly AC, Chou R, Dettori JR, et al. Noninvasive nonpharmacological treatment for chronic pain: a systematic review. Comparative Effectiveness Review No. 209. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No 18-EHC013-EF. Rockville, MD: Agency for Healthcare Research and Quality; June 2018.

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

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

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

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

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

# Policy History/Revision Information

Date	Summary of Changes	
08/01/2024	Applicable Codes	
	Clarified introduction language	
06/01/2024	Template Update	
	Reformatted and reorganized policy; transferred content to new template	
	Changed policy type classification from "Policy Guideline" to "Medical Policy"	

Date	Summary of Changes
	Added Clinical Evidence and References sections
	Updated Instructions for Use
	Coverage Rationale
	Removed content/language addressing documentation requirements
	Overview (T
	<ul> <li>Replaced reference to the "American Osteopathic Association's Glossary of Terminology" with the "Glossary of Osteopathic Terminology"</li> </ul>
	Centers for Medicare & Medicaid (CMS) National Coverage Determinations (NCDs)
	<ul> <li>Added language to indicate Medicare does not have an NCD for osteopathic manipulations (OMT)</li> </ul>
	CMS Local Coverage Determinations (LCDs) and Articles
	Added language to indicate:  Added language to indicate:  Added language to indicate:  Added language to indicate:
	<ul> <li>LCDs/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the CMS Related Documents section of the policy]</li> </ul>
	<ul> <li>Osteopathic manipulative treatment is covered when medically necessary and performed by a qualified physician, in patients whose history and physical examination indicate the presence of somatic dysfunction of one or more regions</li> </ul>
	<ul> <li>Osteopathic manipulative treatment specifically encompasses only the procedure itself;</li> </ul>
	Evaluation and management (E&M) services are covered, as a separate and distinct service when medically necessary and appropriately documented
	Definitions
	Added definition of "Glossary of Osteopathic Terminology"
	CMS Related Documents
	Updated list of documents available in the <i>Medicare Coverage Database</i> to reflect the most
	current information
	<ul> <li>Added list of applicable Medicare Administrative Contractors (MACs) with Corresponding States/Territories</li> </ul>
	Supporting Information
	Archived previous policy version MPG227.09
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# **Instructions for Use**

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to

develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

You are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.