

Clinical Practice Guideline: Spinal Manipulative Therapy (SMT) for Musculoskeletal and Related Disorders

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Product: Specialty

Related Policies:

CPG 87: Non-Motorized Flexion Distraction Technique
 CPG 119 Spinal Manipulative Therapy for Non-Musculoskeletal and Related Disorders
 CPG 120: Spinal Manipulative Therapy for Treatment of Children
 CPG 121: Passive Physiotherapy Modalities
 CPG 132: Spinal Manipulative Therapy for Treatment of Children with Non-Musculoskeletal and Related Disorders
 CPG 135: Physical Therapy Medical Policy/Guideline
 CPG 155: Occupational Therapy Medical Policy/Guideline
 CPG 175: Extra-Spinal Manipulation/Mobilization for the Treatment of Upper Extremity Musculoskeletal Conditions
 CPG 177: Extra-Spinal Manipulation / Mobilization for the Treatment of Lower Extremity Musculoskeletal Conditions

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1 GUIDELINES

2 I. American Specialty Health – Specialty (ASH) considers Spinal Manipulation (or
3 Grade V Mobilization) to be medically necessary when **both of the following** criteria
4 are met:

- 5
- 6 • There is adequate documentation that the member has a symptomatic (acute,
7 subacute, or chronic; with or without radicular components) Musculoskeletal or
8 Related Disorder attributable to a mechanical, structural, or functional disorder
9 of the sacroiliac, lumbosacral; lumbar, thoracic and/or cervical spine or
10 headache disorders including tension-type headache and migraine headache;
11 **and**
- 12 • There is an absence of contraindications to manipulation/mobilization or
13 diagnostic red flags suggesting a possible organic disorder (e.g., tumor,
14 infection, fracture).
15

16 For the purposes of this policy, Musculoskeletal and Related Disorders are defined as
17 conditions with signs and symptoms related to the nervous, muscular, and/or skeletal
18 systems. Musculoskeletal or Related Disorders are conditions typically categorized as:
19 structural, degenerative, or inflammatory disorders; or biomechanical dysfunction of the
20 joints of the body and/or related components of the muscle or skeletal systems (muscles,
21 tendons, fascia, nerves, ligaments/capsules, discs, and synovial structures) and related
22 manifestations or conditions.
23

24 Such spinal disorders may be acute, sub-acute, or chronic and may or may not include
25 radicular components.
26

27 Signs and symptoms of a musculoskeletal or related disorder may include:

- 28 • Pain/tenderness;
- 29 • Stiffness and/or limited motion;
- 30 • Tone or texture changes in the adjacent muscles and soft tissues including muscle
31 tightness or weakness;
- 32 • Asymmetry or malalignment between adjacent spinal segments;
- 33 • Headache disorders (including tension-type headache and migraine headache); and
- 34 • Numbness/tingling or other paresthesia, weakness, loss of deep tendon reflexes, or
35 other signs of nerve or nerve root compression or irritation.
36

37 Note: The population of eligible members for spinal manipulation includes all ages, co-
38 morbid conditions, and other demographic variables as long as the documentation
39 establishes a valid diagnosis and symptomatic status and satisfies the above criteria.

II. Spinal manipulation is considered **not** medically necessary when:

- The above criteria are not met; or
- The patient has become asymptomatic; or
- There is no progress toward the resolution of symptoms within a reasonable and predictable period of time; or
- Maximum therapeutic benefit has been achieved, and chiropractic supportive care is not indicated; or
- The primary aim is to prevent future episodes.

III. Spinal manipulation is considered **not** medical necessary for the treatment of conditions not directly related to the spine including, but not limited to:

- Asthma
- Infantile colic
- Irritable bowel syndrome
- Dysmenorrhea

See the *Spinal Manipulative Therapy for Non-Musculoskeletal Conditions and Related Disorders (CPG 119 – S)* clinical practice guideline for more specific information.

ASH considers use of manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) by chiropractors in performing manual manipulation of the spine or the extremities as a reasonable alternative to high velocity, low amplitude manipulation when the medical necessity criteria above is met. Use of these devices may also be considered a possible alternative when high velocity low amplitude manipulation may be contraindicated.

ASH does not support the use of any examination and/or diagnostic method associated with manual devices. Moreover, ASH does not support claims of benefit(s) associated with instrument assisted methods of assessment. CPT® coding does not change with the use of these devices.

1 **CPT® Codes and Descriptions**

CPT® Code	CPT® Code Description
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
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
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes

2

3 **EVIDENCE REVIEW**4 **Low Back Pain**

5 The body of literature relevant to the subject of this clinical policy is quite extensive at this
6 point. There are more than 150 randomized clinical trials that investigate the effectiveness
7 of spinal manipulation for back pain and related disorders. This volume of studies has also
8 resulted in set of systematic reviews and meta-analyses on the topic. It is these reviews that
9 constitute the primary source of information for this clinical policy guideline. In addition,
10 recent individual clinical trials that have not been included in the systematic reviews will
11 be reviewed.

12

13 Rubinstein et al. performed a systematic review of the effectiveness of spinal manipulative
14 therapy (SMT) for chronic low back pain first in 2011. The authors defined chronic low
15 back pain as pain lasting longer than 12 weeks and SMT as any ‘hands on’ treatment,
16 including both spinal manipulation and mobilization. A total of 26 randomized controlled

1 trials were included in this review, 9 of which were considered as having a low risk of bias.
 2 Studies were included if they were designed to examine the unique contribution of SMT
 3 alone. Comparison therapies were grouped as inert interventions, sham SMT, all other
 4 interventions, and SMT in addition to any intervention versus that intervention alone.
 5 Primary outcomes included pain from a self-reported scale (Visual Analogue Scale [VAS]
 6 or Numerical Rating Scale [NRS]), functional status reported on a back pain specific scale
 7 (Roland-Morris Disability Questionnaire or Oswestry Disability Index), and global
 8 improvement (number of patients reported to be recovered or nearly recovered). The
 9 primary technique used was a high-velocity low-amplitude SMT thrust, followed by
 10 Maitland mobilization, flexion-distraction mobilization, unspecified mobilization, and
 11 unspecified technique. About 1/3 of the studies reported on adverse events, which were
 12 limited to muscle soreness, stiffness, and/or other transient increase in pain. Professions
 13 included in these studies were bonesetters, chiropractors, and manual/physical therapists.
 14 Combinations of these professions were also included. There is high quality evidence that
 15 SMT has a statistically significant effect on short-term pain and functional status, but the
 16 effect size is small and clinically insignificant. Therefore, SMT is neither superior nor
 17 inferior to other low back pain treatments. The authors discuss several possibilities for their
 18 results, including how well investigators were able to successfully blind their participants
 19 from knowing if they had the sham treatment. Another discussion item was that the patients
 20 all had non-specific low back pain, which may be too broad of a category to consider for
 21 treatment comparisons. The authors suggest future studies of SMT examine cost-
 22 effectiveness. If SMT is as effective as other treatments and has demonstrated its safety as
 23 a treatment it makes sense to utilize SMT more often if shown to be a cost-effective form
 24 of treatment.

25
 26 To look at the effectiveness of spinal manipulation in a more pragmatic setting, in 2011
 27 Walker et al. examined 12 randomized controlled studies that combined chiropractic, or
 28 spinal manipulation (SM), with additional therapies. Objectives evaluated included pain,
 29 disability, back-related function, overall improvement, and patient satisfaction. Studies that
 30 were included had a defined region of low back pain and specified duration as acute (less
 31 than 6 weeks), subacute (6 to 12 weeks), or chronic (12 weeks or more). Interventions
 32 included combinations of therapies such as SM and massage, thermotherapies,
 33 electrotherapies, mechanical devices, exercise programs, nutritional advice, orthotics,
 34 lifestyle modification, and patient education. The authors evaluated the evidence of the
 35 studies with the GRADE approach and assessed the risk of bias based on those results.
 36 Only 3 of the 12 studies were classified as having a low risk of bias. Using the VAS,
 37 Oswestry Disability Index and the Roland Morris Disability Questionnaire as outcome
 38 measures, none of the studies provided a clinically significant difference for combined
 39 chiropractic interventions. Individuals with acute and subacute low back pain did
 40 experience pain relief after combined chiropractic, rather than spinal manipulation alone.
 41 Although this was statistically significant, the effect sizes were small and not considered
 42 clinically significant. The authors' suggestions for future research include careful planning

and reporting of studies to reduce bias as well as examination of frequency or dosing effect of treatment visits. In 2012, Goertz et al. performed a systematic review that included 38 articles examining the effectiveness of high-velocity, low-amplitude (HVLA) spinal manipulation for the treatment of low back pain. The authors reviewed randomized controlled trials that focused on patient-centered outcomes of pain and functional health status. The most commonly used pain ratings were the VAS and NRS, while the most commonly used functional health status tools were the Roland Morris Disability Questionnaire (RMDQ) and the Oswestry Low Back Pain Disability Index (OSW). While the authors agreed with previous studies that there is moderate evidence that spinal manipulation is an effective treatment option for both acute and chronic low back pain, they also share concerns that there is high variation in the quality of studies as well as high variation in reported outcomes. The authors concluded that the variation is most likely due to a combination of heterogeneity of low back pain patients, variations in the spinal manipulation itself, and inadequate reporting of trial methodology. Finally, to aid in the ability to adequately compare spinal manipulation trials, the authors recommend adoption of standards for classification of low back pain, reporting of patient outcome data, and content of randomized controlled trials.

A meta-analysis of efficacy, cost-effectiveness, and safety of complementary and alternative medicine (CAM) therapies such as acupuncture, manipulation, mobilization, and massage for neck and low back pain in adults was conducted in 2012 by Furlan et al. Studies were included if they reported efficacy and/or economic data of CAM therapies in comparison with no treatment, placebo, or other active treatments in adults with low back, neck, or thoracic pain. Pain intensity and disability were the primary patient outcomes of interest for efficacy and for cost-effectiveness analysis, data was extracted related to costs to the health care sector, production loss, costs in other sectors, patient and family costs, and total costs. In total, 147 studies were included in this meta-analysis; of the studies that examined low back pain 13 analyzed manipulation, 13 analyzed mobilization, 5 analyzed manipulation and mobilization, and 7 analyzed economic impact. In participants with acute/subacute and mixed duration nonspecific low back pain, manipulation was significantly more effective than placebo or no treatment in reducing pain intensity immediately after treatment. In participants with chronic nonspecific low back pain, manipulation was significantly more effective than placebo in reducing pain intensity (VAS score) immediately after treatment. Manipulation was significantly better or no different than pain medication in improving pain intensity but did not differ from pain medication in reducing pain intensity at follow up after treatment. Participants with acute/subacute and chronic nonspecific low back pain who received mobilization experienced significantly improved pain intensity (VAS score) compared to subjects not receiving any treatment. Results regarding participant-reported disability (RMDQ, OSW) were inconsistent, showing either a significant difference favoring mobilization or showing no difference between mobilization and no treatment. Participants with acute/subacute nonspecific low back pain receiving manipulation plus mobilization were not significantly

1 better than those who received a double placebo (sham manipulation and placebo
 2 analgesic). Manipulation plus mobilization was significantly better in reducing pain than
 3 physiotherapy (e.g., exercise, massage, heat, electrotherapy, ultrasound) in participants
 4 with mixed duration low back pain. However, there was no difference between
 5 manipulation plus mobilization and usual care (analgesics, muscle relaxants, instruction in
 6 proper back care, life-style recommendations, and exercise) in participants with mixed
 7 duration of nonspecific low back pain. Unfortunately, due to the small number of studies
 8 reporting on economic impact, inconsistencies in methods reported and differences in
 9 health care calculations by country, the authors were unable to draw conclusions regarding
 10 cost effectiveness. The authors also noted the evidence is inconclusive for treatment of low
 11 back pain as the majority of the studies cited were of low quality and recommend a
 12 concerted effort to improve study quality in future reporting of CAM studies for
 13 musculoskeletal conditions.

14
 15 Osteopathic approaches to the effectiveness of manipulation for low back pain were
 16 investigated by Orrock and Myers in 2013. Articles were searched for spinal manipulative
 17 therapy as well as osteopathic manipulative therapy but were only included in the review
 18 if they included a form of osteopathy. The authors chose to focus their review on
 19 osteopathic manual interventions performed by osteopathic clinicians in chronic, non-
 20 specific lower back pain in adults. Articles were also evaluated for risk of bias based on
 21 the Systematic Review Guidelines of the Cochrane Back Review Group. The authors
 22 searched many data bases but only found two (2) articles that met the inclusion criteria and
 23 had a low risk of bias. One of the studies concluded the osteopathic intervention was similar
 24 in effect to a sham intervention while the other study suggested osteopathic intervention
 25 was similar to that of exercise and physiotherapy. The authors note that although both
 26 studies had a low risk of bias neither the participants nor the clinicians in the studies were
 27 blinded. The authors felt this could influence the study outcomes. Therefore, the authors
 28 conclude that more research is needed, ideally with appropriate controls and use of
 29 interventions that reflect actual practice, before determining if osteopathic manipulation is
 30 effective in treatment of chronic low back pain in adults.

31
 32 In 2014, Merepeza examined the effectiveness of spinal manipulation versus prescribed
 33 exercises for chronic low back pain. Studies included in the review were those with
 34 participants with low back pain of over 12 weeks duration, spinal manipulation performed
 35 by a health care provider, exercises prescribed by a health care provider, and a measurable
 36 outcome for reducing pain, disability, or improving function. Studies were excluded if
 37 participants were diagnosed with spinal stenosis, spondylolisthesis (2nd degree or more),
 38 lumbar scoliosis (>20° or more), previous vertebral fractures, systemic causes of chronic
 39 low back pain (rheumatoid arthritis), or psychiatric or cognitive co-morbidities. Three
 40 studies were found that met the author's inclusion criteria and were evaluated for risk of
 41 bias with the PEDro scale. While all 3 studies had a fairly low risk of bias, none of the
 42 studies blinded the subjects and the administrators of the treatment therapy. Another bias

present in all three (3) studies is that the outcomes were self-reported in a subjective manner. One study showed spinal manipulation was more effective than individual physiotherapy for pain reduction and improved function. A different study found that spinal manipulation therapy and motor control exercise were better at reducing pain and disability than general exercise in the short term but not in the long term. Finally, another study found that spinal stabilization exercises were more effective than manual therapy in reducing pain intensity and disability and dysfunction. Merepeza (2014) concludes that first, chronic low back pain may itself pose a challenge to study because of the heterogeneity of the condition. Second, the author acknowledges that there are many components to exercise and manual therapy as treatments and more evidence is needed to determine what is considered an effective treatment.

Hidalgo et al. (2014) performed a systematic review focused specifically on different manual therapies for different stages of low back pain. Randomized controlled trials were included only if they had a low risk of bias, appropriate randomization methods, appropriate blinding, and low back pain was treated with manual therapy. The authors used a combination of duration and location of symptoms to specify the population included; participants were classified as having duration of acute-subacute (0-12 weeks) or chronic (>12 weeks). Participants were also categorized as having low back pain defined by the Quebec-Taskforce regarding presence and location of leg pain, with or without neurological deficit. Participants with nerve root pain with neurologic deficit were not included. Manual therapy techniques were categorized into 3 types; high-velocity, low-amplitude thrust with cavitation, mobilization and soft tissue techniques, or a combination. Control groups received no treatment, placebo, usual medical care, or exercise. The authors found 11 studies that met their inclusion criteria that had not previously been reported; 5 were of high level of evidence and 6 were of moderate quality of evidence. In contrast with what other systematic reviews have reported, the authors concluded that there is moderate to strong evidence for the benefits of high-velocity, low-amplitude manual therapy in comparison to sham manual therapy for pain relief, functional improvement, and overall health for short term follow up for all durations of low back pain. The authors also concluded that there was moderate evidence to support high-velocity, low-amplitude manual therapy and combination manual therapy with usual medical care in comparison to usual medical care alone for pain, function, and overall quality of life. Additionally, for chronic low back pain, the authors found moderate evidence in support of combination manual therapy with exercises or usual medical care compared to usual medical care alone for pain and function. The authors recommend future research focus on pragmatic, high quality randomized controlled trials, specific types of manual therapy classification, and classification of participants.

A 2014 systematic review of CAM studies for low back pain was performed by Kizhakkeveettil et al. The authors were specifically interested in examining the effects of an integrative approach to treating low back pain instead of isolating a single therapy.

Studies were included in the review if they had at least 1 outcome measure for pain or disability as well as at least 1 treatment group receiving integrated therapy that included at least 1 CAM therapy. The authors found 21 articles that met their search criteria (13 of which included spinal manipulative therapy) and used the Cochrane Back Review Group scale to determine risk of bias. Integrated CAM therapy with active care appeared to be effective for treatment, while adding passive care to CAM therapy was generally ineffective. The authors found this surprising as it is common to have the combination of CAM therapy with passive care (such as heat or ice) as a standard treatment for low back pain. Even though the authors support integrated therapies, they acknowledge that it may be difficult in a real-world setting to coordinate care between practitioners. The authors also acknowledge that some interventions for low back pain appear to be ineffective in the short term but may help prevent chronicity and disability. Finally, the authors state the need for more high-quality research that examines integration of spinal manipulative therapy with exercise, acupuncture, and conventional care rather than single therapies of any type along with reporting appropriate cost effectiveness data.

In 2014, Tsertsvadze et al. evaluated the cost effectiveness of manual therapies relative to other alternative therapies for management of musculoskeletal conditions. Studies considered for review were classified by which area of the body was being treated (spinal, upper extremity and lower extremity). Twenty-five publications from 11 different trials were included for review that reported specific economic factors for analysis. The risk of bias was rated as low for 7 of the 11 trials and high for 4 of the 11 trials. Of the trials included, 4 reported information regarding low back pain. The first trial found individual physiotherapy more effective and ‘marginally more costly’ than spinal stabilization therapy. The second trial found a combination of manual therapy, stabilization exercise and physician consultation more effective than physician consultation alone at 24-month follow up. The third study evaluated manipulation alone, exercise alone, and manipulation and exercise to general practitioner care. The addition of manipulation had better participant outcomes and lower overall cost. The last study compared manual physiotherapy with a brief pain management program for participants with acute low back pain. Although the manual physiotherapy group had more improvement in disability and was more cost effective, the results were not statistically significant between the groups.

In 2014, Menke performed a comparative effectiveness meta-analysis of manual therapies, including spinal manipulative therapy (SMT), for the treatment of low back pain. Menke searched the literature and found 56 studies from 1974-2010 for a total of 257 study arms. The study arms were then classified into treatment types such as SMT, exercise, physiotherapy modalities, usual medical care, and control groups. The treatment types were then divided into acute and chronic low back pain for short- and long-term effects. Treatments for acute pain levels were no better than the course of natural history while treatment for chronic pain showed a weak response to SMT. Additionally, study quality measurements were taken to measure levels of evidential support. The author found that

overall SMT study quality improved 1.2% each year from 1974 and proposed that the reason SMT has had success was not because of the treatment, but because of the psychosocial support received during treatment and encouraged future research to examine this component of SMT.

Schneider et al. (2015) conducted a study comparing the effectiveness of manual-thrust manipulation (MTM), mechanical-assisted manipulation (MAM), and usual medical care (UMC) in adults with low back pain of less than 3 months duration with a minimum self-reported pain of 3 on a 0-10 scale and a minimum disability of 20 on a 0-100 scale. Participants randomized to the MTM group received high-velocity, low-amplitude thrust manipulations in the side posture position. Participants randomized to the MAM group received activator methods chiropractic using the activator IV adjusting instrument in the prone position following palpation and Activator method of leg length analysis. Participants in the MTM and MAM groups attended 2 office visits per week for 4 weeks and participated in follow-up data collection. Participants randomized to the UMC group were seen by a board-certified physical medicine and rehabilitation physician. They were told most new episodes of low back pain are self-limiting, prescribed over the counter analgesics and nonsteroidal anti-inflammatory drugs, given advice to stay active and avoid bed rest, as per current clinical guidelines for primary care management of non-specific low back pain. The UMC group patients had 3 total office visits; an initial visit and 2 follow up visits occurring at week 2 and week 4. After the week 4 assessment, participants were free to try other forms of treatment if they felt they needed it. All participants in all 3 treatment groups were provided a copy of the same educational handout with information regarding proper posture and movements. The primary outcome assessment was the OSW. Scores range from 0-100, with higher numbers representing higher levels of disability. The secondary outcome was self-reported pain on a scale of 0 ('no pain') to 10 ('unbearable pain'). At 4 weeks, the MTM group showed significantly reduced OSW scores compared to the MAM and UMC groups. Comparing the MAM group to the UMC group showed a non-significant difference. The pain scores showed similar results; MTM had reduced pain scores compared to the MAM and UMC groups, however comparing the MAM to the UMC group showed no significant difference. The authors conclude there was a statistically significant decrease in disability and pain for the MTM group for the short-term measurement. The benefit of MTM was not statistically significant at the 3 or 6 month follow ups. Manipulation should be offered as an effective treatment for short term relief of low back pain, especially for patients who prefer to make an informed treatment decision in accordance with their individual values and preferences; this leads to enhanced patient satisfaction. Another important factor the authors discuss is the presence of a statistically significant difference between the MTM and MAM groups, indicating that not all forms of manipulation may have the same effect on all low back pain patients.

In 2016, Chou et al. published (under the auspices of the Agency for Healthcare Research and Quality [AHRQ] and currently archived) a systematic review—*Noninvasive Treatment for Low Back Pain*. This review included both pharmacological and non-pharmacological treatments. The latter included spinal manipulation, acupuncture, exercise, low-level laser, heat, yoga, relaxation techniques, cognitive behavioral therapy (CBT), and electrical stimulation of various types, ultrasound, lumbar supports, and traction. Findings for SMT included:

- For acute low back pain, two trials (one included in a systematic review) found spinal manipulation associated with better effects on function versus sham manipulation (statistically significant in one trial); in one trial effects on pain favored manipulation but were small and not statistically significant (strength of evidence (SOE): low for function, insufficient for pain).
- For chronic low back pain, a systematic review found spinal manipulation associated with small, statistically nonsignificant effects versus sham manipulation on pain at 1 month; one trial reported similar results for function; one trial not included in the systematic review reported generally consistent results (SOE: low for pain, insufficient for function).
- For acute low back pain, a systematic review found no differences between spinal manipulation versus and inert treatment in pain relief at 1 week, though one trial found SMT associated with better longer-term pain relief; there were no differences in function at 1 week or at 3 months (SOE: low for pain and function).
- For chronic low back pain, one high-quality trial found spinal manipulation associated with greater improvement in the “main complaint” versus an inert treatment; results from three low risk of bias trials and three additional trials not included in the systematic review were somewhat inconsistent, though some trials reported effects that favored manipulation (SOE: low).
- For acute low back pain, a systematic review found no difference between spinal manipulation versus other active interventions in pain relief at 1 week, 1 month, 3 to 6 months, or 1 year. Findings were similar for function, with no differences observed at any time point. A subsequent trial of patients with acute or subacute low back pain found spinal manipulation associated with moderate effects versus usual care on pain and small effects on function at short-term follow-up, but effects were smaller and no longer statistically significant at 3 and 6 months (SOE: moderate for pain and function).
- For chronic low back pain, a systematic review found spinal manipulation associated with better short-term pain relief versus other active interventions at 1 month and 6 months, though the magnitude of effects was below the small/slight threshold. There was no difference at 12 months. Manipulation was also associated with greater function improvement in function versus other active interventions at 1 month; effects were smaller and no longer statistically significant at 6 and 12 months. Three trials not included in the systematic reviews reported results consistent with these findings (SOE: moderate for pain and function).

- For acute low back pain, four trials in a systematic review found spinal manipulation plus either exercise or advice associated with greater improvement in function at 1 week versus exercise or advice alone, but there were no differences at 1 month or 3 months (SOE: low).
- For chronic low back pain, a systematic review found spinal manipulation plus another active treatment associated with greater pain relief at 1 month, 3 months, and 12 months versus the other treatment alone, combination therapy was also associated with better function at 1 month, 3 months and 12 months. One trial not included in the systematic review reported results consistent with these findings (SOE: low).
- For radicular low back pain, one good-quality trial found spinal manipulation plus home exercise and advice associated with greater improvement in leg and back pain at 12 weeks versus home exercise and advice alone, but effects were smaller and no longer statistically significant at 52 weeks (SOE: low).
- Harms were not reported well in most trials of spinal manipulation. No serious adverse events were reported, and most adverse events were related to muscle soreness or transient increases in pain (SOE: low).

Chou et al. (2017) also published a systematic review on nonpharmacologic therapies for low back pain for an American College of Physicians Clinical Practice Guideline. Results were consistent with the conclusion stated previously from the AHRQ publication. Similar findings were noted within the Veteran's Administration/Department of Defense guidelines for treatment of low back pain. They suggest offering spinal mobilization/manipulation as part of a multimodal program for patients with acute or chronic low back pain (VA/DoD, 2017). Clinical Guidelines Committee of the American College of Physicians published a Clinical Practice Guideline from the American College of Physicians on noninvasive treatments for acute, subacute, and chronic low back pain. This guideline states that for patients with acute or chronic low back pain, SMT is recommended as one of several nonpharmacologic initial treatment options (Qaseem et al., 2017). Paige et al. (2017) systematically reviewed studies of the effectiveness and harms of SMT for acute (≤ 6 weeks) low back pain. Of 26 eligible RCTs identified, 15 RCTs (1,711 patients) provided moderate-quality evidence that SMT has a statistically significant association with improvements in pain. Twelve RCTs (1,381 patients) produced moderate-quality evidence that SMT has a statistically significant association with improvements in function. Heterogeneity was not explained by type of clinician performing SMT, type of manipulation, study quality, or whether SMT was given alone or as part of a package of therapies. No RCT reported any serious adverse event. Minor transient adverse events such as increased pain, muscle stiffness, and headache were reported 50% to 67% of the time in large case series of patients treated with SMT. Authors concluded that 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.

Skelly et al. (2018) reports in a review on chronic pain non-invasive non-pharmacological treatments that at short and intermediate terms, spinal manipulation, was associated with slight improvements in function compared with usual care or inactive controls. Skelly et al. (2020) updated the evidence from their 2018 report assessing persistent improvement in outcomes following completion of therapy for noninvasive nonpharmacological treatment for selected chronic pain conditions. They included 233 RCTs (31 new to this update). Many were small ($N < 70$), and evidence beyond 12 months after treatment completion was sparse. The most common comparison was with usual care. Evidence on harms was limited, with no evidence suggesting increased risk for serious treatment-related harms for any intervention. Effect sizes were generally small for function and pain. For chronic low back pain, function improved over short and/or intermediate term for spinal manipulation, (SOE: low). At intermediate term, spinal manipulation (SOE: moderate) was associated with improved pain. Coulter et al. (2018) aimed to determine the efficacy, effectiveness, and safety of various mobilization and manipulation therapies for treatment of chronic low back pain in a systematic literature review and meta-analysis. Fifty-one trials were included in the systematic review. Nine trials (1,176 patients) provided sufficient data and were judged similar enough to be pooled for meta-analysis. Subgroup analyses showed that manipulation significantly reduced pain and disability, compared with other active comparators including exercise and physical therapy. Mobilization interventions, compared with other active comparators including exercise regimens, significantly reduced pain, but not disability. Studies comparing manipulation or mobilization with sham or no treatment were too few or too heterogeneous to allow for pooling as were studies examining relationships between dose and outcomes. Few studies assessed health-related quality of life. Twenty-six of 51 trials were multimodal studies and narratively described. Authors concluded that there is moderate-quality evidence that manipulation and mobilization are likely to reduce pain and improve function for patients with chronic low back pain; manipulation appears to produce a larger effect than mobilization. Both therapies appear safe. Multimodal programs may be a promising option

Evans et al. (2018) conducted a multicenter randomized trial comparing 12 weeks of spinal manipulative therapy (SMT) combined with exercise therapy (ET) to ET alone. Participants were 185 adolescents aged 12 to 18 years with chronic low back pain (LBP). The primary outcome was LBP severity at 12, 26, and 52 weeks. Secondary outcomes included disability, quality of life, medication use, patient- and caregiver-rated improvement, and satisfaction. Outcomes were analyzed using longitudinal linear mixed effect models. An omnibus test assessing differences in individual outcomes over the entire year controlled for multiplicity. Of the 185 enrolled patients, 179 (97%) provided data at 12 weeks and 174 (94%) at 26 and 52 weeks. Adding SMT to ET resulted in a larger reduction in LBP severity over the course of 1 year ($P = 0.007$). The group difference in LBP severity (0-10 scale) was small at the end of treatment (mean difference = 0.5; $P = 0.08$) but was larger at weeks 26 (mean difference = 1.1; $P = 0.001$) and 52 (mean difference = 0.8; $P = 0.009$). At 26 weeks, SMT with ET performed better than ET alone for disability

($P = 0.04$) and improvement ($P = 0.02$). The SMT with ET group reported significantly greater satisfaction with care at all time points ($P \leq 0.02$). There were no serious treatment-related adverse events. For adolescents with chronic LBP, spinal manipulation combined with exercise was more effective than exercise alone over a 1-year period, with the largest differences occurring at 6 months. These findings warrant replication and evaluation of cost effectiveness.

Rubenstein et al. (2019) assessed the benefits and harms of spinal manipulative therapy (SMT) for the treatment of chronic low back pain. Forty-seven randomized controlled trials 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 and a small, clinically better improvement in function. According to authors, high quality evidence suggested that compared with non-recommended therapies SMT results in small, not clinically better effects for short term pain relief and small to moderate clinically better improvement in function. In general, these results were similar for the intermediate and long-term outcomes as were the effects of SMT as an adjuvant therapy. Most of the observed adverse events reported were musculoskeletal related, transient in nature, and of mild to moderate severity. 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.

Thomas et al. (2020) evaluated the comparative effectiveness of spinal manipulation and spinal mobilization at reducing pain and disability compared with a placebo control group (sham cold laser) in a cohort of young adults with chronic LBP. Participants received 6 treatment sessions of (1) spinal manipulation, (2) spinal mobilization, or (3) sham cold laser therapy (placebo) during a 3-week period. Main outcomes and measures: Coprimary outcome measures were the change from baseline in Numerical Pain Rating Scale (NPRS) score over the last 7 days and the change in disability assessed with the Roland-Morris Disability Questionnaire (scores range from 0 to 24, with higher scores indicating greater disability) 48 to 72 hours after completion of the 6 treatments. A total of 162 participants (mean [SD] age, 25.0 [6.2] years; 92 women [57%]) with chronic LBP (mean [SD] NPRS score, 4.3 [2.6] on a 1-10 scale, with higher scores indicating greater pain) were randomized; 54 participants to the spinal manipulation group, 54 to the spinal mobilization group, and 54 to the placebo group. There were no significant group differences for sex, age, body mass index, duration of LBP symptoms, depression, fear avoidance, current pain, average pain over the last 7 days, and self-reported disability. At the primary end point, there was no significant difference in pain score change between spinal manipulation and spinal mobilization, spinal manipulation and placebo, or spinal mobilization and placebo. There was no significant difference in self-reported disability score change between spinal

manipulation and spinal mobilization, spinal manipulation and placebo or spinal mobilization and placebo. Authors concluded that in this trial, neither spinal manipulation nor spinal mobilization appeared to be effective treatments for mild to moderate chronic LBP. According to Flynn (2020) in a review of treatments for chronic musculoskeletal pain, spinal manipulation leads to a small benefit for chronic neck and low back pain.

Hawk et al. (2020) developed an evidence-based clinical practice guideline through a broad-based consensus process on best practices for chiropractic management of patients with chronic musculoskeletal (MSK) pain. Delphi process was conducted January-February 2020. The 62-member Delphi panel reached consensus on chiropractic management of five common chronic MSK pain conditions: low-back pain, neck pain, tension headache, osteoarthritis (knee and hip), and fibromyalgia. Recommendations were made for nonpharmacological treatments, including acupuncture, spinal manipulation/mobilization, and other manual therapy; modalities such as low-level laser and interferential current; exercise, including yoga; mind-body interventions, including mindfulness meditation and cognitive behavior therapy; and lifestyle modifications such as diet and tobacco cessation. Authors concluded that clinicians should consider multiple approaches. Both active and passive, and both physical and mind-body interventions should be considered in the management plan. Spinal manipulation/mobilization was included in this recommendation for low back pain.

Chou et al. (2020) evaluated the effectiveness and comparative effectiveness of opioid, nonopioid pharmacologic, and nonpharmacologic therapy in patients with specific types of acute pain, including effects on pain, function, quality of life, adverse events, and long-term use of opioids. One hundred eighty-three RCTs on the comparative effectiveness of therapies for acute pain were included. Findings noted that spinal manipulation might be effective for acute back pain with radiculopathy. Most studies had methodological limitations. Effect sizes were primarily small to moderate for pain, the most commonly evaluated outcome.

Thornton et al. (2021) summarized the evidence for non-pharmacological management of LBP in athletes, a common problem in sport that can negatively impact performance and contribute to early retirement. Among 1,629 references, 14 RCTs involving 541 athletes were included. Treatments included exercise, biomechanical modifications, and manual therapy. Exercise was the most frequently investigated treatment. There was a reduction in pain and disability reported after all treatments. Authors concluded that while several treatments for LBP in athletes improved pain and function, it was unclear what the most effective treatments were, and for whom. Exercise approaches generally reduced pain and improved function in athletes with LBP. No conclusions regarding the value of manual therapy (massage, spinal manipulation) or biomechanical modifications alone could be drawn because of insufficient evidence. High-quality RCTs are urgently needed to determine the effect of commonly used interventions in treating LBP in athletes.

Compared to traditional aggregate analyses individual participant data (IPD) meta-analyses allows for a more precise estimate of the treatment effect. Given this, de Zoete et al. (2021) assessed the effect of SMT on pain and function for chronic LBP in a IPD meta-analysis. Of the 42 RCTs fulfilling the inclusion criteria, they obtained IPD from 21 ($n=4,223$). Most trials ($s=12$, $n=2,249$) compared SMT to recommended interventions. There is moderate quality evidence that SMT vs recommended interventions resulted in similar outcomes on pain and functional status at one month. Effects at other follow-up measurements were similar. Results for other comparisons (SMT vs non-recommended interventions; SMT as adjuvant therapy; mobilization vs manipulation) showed similar findings. Authors concluded that sufficient evidence suggest that SMT provides similar outcomes to recommended interventions, for pain relief and improvement of functional status. SMT would appear to be a good option for the treatment of chronic LBP. Study design: Individual participant data (IPD) meta-analysis. In another study, de Zoete et al. (2021) aimed to identify which participant characteristics moderate the effect of spinal manipulative therapy (SMT) on pain and functioning in chronic LBP. IPD were requested from RCTs examining the effect of SMT in adults with chronic LBP for pain and function compared to various other therapies (stratified by comparison). Potential patient moderators ($n = 23$) were a priori based on their clinical relevance. They received IPD from 21 of 46 RCTs ($n = 4,223$). The majority (12 RCTs, $n = 2,249$) compared SMT to recommended interventions. The duration of LBP, baseline pain (confirmatory), smoking, and previous exposure to SMT (exploratory) had a small moderating effect across outcomes and follow-up points; these estimates did not represent minimally relevant differences in effects. No other moderators demonstrated a consistent pattern across time and outcomes. Few moderator analyses were conducted for the other comparisons because of too few data. Authors state they did not identify any moderators that enable clinicians to identify which patients are likely to benefit more from SMT compared to other treatments.

Jenks et al. (2022) assessed the effects of SMT on pain and function in older adults with chronic LBP in an individual participant data (IPD) meta-analysis. RCTs which examined the effects of SMT in adults with chronic LBP compared to interventions recommended in international LBP guidelines were included. Pain and functional status were examined at 4, 13, 26, and 52 weeks. 10 studies were retrieved, including 786 individuals, of which 261 were between 65 and 91 years of age. There is moderate-quality evidence that SMT results in similar outcomes at 4 weeks. Second stage and sensitivity analysis confirmed these findings. Authors concluded that SMT provides similar outcomes to recommended interventions for pain and functional status in the older adult with chronic LBP. SMT should be considered a treatment for this patient population. Trager et al. (2022) examined the relationship between chiropractic spinal manipulative therapy (CSMT) and lumbar discectomy are both used for lumbar disc herniation (LDH) and lumbosacral radiculopathy (LSR). Adults ages 18-49 with newly diagnosed LDH/LSR (first date of diagnosis) were included. Exclusions were prior lumbar surgery, absolute indications for surgery, trauma,

spondylolisthesis, and scoliosis. Propensity score matching controlled for variables associated with the likelihood of discectomy (e.g., demographics, medications). Patients were divided into cohorts according to receipt of CSMT. After matching, there were 5785 patients per cohort (mean age 36.9 ± 8.2). The odds ratio (95% CI) for discectomy were significantly reduced in the CSMT cohort compared with the cohort receiving other care over 1-year and 2-year follow-up. Authors findings suggest receiving CSMT compared with other care for newly diagnosed LDH/LSR is associated with significantly reduced odds of discectomy over 2-year follow-up. Given socioeconomic variables were unavailable, and an observational design precludes inferring causality, the efficacy of CSMT for LDH/LSR should be examined via randomized controlled trial to eliminate residual confounding.

Trager et al. (2022) examined the relationship between chiropractic spinal manipulative therapy (CSMT) and prescription benzodiazepines for radicular low back pain (rLBP). Adults aged 18-49 with an index diagnosis of rLBP were included. Serious etiologies of low back pain, structural deformities, alternative neurological lesions, and absolute benzodiazepine contraindications were excluded. Patients were assigned to cohorts according to CSMT receipt or absence. Propensity score matching was used to control for covariates that could influence the likelihood of benzodiazepine utilization. After matching, there were 9,206 patients (mean (SD) age, 37.6 (8.3) years, 54% male) per cohort. Odds of receiving a benzodiazepine prescription were significantly lower in the CSMT cohort over all follow-up windows pre-matching and post-matching. Authors suggest that receiving CSMT for newly diagnosed rLBP is associated with reduced odds of receiving a benzodiazepine prescription during follow-up. These results provide real-world evidence of practice guideline-concordance among patients entering this care pathway.

Zaina et al. (2023) sought to identify evidence-based rehabilitation interventions for persons with non-specific low back pain (LBP) with and without radiculopathy and to develop recommendations from high-quality clinical practice guidelines (CPGs) to inform the World Health Organization's Package of Interventions for Rehabilitation. Authors identified 4 high-quality CPGs. Recommended interventions included (1) education about recovery expectations, self-management strategies, and maintenance of usual activities; (2) multimodal approaches incorporating education, exercise, and spinal manipulation; (3) nonsteroidal anti-inflammatory drugs combined with education in the acute stage; and (4) intensive interdisciplinary rehabilitation that includes exercise and cognitive/behavioral interventions for persistent pain. They did not identify high-quality CPGs for people younger than 16 years of age. Authors concluded that for people with LBP with and without radiculopathy, recommendations emphasize the potential benefits of education, exercise, manual therapy, and cognitive/behavioral interventions.

Sørensen et al. (2023) examined whether targeting spinal manipulative therapy (SMT) by applying the intervention to a specific vertebral level produces superior clinical outcomes than a nontargeted approach in patients with nonspecific low back pain. Ten randomized controlled trials ($n = 931$ patients) were included. There was moderate-certainty evidence of no difference between targeted SMT and a nontargeted approach for pain intensity at post-intervention and at follow-up. For patient-reported disability, there was moderate-certainty evidence of no difference at post-intervention and at follow-up. Adverse events were reported in 4 trials and were minor and evenly distributed between groups. Authors concluded that targeting a specific vertebral level when administering SMT for patients with nonspecific low back pain did not result in improved outcomes on pain intensity and patient-reported disability compared to a nontargeted approach.

Feise et al. (2023) compared the benefits and harms of treatments for the management of chronic low back pain without radiculopathy. Systematic review and meta-analysis of randomized controlled trials were evaluated. Adults with chronic nonspecific low back pain, excluding radicular pain, in any clinical setting were included. Outcome measures included comparison of pain at immediate-term (≤ 2 weeks) and short-term (> 2 weeks to ≤ 12 weeks) and serious adverse events. Three studies provided data on the benefits of interventions, and 30 provided data on harms. Studies included interventions of acupuncture ($n=8$); manipulation ($n=2$); pharmacological therapies ($n=9$), including NSAIDs and opioid analgesics; surgery ($n=8$); and epidural corticosteroid injections ($n=3$). Acupuncture (moderate quality of evidence, benefit rating of 3) and manipulation (moderate quality of evidence, benefit rating of 5) were effective in reducing pain intensity compared to sham. The benefit of the other interventions was scored as uncertain due to not being effective, statistical heterogeneity preventing pooling of effect sizes, or the absence of relevant trials. The harms level warnings were at the lowest (e.g., indicating rarer risk of events) for acupuncture, spinal manipulation, NSAIDs, combination ingredient opioids, and steroid injections, while they were higher for single ingredient opioid analgesics (level 4) and surgery (level 6). Authors concluded that there is uncertainty about the benefits and harms of all the interventions reviewed due to the lack of trials conducted in patients with chronic nonspecific low back pain without radiculopathy. From the limited trials conducted, nonpharmacological interventions of acupuncture and spinal manipulation provide safer benefits than pharmacological or invasive interventions. However, more research is needed. There were high harms ratings for opioids and surgery.

Trager et al. (2024) reviewed chiropractic research trends since 1972 and recent clinical practice guideline (CPG) recommendations regarding SMT. Authors searched for articles associated with chiropractic (spanning 1972–2024), analyzing publication trends and keywords, and also searched CPGs addressing SMT use (spanning 2013–2024). They identified 6286 articles on chiropractic. The rate of publication trended upward. Keywords initially related to historical evolution, scope of practice, medicolegal, and regulatory aspects evolved to include randomized controlled trials and systematic reviews. They

identified 33 CPGs, providing a total of 59 SMT-related recommendations. The recommendations primarily targeted low back pain (n = 21) and neck pain (n = 14); of these, 90% favored SMT for low back pain while 100% favored SMT for neck pain. Recent CPG recommendations favored SMT for tension-type and cervicogenic headaches. There has been substantial growth in the number and quality of chiropractic research articles over the past 50 years, resulting in multiple CPG recommendations favoring SMT. These findings reinforce the utility of SMT for spine-related disorders.

Farley et al. (2024) evaluated spinal manipulative therapy (SMT), dry needling (DN), and exercise for LBP. The study was a 3-armed parallel-group design randomized clinical trial. They enrolled and randomized 96 participants with LBP into a multimodal strategy of treatment consisting of a combination of DN and SMT, DN only, and SMT only, followed by an at-home exercise program. All participants received 4 treatment sessions in the first 2 weeks followed by a 2-week home exercise program. Outcomes included clinical (Oswestry Disability Index, numeric pain intensity rating) and mechanistic (lumbar multifidus, erector spinae, and gluteus medius muscle activation) measures at baseline, 2, and 4 weeks. Participants in the DN and SMT groups showed larger effects and statistically significant improvement in pain and disability scores, and muscle percent thickness change at 2 weeks and 4 weeks of treatment when compared to the other groups.

Gevers-Montoro et al. (2024) aimed to investigate the efficacy of SMT to improve CPLBP and its underlying mechanisms in a randomized placebo-controlled dual-blind mixed experimental trial. Ninety-eight individuals with CPLBP and 49 controls were recruited. Individuals with CPLBP received SMT (n = 49) or a control intervention (n = 49), 12 times over 4 weeks. The primary outcomes were CPLBP intensity (0-100 on a numerical rating scale) and disability (Oswestry Disability Index). Secondary outcomes included pressure pain thresholds in 4 body regions, pain catastrophizing, Central Sensitization Inventory, depressive symptoms, and anxiety scores. Individuals with CPLBP showed widespread mechanical hyperalgesia and higher scores for all questionnaires. SMT reduced pain intensity compared with the control intervention, but not disability. Similar mild to moderate adverse events were reported in both groups. Mechanical hyperalgesia at the manipulated segment was reduced after SMT compared with the control intervention. Pain catastrophizing was reduced after SMT compared with the control intervention, but this effect was not significant after accounting for changes in clinical pain. Although the reduction of segmental mechanical hyperalgesia likely contributes to the clinical benefits of SMT, the role of pain catastrophizing remains to be clarified. This randomized controlled trial found that 12 sessions of SMT yield greater relief of CPLBP than a control intervention. These clinical effects were independent of expectations and accompanied by an attenuation of hyperalgesia in the targeted segment and a modulation of pain catastrophizing.

Yu et al. (2024) evaluated benefits and harms of rehabilitation interventions for non-specific low back pain (LBP) or thoracic spine pain in the pediatric population. They screened 8461 citations and 307 full-text articles. Ten quantitative studies (i.e., 8 RCTs, 2 non-randomized clinical trials) and one qualitative study were included. With very low to moderate certainty evidence, in adolescents with LBP, spinal manipulation (1-2 sessions/week over 12 weeks, 1 RCT) plus exercise may be associated with a greater likelihood of experiencing clinically important pain reduction versus exercise alone; and group-based exercise over 8 weeks (2 RCTs and 1 non-randomized trial) may reduce pain intensity. The qualitative study found information provided via education/advice and compliance of treatment were related to effective treatment. No economic studies or studies examining thoracic spine pain were identified. Authors concluded that spinal manipulation and group-based exercise may be beneficial in reducing LBP intensity in adolescents. Education should be provided as part of a care program. The overall evidence is sparse. Methodologically rigorous studies are needed.

Nim et al. (2024) assessed whether spinal manipulative therapy (SMT) application procedures (i.e., target, thrust, and region) impacted changes in pain and disability for adults with spine pain in a systematic review with network meta-analysis. They included randomized controlled trials (RCTs) from recent systematic reviews and newly identified RCTs published during the review process and employed artificial intelligence to identify potentially relevant articles not retrieved through electronic database searches. Authors included RCTs of the effects of high-velocity, low-amplitude SMT, compared to other SMT approaches, interventions, or controls, in adults with spine pain. The outcomes were spinal pain intensity and disability measured at short-term (end of treatment) and long-term (closest to 12 months) follow-ups. They included 161 RCTs (11,849 participants). Most SMT procedures were equal to clinical guideline interventions and were slightly more effective than other treatments. When comparing inter-SMT procedures, effects were small and not clinically relevant. A general and nonspecific rather than a specific and targeted SMT approach had the highest probability of achieving the largest effects. Results were based on very low- to low-certainty evidence, mainly downgraded owing to large within-study heterogeneity, high risk of bias, and an absence of direct comparisons. Authors concluded that there was low-certainty evidence that clinicians could apply SMT according to their preferences and the patients' preferences and comfort. Differences between SMT approaches appear small and likely not clinically relevant.

Neck Pain

A review conducted by Walser et al. (2009) assessing the effectiveness of thoracic spinal manipulation (TSM) in managing musculoskeletal conditions. Thirteen studies were included in the review with 9 investigating the use of TSM for the treatment of neck pain. Four high-quality and 1 fair-quality studies reported significant improvement in pain in participants who received TSM over a comparison group. Two studies with fair to poor quality found significant within-group increases in cervical rotation. The authors

concluded there is satisfactory evidence to support TSM as a treatment for certain patients with neck pain in the short-term. The efficacy of TSM alone or in combination with other conservative interventions for the management of patients with non-specific neck pain was assessed by Huisman et al. (2013). Ten studies met the criteria for inclusion, with a range in methodological quality from “average” to “good.” The authors concluded that overall, there was insufficient evidence to support or refute TSM as a more effective treatment than control treatments in reducing pain and disability. However, the results of the review showed evidence that combining TSM with other treatments such as exercise, spinal mobilization, electro-thermal therapy, infrared radiation therapy, and education was more effective than any of those treatments delivered without TSM.

D’Sylva et al. (2010) published a systematic review assessing the effectiveness of combination therapy approaches on neck pain with multiple outcomes including pain, function, disability, and patient satisfaction. The combination therapies were defined as manipulation and mobilization; manipulation, mobilization, and soft tissue work; and manual therapy and physical medicine modalities. The authors selected 19 trials, 37% (7/19) of which had a low risk of bias. Most of the methodological weaknesses found pertained to allocation concealment and blinding procedures. However, the authors noted that when performing manual treatments, blinding the patient is difficult and blinding the provider is impossible. Regarding an ideal combined treatment approach, using manipulation and mobilization alone provide short-term (but not long-term) pain relief. Manipulation, mobilization, and soft tissue work were also shown to relieve pain and increase patient satisfaction in the short-term. Combining manual therapy and exercise seems to produce longer-term improvements across multiple outcomes.

The literature on the efficacy of manual therapies alone or with exercises in patients with nonspecific neck pain was reviewed by Vincent et al. (2013). The authors divided the studies into 3 groups based on symptom duration: acute (defined as <3 months), chronic (>3 months) and neck pain of variable duration. The selection criteria rendered 27 RCTs of which 9 were determined to be low quality and 18 high quality. In general, the evidence suggests that manual therapy contributes to improvements in pain and function, especially when used in combination with other therapies. For patients with acute neck pain, manipulation produced better short-term results than electro-thermal therapy and better long-term results than anti-inflammatory or analgesic medications (with varied treatment protocols). Multimodal management that included manual therapy was favored over passive interventions such as a cervical collar or rest, and contradictory results were found when cervical and thoracic manipulation was compared. For chronic neck pain, regardless of follow-up duration, manual therapy combined with exercise provided better improvements in pain and function than did manual therapy or exercise alone. In the short-term, results were better with manipulation than with medications or acupuncture; however, in the long-term, no differences were found between these groups. For patients with a varied duration of neck pain, the combination of manipulation and mobilization or

exercise and mobilization was better than exercise alone, medications and passive interventions. Cervical manipulation combined with laser therapy was more effective than either treatment performed alone.

Miller et al. (2010) reviewed the evidence for trials investigating the effectiveness of manual therapy, which included manipulation and mobilization, and exercise for neck pain in adults with neck pain. Seventeen studies were included in the review and examined acute, subacute, chronic, and mixed durations of pain. The range in risk of bias was low (5 trials) to high risk (12 trials), and the authors again cite blinding as a limitation in applying methodological criteria. Patient-reported outcomes cannot meet observer blinding criteria, and manual therapies prohibit the provider from being blinded to the treatment. Mobilization and manipulation provided similar benefits, and the use of these treatments alone was shown to relieve pain in the short-term. Exercise alone was shown to improve pain and function in the long-term. Combining manual therapy and exercise produced greater short-term pain reduction than exercise alone and longer-term improvements across multiple outcomes when compared to manual therapy alone. Salt et al. (2011) conducted a systematic review to investigate evidence for the non-invasive management of cervicobrachial pain. Eleven studies were included. There was conflicting evidence that manual therapy and exercise provided a long-term reduction in pain and influenced function and disability. Meta-analyses suggested that manual therapy and exercise improved pain immediately following treatment, but results were not statistically significant. One trial compared cervical manipulation and medication to a medication-only group in patients with pain in the neck, arm or hand related to cervical joint hypomobility. A significant between-group difference was found when measuring immediate results, however; differences were not sustained at 1- and 3-week follow-up.

Martel et al. (2011) hypothesized that participants with chronic neck pain who received preventative SMT in combination with a home exercise program would experience improvements in pain, disability and function compared to a group receiving only SMT or no treatment. The authors performed a 2-phase RCT in which the first phase (symptomatic) consisted of 10-15 treatments that were provided over a 5- to 6-week period. The results of this phase revealed a clinically and statistically significant average decrease of 1.1 cm on the VAS (Visual Analog Scale) for pain and 6.5 points on the BQ (Bournemouth Questionnaire) for disability. Function (measured by ROM) significantly improved as well, except for lateral flexion. Participants were randomized into a SMT, SMT with exercise or an attention-controlled group (no treatment, but self-management such as applying ice was allowed and discussed condition at each visit) during the second phase (preventative). This phase entailed 10 months of treatment at approximately 1x/month for the active groups and every 2 months for the inactive. Significant group differences were not found for outcomes in this phase, however; most of the participants in each group retained a level of pain below clinically acceptable (2-point difference from baseline symptomatic phase VAS). Therefore, results indicated no additional benefit to participants receiving monthly

preventative SMT or SMT with home exercise compared with a consultation visit to a chiropractor every other month and the hypothesis was rejected. This suggests by simply managing a patient for neck pain may decrease recurrence of incidents, and that strategies for treatment vs. those for prevention need further investigation and delineation.

In a randomized controlled trial by Casanova-Mendez et al., (2014) two different thoracic spinal manipulative techniques were compared for immediate and short-term effects on patients with chronic neck pain. Sixty-four participants were allocated, received a single active treatment, and completed the study. The intervention for the dog-technique group was described as directing the patient to assume a supine position with their arms folded across their chest. The right hand of the therapist was positioned to contact the T4 vertebrae; the other hand was placed on the participant's elbows to add flexion, reduce slack, and deliver a HVLA thrust in the anteroposterior direction. The other intervention, toggle-recoil (TR), was described as the therapist contacting the T4 transverse processes with the pisiforms in crossed-hand set-up on a participant lying prone. A posterior anterior HVLA thrust was delivered. Outcomes measured were pain pressure threshold (PPT), ROM and self-reported pain, and all outcomes improved using both techniques. The TR group results were superior, showing statistical significance in all outcomes, however; there were no clinical differences between the groups except for slightly better effects from TR on left rotation, extension, and right lateral flexion.

Low-force mobilization was examined against high-force mobilization and placebo in a RCT conducted by Snodgrass et al. (2014) to add to the evidence regarding optimal dosing for chronic neck pain treatment. The primary outcome was PPT, and resting pain, ROM and spinal stiffness measured as secondary outcomes immediately following treatment and at a 4-day follow-up session. Sixty-four participants were randomized into 1 of the 3 groups receiving a single session of treatment. In the low-force group, the average mean force applied was 30.8 N and 88.6 N for the high-force group during 3 sets of 1-minute posteroanterior mobilization applied to the most painful spinous process. The placebo treatment consisted of detuned laser for 3 sets of 1 minute. No differences were found between groups in PPT or ROM at immediate or follow-up measurements. The high-force group fared better than placebo in spinal stiffness at follow-up but was not significantly different from the low-force group. However, regarding pain, participants in the high-force group reported significant pain reduction at follow-up over the low-force group (not over placebo).

Young et al. (2014) performed a review examining the effects of thoracic spinal manipulation (TSM) for the treatment of mechanical neck pain. The quality of evidence overall was determined to be fair (measured with the PEDro scale), and the authors' inclusion criteria rendered 14 studies. This review aimed to focus on literature comparing the effectiveness of TSM versus mobilization, however; only 1 study was found that directly compared these treatments. Additionally, only short-term outcomes were collected

in all trials. Results showed that TSM was superior to mobilization, placebo, modalities, and no treatment. These results prompted the authors to conclude that the evidence is scarce and of questionable methodological quality regarding the use of thoracic mobilization, but a considerable amount of varied quality evidence exists supporting TSM as an intervention for improvements in pain, disability, and ROM in the short-term.

A systematic review was conducted by Tsertsvadze et al. (2014) of trial-based economic evaluations of manual therapy compared to other alternative treatments. Two trials out of the included 25 reported results of the effectiveness of manual therapy in treating neck pain. One trial found that spinal mobilization, defined as low velocity passive movements within or at the limit of joint ROM, had significantly lower costs and slightly better effects compared to either physiotherapy or general practitioner care at 1-year follow-up. Clinical outcomes showed manual therapy provided a faster recovery rate than physiotherapy and general practitioner care after 7 weeks, with respective rates at 68%, 51% and 36%. Another trial evaluated manual therapy, defined as manipulation and mobilization, against a behavioral graded activity (BGA) program. The authors concluded that their cost-effective analyses showed that BGA is not cost-effective in comparison with manual therapy in measures of recovery and quality of life.

Chu et al. (2014) focused their review and meta-analysis to the evaluation of sympathetic nervous system responses and clinical outcomes using spinal manual therapy (SMT) to the cervical or thoracic spine in the management of neck, upper back, or upper extremity pain. Spinal manipulation was a term used in the search strategy but did not render any results after applying the inclusion criteria. For this review, the intervention most described consisted of a Grade III mobilization technique (using Maitland classification), where the researcher contacted the designated vertebral segment using oscillatory pressure. In total, 11 studies were included; 3 of those studies used a pain outcome and 4 measured ROM. In studies that included a comparison group, between-group analysis was calculated using data from a control group. Within-group analyses were also performed, and authors reported both the between- and within-group analyses showed small but significant effect sizes in improved pain and ROM. Manual therapy produced increased peripheral skin conductance and upper extremity ROM as well as decreased skin temperature and patient-reported pain.

Lopez-Lopez et al. (2015) investigated the differences in effectiveness between manipulation, mobilization and sustained natural apophyseal glide (SNAG) techniques and their relationship to psychological factors in the treatment of chronic neck pain. The primary outcome was pain, and ROM and pressure pain threshold (PPT) were secondary outcomes measured immediately following a single treatment. The group assigned to manipulation received a high-velocity low-amplitude supine technique, the mobilization group received a unilateral posteroanterior grade III passive oscillatory technique in the prone position, and the SNAG technique was performed on a seated patient while they

1 simultaneously moved their head from a standardized position. The mean difference in pain
 2 at rest was 3.08 ($P<0.01$) in the HVLA group, 1.51 ($P<0.05$) in the mobilization group,
 3 and 0.26 (not significant) in the SNAG group. However, in pain and functional
 4 measurements with movement and PPT, there were no differences between the groups
 5 overall as all significantly improved. Concerning psychological factors, better outcomes
 6 were shown with mobilization if the participant had high levels of anxiety. If anxiety was
 7 low, the manipulation and SNAG techniques produced better results.

8
 9 A Cochrane review was conducted by Gross et al. in 2015 as an update of 2 previous
 10 reviews (performed in 2004 and 2010) assessing the effects of manipulation or
 11 mobilization alone compared to a control or another treatment on pain and other outcomes
 12 in adults with neck pain. The review included 51 randomized controlled trials with a total
 13 of 2,920 participants, and 80% (41/51) of the studies were of low or very low quality.
 14 Eighteen of the trials compared manipulation/mobilization to a control, 34 compared
 15 manipulation/mobilization to another treatment, and one trial had two comparisons.
 16 Manipulation was evaluated for both the cervical and thoracic spinal regions. For subacute
 17 or chronic neck pain, a single session of cervical manipulation provided temporary pain
 18 relief when compared to an inactive control. Multiple treatments produced conflicting
 19 evidence at short-term follow-up. However, multiple sessions of thoracic spinal
 20 manipulation were shown to reduce pain at short-term and intermediate-term follow-up in
 21 patients with acute or subacute neck pain and improve function in patients with acute to
 22 chronic neck pain when compared to control. Cervical manipulation for acute to subacute
 23 neck pain was more effective for improving pain and function than various combinations
 24 of analgesics, muscle relaxants and non-steroidal anti-inflammatory medications.

25
 26 For the conservative treatment of cervical radiculopathy, Zhu et al. (2015) examined the
 27 evidence for the effectiveness and safety of using cervical spine manipulation. Three
 28 studies, published in Chinese, met the criteria for inclusion in the systematic review, and
 29 the analysis represented a total of 502 patients with a diagnosis of degenerative cervical
 30 radiculopathy. Each was a two-arm RCT comparing manipulation to cervical computer
 31 traction (serving as a control group) where active treatment frequency was approximately
 32 2x/ week and inactive frequency varied from 3-7x/week. The duration of the treatments in
 33 2 of the trials was 2 weeks (1 including a 4-week follow-up), and 4 weeks in the other.
 34 Mean differences in pain measured by VAS showed statistically significant improvements
 35 in the active groups in all 3 studies. Overall, the authors deemed the level of evidence to
 36 be of moderate quality due to statistical heterogeneity ($I^2 >50\%$). They used the PEDro
 37 scale to determine methodological quality; a score of 5 or above (out of a possible 10) was
 38 considered acceptable and indicated low risk of bias. Two of the 3 studies scored a 5, and
 39 1 scored a 6. The items related to blinding considerations were not met in all 3 of the
 40 studies, and the authors echoed the opinions of many other authors regarding the limitations
 41 or difficulties in blinding during trials involving spinal manipulation. However, other
 42 methods of more concern were a lack of detail regarding sample size calculations,

randomization, allocation concealment, and intention-to-treat analyses. Additionally, adverse event reporting was not prevalent, leading to inconclusive safety results.

In a revised clinical practice guideline linked to the International Classification of Functioning, Disability and Health From the Orthopaedic Section of the American Physical Therapy Association, Blanpied et al. (2017) reports that for acute neck pain with mobility deficits, clinicians should provide thoracic manipulation, a program of neck ROM exercises, and scapulothoracic and upper extremity strengthening to enhance program adherence and clinicians may provide cervical manipulation and/or mobilization. For subacute neck pain with mobility deficits included whiplash associated disorders, clinicians may provide thoracic manipulation and cervical manipulation and/or mobilization. For chronic neck pain with mobility deficits, clinicians should provide a multimodal approach of the following:

- Thoracic manipulation and cervical manipulation or mobilization
- Mixed exercise for cervical/scapulothoracic regions: neuromuscular exercise (e.g., coordination, proprioception, and postural training), stretching, strengthening, endurance training, aerobic conditioning, and cognitive affective elements

For patients with subacute or chronic neck pain with headache, clinicians should provide cervical manipulations or mobilizations. For patients with chronic neck pain with radiating pain, clinicians should provide mechanical intermittent cervical traction, combined with other interventions such as stretching and strengthening exercise plus cervical and thoracic mobilization/manipulation.

Griswold et al. (2018) compared the clinical effectiveness of concordant cervical and thoracic non-thrust manipulation (NTM) and thrust manipulation I for patients with mechanical neck pain. The Neck Disability Index (NDI) was the primary outcome. Secondary outcomes included the Patient-Specific Functional Scale (PSFS), numeric pain-rating scale (NPRS), deep cervical flexion endurance (DCF), global rating of change (GROC), number of visits, and duration of care. Outcomes were collected at baseline, visit 2, and discharge. Patients were randomly assigned to receive either NTM or TM directed at the cervical and thoracic spines. Techniques and dosages were selected pragmatically and applied to the most symptomatic level. One hundred three patients were included in the analyses (NTM, $n = 55$ and TM, $n = 48$). The between-group analyses revealed no differences in outcomes on all outcome measures, number of visits and duration of care. Authors concluded that NTM and TM produce equivalent outcomes for patients with mechanical neck pain.

Masaracchio et al. (2019) investigated the role of thoracic spine manipulation (TSM) on pain and disability in the management of mechanical neck pain (MNP). Across the included studies, there was increased risk of bias for inadequate provider and participant blinding. The GRADE approach demonstrated an overall level of evidence ranging from very low

to moderate. Meta-analysis that compared TSM to thoracic or cervical mobilization revealed a significant effect favoring the TSM group for pain and disability. Meta-analysis that compared TSM to standard care revealed a significant effect favoring the TSM group for pain and disability at short-term follow-up, and a significant effect for disability at long-term follow-up. Meta-analysis that compared TSM to cervical spine manipulation revealed a non-significant for pain without a distinction between immediate and short-term follow-up. Limitations include heterogeneity among the studies making it difficult to assess the true clinical benefit, as well as the overall level of quality of evidence. Authors conclude that TSM has been shown to be more beneficial than thoracic mobilization, cervical mobilization, and standard care in the short-term, but no better than cervical manipulation or placebo thoracic spine manipulation to improve pain and disability. Coulter et al. (2019) sought to determine the efficacy, effectiveness, and safety of various mobilization and manipulation therapies for treatment of chronic nonspecific neck pain. A total of 47 randomized trials were included in the systematic review and included a total of 4,460 patients with nonspecific chronic neck pain who were being treated by a practitioner using various types of manipulation and/or mobilization interventions. A total of 37 trials were categorized as unimodal approaches and involved thrust or non-thrust compared with sham, no treatment, or other active comparators. Of these, only 6 trials with similar intervention styles, comparators, and outcome measures/timepoints were pooled for meta-analysis at 1, 3, and 6 months, showing a small effect in favor of thrust plus exercise compared to an exercise regimen alone for a reduction in pain and disability. Multimodal approaches appeared to be effective at reducing pain and improving function from the 10 studies evaluated. Authors concluded that studies provide low-moderate quality evidence that various types of manipulation and/or mobilization will reduce pain and improve function for chronic nonspecific neck pain compared to other interventions. It appears that multimodal approaches, in which multiple treatment approaches are integrated, might have the greatest potential impact. According to the published trials reviewed, manipulation and mobilization appear safe.

Bernal-Utrera et al. (2020) compared the effects of two experimental treatments based on manual therapy and therapeutic exercise. The short-term and mid-term changes produced by different therapies on subjects ($n=69$) with non-specific chronic neck pain were studied. The sample was randomized divided into three groups: manual therapy, therapeutic exercise, and placebo. No statistically significant differences ($P 0.05$) were obtained between the experimental groups, if they exist against the control group. Nonetheless, they found that manual therapy improved perceived pain before than therapeutic exercise, while therapeutic exercise reduced cervical disability before than manual therapy. Authors concluded that there were no differences between groups in short and medium terms. Manual therapy achieves a faster reduction in pain perception than therapeutic exercise. Therapeutic exercise reduces disability faster than manual therapy. Clinical improvement could potentially be influenced by central processes.

Hawk et al. (2020) developed an evidence-based clinical practice guideline through a broad-based consensus process on best practices for chiropractic management of patients with chronic musculoskeletal (MSK) pain. Delphi process was conducted January-February 2020. The 62-member Delphi panel reached consensus on chiropractic management of five common chronic MSK pain conditions: low-back pain (LBP), neck pain, tension headache, osteoarthritis (knee and hip), and fibromyalgia. Recommendations were made for nonpharmacological treatments, including acupuncture, spinal manipulation/mobilization, and other manual therapy; modalities such as low-level laser and interferential current; exercise, including yoga; mind-body interventions, including mindfulness meditation and cognitive behavior therapy; and lifestyle modifications such as diet and tobacco cessation. Authors concluded that clinicians should consider multiple approaches for neck pain. Both active and passive, and both physical and mind-body interventions should be considered in the management plan. Spinal manipulation/mobilization was included in this recommendation for neck pain.

Chaibi et al. (2021) reviewed original randomized controlled trials (RCTs) assessing the effect of spinal manipulative therapy (SMT) for acute neck pain. Six studies were included. The overall pooled effect size for neck pain was very large -1.37 favoring treatments with SMT compared with controls. Minor transient adverse events reported included increased pain and headache, while no serious adverse events were reported. Authors concluded that SMT alone or in combination with other modalities was effective for patients with acute neck pain. However, limited quantity and quality, pragmatic design, and high heterogeneity limit the findings. Bakken et al. (2021) investigated the combination of home stretching exercises and spinal manipulative therapy in a multicenter randomized controlled clinical trial, carried out in multidisciplinary primary care clinics. The treatment modalities utilized were spinal manipulative therapy and home stretching exercises compared to home stretching exercises alone. Both groups received 4 treatments for 2 weeks. The primary outcome was pain, where the subjective pain experience was investigated by assessing pain intensity (Numerical Rating Scale - 11) and the quality of pain (McGill Pain Questionnaire). Neck disability and health status were secondary outcomes, measured using the Neck Disability Index the EQ-5D, respectively. One hundred thirty-one adult subjects were randomized to one of the two treatment groups. All subjects had experienced persistent or recurrent neck pain the previous 6 months and were blinded to the other group intervention. The clinicians provided treatment for subjects in both group and could not be blinded. The researchers collecting data were blinded to treatment allocation, as was the statistician performing data analyses. An intention-to-treat analysis was used. Sixty-six subjects were randomized to the intervention group, and sixty-five to the control group. Authors concluded that based on their findings, there is no additional treatment effect from adding spinal manipulative therapy to neck stretching exercises over 2 weeks for patients with persistent or recurrent neck pain.

Thoomes et al. (2022) aimed to establish consensus on effective nonsurgical treatment modalities at different stages (i.e., acute, subacute, or chronic) of cervical radiculopathy (CR) using the Delphi method approach. Experts within the field rated their agreement with a list of proposed treatment modalities according to the stage of CR. Agreement was measured using a 5-point Likert scale. Descriptive statistics were used to measure agreement (median, interquartile ranges, and percentage of agreement). Consensus criteria were defined a priori for each round. Consensus for Round 3 was based on ≥ 2 of the following: a median Likert scale value of ≥ 4 , interquartile range value of ≤ 1 , and/or a percentage of agreement $\geq 70\%$. Data analysis produced a consensus list of effective treatment modalities in different stages of recovery. According to experts, the focus of multimodal management in the acute stage should consist of patient education and spinal manipulative therapy, specific (foraminal opening) exercises, and sustained pain-relieving positions. In the subacute stage, increasing individualized physical activity including supervised motor control, specific exercises, and/or neurodynamic mobilization could be added. In the chronic stage, focus should shift to include general aerobic exercise as well as focused strength training. Postural education and vocational ergonomic assessment should also be considered. Authors concluded that multimodal conservative management of individuals with CR should take the stage of the condition into consideration. The focus of therapeutic interventions should shift from passive pain-relieving intervention in the acute stage to increasingly more individualized physical activity and self-management in the chronic stage.

Minnucci et al. (2023) aimed to estimate the benefits and harms of cervical spinal manipulative therapy (SMT) for treating neck pain. RCTs evaluating SMT compared to guideline-recommended and non-recommended interventions, sham SMT, and no intervention for adults with neck pain were eligible for this systematic review. Prespecified outcomes included pain, range of motion, disability, and health-related quality of life. Authors included 28 RCTs. There was very low to low certainty evidence that SMT was more effective than recommended interventions for improving pain at short term and long term and for reducing disability at short-term and long term. Transient side effects only were found (e.g., muscle soreness). Authors concluded that there was very low certainty evidence supporting cervical SMT as an intervention to reduce pain and improve disability in people with neck pain.

Liu et al. (2023) aimed to determine the effectiveness of manipulative therapy for chronic neck pain in a systematic review and meta-analysis. Seventeen RCTs, including 1,190 participants, were included in this meta-analysis. Manipulative therapy showed better results regarding pain intensity and neck disability than the control group. Manipulative therapy was shown to relieve pain intensity and neck disability. However, the studies had high heterogeneity, which could be explained by the type and control interventions. In addition, there were no significant differences in adverse events between the intervention

and the control groups. Authors concluded that manipulative therapy reduces the degree of chronic neck pain and neck disabilities.

Carrasco-Uribarren et al. (2024) investigated the effects of cervical thrust or non-thrust manipulations compared to thoracic or cervicothoracic manipulations for improving pain, disability, and range of motion in patients with neck pain. Six studies were included. Meta-analyses revealed no differences between cervical thrust or non-thrust manipulations and thoracic or cervicothoracic manipulations in pain intensity, disability, or cervical range of motion in any plane. The certainty of evidence was downgraded to very low for pain intensity, to moderate or very low for disability and to low or very low for cervical range of motion. There is moderate to very low certainty evidence that there is no difference in effectiveness between cervical thrust or non-thrust manipulations and thoracic or cervicothoracic manipulations for improving pain, disability, and range of motion in patients with neck pain.

Akgüller et al. (2025) aimed to compare the effectiveness of cervical thrust manipulation and exercise in patients with mechanical neck pain (MNP). Sixty (mean age 31.45 ± 7.31 years) patients were randomized into three groups: manipulation (Group 1); exercise (Group 2); and manipulation plus exercise (Group 3). All interventions were performed 2 days a week for 6 weeks. The visual analog scale (VAS) and Neck Disability Index (NDI) were primary outcome measures; pressure pain threshold (PPT), range of motion (ROM), Short form-36 (SF-36), and Global Rating of Change (GROC) were secondary outcome measures. All parameters improved in all groups. Only the minimal clinically important difference (MCID) for NDI was achieved in Group 3. Group 3 had greater improvement in: VAS-rest; NDI; PPT-left; and vitality, as well as higher GROC compared to the other groups. Group 3 was superior to Group 2 in terms of: ROM; and emotional well-being. Group 1 was superior to Group 2 in terms of ROM. Authors concluded that the combined application of cervical thrust manipulation and exercise in MNP resulted in greater improvement in clinical parameters, especially function, and higher patient satisfaction in the short term compared to their application alone. Because of its positive effects, cervical thrust manipulation can be added to the exercise program according to the patient's needs and suitability for manipulation.

Thoracic Spine Pain

Spinal manipulation has not been studied in any systematic way (e.g., through RCTs) for the treatment of pain in the mid-back region. Some studies cited have included thoracic spine manipulation as part of a treatment package for neck pain, but none have looked at pain in the thoracic spine itself as an outcome. Indeed, there are virtually no experimental studies that have evaluated the treatment of thoracic spine pain of mechanical origin.

1 This scientific vacuum cannot be interpreted to constitute a virtual ban on the treatment of
 2 thoracic spine pain. Patients with such complaints are going to present themselves and are
 3 entitled to a reasoned response by the healthcare provider.

4
 5 Given the literature on analogous disorders of the lumbar and cervical spine and given the
 6 likelihood that the active mechanisms of manual therapies such as spinal manipulation are
 7 comparable in the thoracic spine, this clinical policy guideline views spinal manipulation
 8 as a valid treatment option for thoracic spinal pain. As such, spinal manipulation is
 9 considered medically necessary when:

- 10 • There is a diagnosis of spinal pain of mechanical origin;
- 11 • There are no diagnostic red flags;
- 12 • There is adequate documentation; and
- 13 • Adequate clinical progress continues to be made.

14 **Headache Disorders**

15 A study by Chaibi et al. (2011) was completed reviewing the efficacy of MT for the
 16 treatment of migraine. Seven studies were included in the review of which 4 applied SMT.
 17 A group of authors performed 2 of the studies where the first was a controlled trial and the
 18 second was a follow-up questionnaire. The authors of the systematic review gave these
 19 studies a low methodological quality score. The first study compared 3 groups: cervical
 20 SMT by a chiropractor, cervical SMT by physician or physical therapist, and cervical
 21 mobilization (control group) by a physician or physical therapist. The resultant mean
 22 reductions in frequency, intensity, and duration (pre- and post-treatment) were 40, 43 and
 23 36% in the chiropractic SMT group, 13, 12 and 8% in the physician/PT SMT group, and
 24 34, 15 and 20% in mobilization group with no statistically significant differences between
 25 the groups. At the 20-month follow-up, further improvement was reported from pre- to
 26 post-trial mean reduction in attack frequency at 58, 29 and 54% in the respective groups.
 27 Another RCT (with a good methodological score) with 3 groups compared SMT by
 28 diversified technique, amitriptyline, and a combination of SMT/amitriptyline during and
 29 after an 8-week intervention period. From baseline to the last 4 weeks of treatment and
 30 from baseline to 4 weeks post-treatment, mean intensity decreased by 40 and 42% in SMT
 31 group, 49 and 24% in amitriptyline group, and 41 and 25% in the combination group. Mean
 32 frequency was reduced equally between the groups. From baseline to post-treatment, over-
 33 the-counter medication was reduced by 55%, 28% and 15% in the groups, respectively.
 34 With a good methodological quality score, the 4th study found statistically significant
 35 improvement favoring the SMT group over the control. Reductions in frequency ($p < 0.05$),
 36 duration ($P < 0.01$), disability ($p < 0.05$) and medication use ($p < 0.001$) were shown. The
 37 authors concluded that providers may want to consider referring migraine patients for SMT
 38 if they are not responding to prophylactic medication or if reasons exist against medication
 39 as SMT might be an equally effective treatment. Again, Posadzki and Ernst performed a
 40 parallel systematic review and included 3 of the same studies. They did not regard SMT as
 41 a treatment recommendation based on the scarcity of evidence and poor quality of studies.
 42

Posadzki and Ernst (2012) performed a review of SMT for tension type headache (TTH) and found favorable results for the treatment but could not pool data due to the statistical and clinical heterogeneity of the included studies. The results of this meta-analysis found a moderate effect size supporting MT and suggest that it is more effective than medication in the short term for patients with TTH. Chaibi and Russell (2012) conducted a systematic review assessing the efficacy of MT for the treatment of primary chronic headache. The search terms contained various headache conditions combined with MT terms including ‘manipulative therapy,’ ‘spinal manipulative therapy,’ and ‘chiropractic treatment.’ Out of the 6 studies that met the review criteria, 1 evaluated massage therapy and 5 evaluated physical therapy for treatment effects for chronic TTH. The physical therapy interventions consisted of soft tissue therapy, exercises, stretching, TENS, postural correction, and mobilization; therefore, SMT was not evaluated. However, the results showed that MT was equal in efficacy to prophylactic medication with tricyclic antidepressant. The massage group had significant reduction in headache intensity when compared to detuned ultrasound. In 3 of the physical therapy trials, 54-85% of participants had $\geq 50\%$ reduction in headache frequency post-treatment, and 2 of the studies reported a maintained effect at a 6-month follow-up.

Racicki et al. (2013) conducted a study assessing the effectiveness of various non-invasive treatments for cervicogenic headaches. The conservative interventions included were MT or exercise. Six studies were included in the review, and all were determined to have good methodological quality scores on the PEDro scale. One of the most common methodological weaknesses involved blinding. The therapists were not blinded in all 6 studies, but as is the case with all MT studies, the intervention that is delivered must be known. Three of the trials did not blind the participants. Three studies had weaknesses associated with not offering point measures or measures of variability for 1 key outcome and intention to treat analysis. Some conflicting evidence was found among the studies; 4 concluded that manipulative therapy had a significant effect, but 2 showed no clinically or statistically significant differences (1 of which was conducted with participants aged 7-15 years). Five studies evaluated manipulation (1 included cervico-scapular strengthening exercises and mobilization) and 1 evaluated mobilization only. The cervical spine was the main region where the interventions were applied, but 1 study also incorporated upper thoracic SMT. After calculating effect sizes and reviewing all results, the authors found improvements in headache intensity, frequency and in neck pain when utilizing cervical manipulation, mobilization, and exercise. These findings echoed those of 2 previous reviews.

Chaibi and Russell (2014) also performed a systematic review to assess efficacy of manual therapies for the treatment of cervicogenic headache. The authors identified 7 studies that met the inclusion criteria with 6 involving a cervical SMT intervention. All studies were deemed to have at least good methodological quality based on scores of over 50 out of 100, and 1 study with excellent quality scoring 81. The most common methodological issues

were related to blinding and the number of participants. Two studies reported a statistically significant reduction in NSAID consumption from pre- to post-treatment in the cervical SMT group, but no statistically significant difference in consumption between cervical SMT and control groups. Another trial found a 50% reduction in the frequency of participant's headaches in the exercise group (76%), cervical SMT group (71%), combined exercise and SMT group (81%) and control (29%) and 100% reduction in 31, 33, 42 and 4% of the groups respectively. The combined group also showed significantly reduced durations of headaches immediately post-treatment ($P<0.05$) and at 12-month follow-up ($P<0.05$). Dose response was evaluated in 2 of the studies. One reported percentages of improvement in headache intensity and frequency that increased as treatment incidence increased; however, significant reductions in intensity were shown in the SMT 4x/week group compared to 1x/week at 4-week follow-up and in the SMT 3 and 4x/week compared to 1x/week at 12-week follow-up. The other study compared 1 and 2x/week SMT and light massage control groups and found more improvement in the treatment groups over the controls, but significant improvement was found specifically in the 2x/week SMT group ($P<0.05$) compared to the control group at 4, 12 and 24-week follow-up concerning headache intensity. Based on 1 treatment, another study showed significant reductions in headache days from baseline to 2-month follow-up in both the cervical SMT ($P<0.01$) and sham ($P<0.03$) groups but no statistically significant change in either group regarding headache frequency, total duration, and intensity. The authors concluded that the results were difficult to evaluate due to only 1 study incorporating a control group, but SMT may be an effective treatment for cervicogenic headache. A very similar systematic review was published by Posadzki and Ernst (2011), who concluded that evidence for the effectiveness of SMT for cervicogenic headaches is inconclusive.

Espi-Lopez et al. (2014) designed a study to determine the effectiveness of delivering one MT technique versus a combination of MT techniques in patients with tension type headache (TTH). Patients were randomized into 1 of the 3 active treatment groups or the control (4th group) at 19 per group. The treatment plan for each group consisted of 4 visits at 7-day intervals. The active treatments were either a suboccipital soft tissue inhibition therapy (SI); manipulation of the occiput, atlas, and axis (OAA); or combined SI + OAA. Outcomes measured varying factors of headache disability including the Headache Disability Inventory (HDI assesses an overall score and subscales of pain severity, frequency, function, and emotions) and presence of associated symptoms such as photo/phonophobia and pericranial tenderness). Both the OAA and combined groups showed significant reductions in headache frequency and differences in functional and emotional subsets of HDI score ($P<0.05$). No change in frequency was observed in the SI or control groups. In all 3 active groups, headache severity was significantly reduced ($P<0.05$) where no change was noted for the control. Only participants receiving the combined treatment reported significantly less frequency of photo/phonophobia and pericranial tenderness. Regarding between-group differences, results favored the OAA and combined groups. The authors concluded that individual techniques have different effects,

1 but that manipulative OAA alone was effective for reducing severity, frequency, and
2 functional and emotional features of disability related to TTH.

3
4 Espi-Lopez et al. (2014) also evaluated the effectiveness of manual and manipulative
5 therapy for patients with TTH. Patients were randomly assigned to either receive 1 of 3
6 active treatments (SI, OAA or a combination) or no treatment. Outcomes included a
7 perception of pain questionnaire, cervical ranges of motion, and frequency and intensity of
8 headaches. Measures were collected pre-treatment and at the end of a 4-week treatment
9 period, and again at a 4-week follow-up. Perception of pain improved significantly in all
10 treatment groups with manipulation showing greatest treatment effect. All treatment
11 groups showed increased left and right rotation; however, only the SI and OAA groups had
12 sustained benefit at the 4-week follow-up. The frequency of headaches was significantly
13 reduced through the end of the study in the combined group, and intensity improved in the
14 OAA, combined and control group at treatment conclusion and at follow-up. MT and
15 manipulation, alone and in combination, were effective in reducing pain perception, but
16 manipulation seemed to fare the best. The manipulation and combination treatments were
17 effective in reducing frequency and intensity. Mesa-Jimenez et al. (2015) conducted a
18 meta-analysis to evaluate the efficacy of manual therapies compared to pharmacological
19 drugs in the management of TTH. Five studies were included with methodological quality
20 scores ranging from fair to excellent. Manual therapy (MT) involving SMT/mobilization,
21 soft tissue therapy or exercise or a combination of these was shown to be more effective in
22 reducing headache frequency and intensity immediately following treatment. Additionally,
23 MT was associated with a statistically significant reduction in the number of headache days
24 per month as well as number of hours per day with a headache when compared to
25 medication. However, at long-term follow-up (24 weeks), there were no differences
26 between the treatments on headache intensity.

27
28 In a pragmatic RCT, Vernon et al. (2015) studied patients with TTH and cervicogenic
29 headaches. They compared one group who received 5 weeks of usual chiropractic treatment
30 to another group who received the same treatment in addition to 4 weeks of a self-
31 acupressure pillow. Usual chiropractic treatment consisted of SMT to the cervical and
32 upper thoracic spine, and could include mobilizations, soft tissue therapy or postural
33 exercises, and the groups received nearly the same levels of all interventions. The pillow
34 was prescribed to be used 2x/day for 5 minutes and during a headache episode up to
35 3x/episode. Although a true comparison between the groups could not be made due to a
36 failure in randomization, post hoc analysis revealed statistically and clinically significant
37 reductions in headache frequency (>40% reduction) in the chiropractic-only group (71%).

38
39 Dunning et al. (2016) compared the effects of manipulation to mobilization and exercise
40 in individuals with cervicogenic headache (CH). One hundred and ten participants ($n =$
41 110) with CH were randomized to receive both cervical and thoracic manipulation ($n = 58$)
42 or mobilization and exercise ($n = 52$). The primary outcome was headache intensity as

measured by the Numeric Pain Rating Scale (NPRS). Secondary outcomes included headache frequency, headache duration, disability as measured by the Neck Disability Index (NDI), medication intake, and the Global Rating of Change (GRC). The treatment period was 4 weeks with follow-up assessment at 1 week, 4 weeks, and 3 months after initial treatment session. Results demonstrated that individuals with CH who received both cervical and thoracic manipulation experienced significantly greater reductions in headache intensity ($p < 0.001$) and disability ($p < 0.001$) than those who received mobilization and exercise at a 3-month follow-up. Individuals in the upper cervical and upper thoracic manipulation group also experienced less frequent headaches and shorter duration of headaches at each follow-up period ($p < 0.001$ for all). Additionally, patient perceived improvement was significantly greater at 1 and 4-week follow-up periods in favor of the manipulation group ($p < 0.001$). Authors concluded that six to eight sessions of upper cervical and upper thoracic manipulation were shown to be more effective than mobilization and exercise in patients with CH, and the effects were maintained at 3 months.

Côté et al. (2019) developed an evidence-based guideline for the non-pharmacological management of persistent headaches associated with neck pain (i.e., tension-type or cervicogenic). Authors concluded that when managing patients with headaches associated with neck pain, clinicians should (a) rule out major structural or other pathologies, or migraine as the cause of headaches; (b) classify headaches associated with neck pain as tension-type headache or cervicogenic headache once other sources of headache pathology has been ruled out; (c) provide care in partnership with the patient and involve the patient in care planning and decision making; (d) provide care in addition to structured patient education; (e) consider low-load endurance craniocervical and cervicospinal exercises for tension-type headaches (episodic or chronic) or cervicogenic headaches >3 months duration; (f) consider general exercise, multimodal care (spinal mobilization, craniocervical exercise and postural correction) or clinical massage for chronic tension-type headaches; (g) do not offer manipulation of the cervical spine as the sole form of treatment for episodic or chronic tension-type headaches; (h) consider manual therapy (manipulation with or without mobilization) to the cervical and thoracic spine for cervicogenic headaches >3 months duration. However, there is no added benefit in combining spinal manipulation, spinal mobilization, and exercises; and (i) reassess the patient at every visit to assess outcomes and determine whether a referral is indicated. Neck pain and headaches are very common comorbidities in the population. Authors Tension-type and cervicogenic headaches can be treated effectively with specific exercises. Manual therapy can be considered as an adjunct therapy to exercise to treat patients with cervicogenic headaches. The management of tension-type and cervicogenic headaches should be patient-centered.

Fernandez et al. (2020) evaluated the effectiveness of SMT for cervicogenic headache (CGHA). Seven trials were eligible. At short-term follow-up, there was a significant, small effect favoring SMT for pain intensity and small effects for pain frequency. There was no

effect for pain duration. There was a significant, small effect favoring SMT for disability. At intermediate follow-up, there was no significant effects for pain intensity and a significant, small effect favoring SMT for pain frequency. At long-term follow-up, there was no significant effects for pain intensity and for pain frequency. Authors concluded that for CGHA, SMT provides small, superior short-term benefits for pain intensity, frequency, and disability, but not pain duration, however, high-quality evidence in this field is lacking. The long-term impact is not significant. Hawk et al. (2020) developed an evidence-based clinical practice guideline through a broad-based consensus process on best practices for chiropractic management of patients with chronic musculoskeletal (MSK) pain. Delphi process was conducted January-February 2020. The 62-member Delphi panel reached consensus on chiropractic management of five common chronic MSK pain conditions: low-back pain, neck pain, tension headache, osteoarthritis (knee and hip), and fibromyalgia. Recommendations were made for nonpharmacological treatments, including acupuncture, spinal manipulation/mobilization, and other manual therapy; modalities such as low-level laser and interferential current; exercise, including yoga; mind-body interventions, including mindfulness meditation and cognitive behavior therapy; and lifestyle modifications such as diet and tobacco cessation. Authors concluded that clinicians should consider multiple approaches for chronic tension headache. Both active and passive, and both physical and mind-body interventions should be considered in the management plan. Spinal manipulation/mobilization was included in this recommendation for chronic tension headache.

Núñez-Cabaleiro et al. (2022) aimed to identify the manual therapy (MT) methods and techniques that have been evaluated for the treatment of cervicogenic headache (CH) and their effectiveness. Of a total of 14 articles selected, 11 were randomized control trials and three were quasi-experimental studies. 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. 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.

McDevitt et al. (2022) sought to determine if thoracic spine manipulation (TSM) improves pain and disability in individuals with cervicogenic headache (CeH). A randomized controlled crossover trial was conducted on 48 participants (mean age: 34.4 years) with CeH symptoms. Participants were randomized to 6 sessions of TSM or no treatment (Hold) and after 4-weeks, groups crossed over. Outcomes were collected at 4, 8 and 12 weeks and included: headache disability inventory (HDI), neck disability index (NDI), and the global

rating of change (GRC). Scores at 4 weeks represent the only timepoint where 1 group is fully treated and other group has not received any treatment. Comparing hold to active treatment, HDI were not significantly different between groups at any timepoint; the NDI was significant at 4 weeks. Odds of achieving the +4 MCID on the GRC favored TSM at 4 weeks. Authors concluded that TSM had no effect on headache-related disability but resulted in significant improvements in neck-related disability and participant reported perceived improvement.

Nambi et al. (2024) sought to find and compare the clinical effects of cervical spine over thoracic spine manipulation and conventional physiotherapy in patients with Cervicogenic Headache (CgH) given no technique can be singled as the best available treatment for patients with CgH. This prospective, randomized controlled study was conducted between July 2020 and January 2023 at the University hospital. Ninety-six eligible patients with CgH were selected based on selection criteria and they were divided into cervical spine manipulation (CSM; n = 32), thoracic spine manipulation (TSM; n = 32) and conventional physiotherapy (CPT; n = 32) groups, and received the respective treatment for four weeks. Primary (CgH frequency) and secondary CgH pain intensity, CgH disability, neck pain frequency, neck pain intensity, neck pain threshold, cervical flexion rotation test (CFRT), neck disability index (NDI) and quality of life (QoL) scores were measured. The reports of the CSM, TSM and CPT groups were compared between the groups. Four weeks following treatment CSM group showed more significant changes in primary (CgH frequency) and secondary (CgH pain intensity, CgH disability, neck pain frequency, pain intensity, pain threshold, CFRT, NDI and QoL) than the TSM and CPT groups. The same gradual improvement was seen in the CSM group when compared to TSM and CPT groups in the above variables at 8 weeks and 6 months follow-up. The reports of this randomized clinical study found that CSM resulted in significantly better improvements in pain parameters (intensity, frequency and threshold) functional disability and quality of life in patients with CgH than thoracic spine manipulation and conventional physiotherapy.

SAFETY

A RCT by Maiers et al. (2015) collected data on adverse events that occurred as a result of cervical SMT and exercise interventions in a senior population. Of those who received SMT with home exercise, 74 out of 78 reported non-serious adverse events that were mostly musculoskeletal in nature such as muscle soreness, stiffness, headache, and joint pain. Aggravated neck pain was the most reported symptom. It was noted that no subjects withdrew from study participation due to these events. Also, in this group, three serious adverse events were reported but deemed as likely unrelated due to the nature and absence of a temporal association. These included bradycardia and arrhythmia (n=2) and myocardial infarction (n=1).

Overall, no causal relationship between SMT and cervical artery dissection or stroke has been established. Cervical artery dissection is a rare event in itself and has been associated

with SMT, other treatments disparate from any manual therapy, and general movements of the neck. Prior to delivering an intervention such as SMT, clinicians are advised to attempt to identify a potential arterial or ischemic event in progress. The primary appropriate screening method seems to be taking an effective history to recognize conjunctive features.

Cervical mobilization and manipulation have been suspected of creating a cervical artery dissection (CAD) as an adverse event. However, these assumptions are based on case studies which are unable to establish direct causality. Chaibi and Bjørn Russel (2019) conducted a literature review to provide clinicians with an updated step-by-step risk–benefit assessment strategy tool to (a) facilitate clinicians understanding of CAD, (b) appraise the risk and applicability of cervical manual-therapy, and (c) provide clinicians with adequate tools to better detect and exclude CAD in clinical settings. Cervical artery dissection refers to a tear in the internal carotid or the vertebral artery that results in an intramural haematoma and/or aneurysmal dilatation. Although cervical artery dissection is thought to occur spontaneously and is rare, physical trauma to the neck, especially hyperextension and rotation, has been reported as a trigger. Headache and/or neck pain is the most common initial symptom of cervical artery dissection. Other symptoms include Horner’s syndrome and lower cranial nerve palsy. Both headache and/or neck pain are common symptoms and leading causes of disability. Because manual-therapy interventions can alleviate headache and/or neck pain, many patients seek manual therapists, such as chiropractors and physiotherapists to help them manage symptoms. There is debate as to whether CAD symptoms lead the patient to seek cervical manual-therapy or whether the cervical manual therapy provoked CAD along with the non-CAD presenting complaints. Thus, practitioners need to be diligent with subjective and objective evaluations of patients to understand the risk for CAD and whether to address its potential existence.

Chu et al. (2022) examined the incidence and severity of adverse events (AEs) of patients receiving chiropractic spinal manipulative therapy (SMT), with the hypothesis that < 1 per 100,000 SMT sessions results in a grade ≥ 3 (severe) AE. A secondary objective was to examine independent predictors of grade ≥ 3 AEs. They identified patients with SMT-related AEs from January 2017 through August 2022 across 30 chiropractic clinics in Hong Kong. AE data were extracted from a complaint log, including solicited patient surveys, complaints, and clinician reports, and corroborated by medical records. AEs were independently graded 1-5 based on severity (1-mild, 2-moderate, 3-severe, 4-life-threatening, 5-death). Among 960,140 SMT sessions for 54,846 patients, 39 AEs were identified, two were grade 3, both of which were rib fractures occurring in women age > 60 with osteoporosis, while none were grade ≥ 4 , yielding an incidence of grade ≥ 3 AEs of 0.21 per 100,000 SMT sessions (95% CI 0.00, 0.56 per 100,000). There were no AEs related to stroke or cauda equina syndrome. The sample size was insufficient to identify predictors of grade ≥ 3 AEs using multiple logistic regression. In this study, severe SMT-related AEs were reassuringly very rare.

Whedon et al. (2022) evaluated the association between cervical spinal manipulation and cervical artery dissection among older Medicare beneficiaries in the United States. The primary exposure was cervical spinal manipulation; the secondary exposure was a clinical encounter for evaluation and management for neck pain or headache. They created a 3-level categorical variable, (1) any cervical spinal manipulation, (2) evaluation and management but no cervical spinal manipulation and (3) neither cervical spinal manipulation nor evaluation and management. The primary outcomes were occurrence of cervical artery dissection, either (1) vertebral artery dissection or (2) carotid artery dissection. The cases had a new primary diagnosis on at least one inpatient hospital claim or primary/secondary diagnosis for outpatient claims on at least two separate days. Cases were compared to 3 different control groups: (1) matched population controls having at least one claim in the same year as the case; (2) ischemic stroke controls without cervical artery dissection; and (3) case-crossover analysis comparing cases to themselves in the time period 6-7 months prior to their cervical artery dissection. Comparison across three different time frames occurred: up to (1) 7 days; (2) 14 days; and (3) 30 days prior to index event. The odds of cervical spinal manipulation versus evaluation and management did not significantly differ between vertebral artery dissection cases and any of the control groups at any of the timepoints (odds ratio 0.84 to 1.88; $p > 0.05$). Results for carotid artery dissection cases were similar. Authors concluded that among Medicare beneficiaries aged 65 and older who received cervical spinal manipulation, the risk of cervical artery dissection is no greater than that among control groups.

Gorrell et al. (2023) sought to describe if there has been a change in the reporting of adverse events associated with spinal manipulation in randomized clinical trials (RCTs) since 2016 in a systematic review. There were 5,399 records identified by the electronic searches, of which 154 (2.9%) were included in the analysis. Of these, 94 (61.0%) reported on adverse events with only 23.4% providing an explicit description of what constituted an adverse event. Reporting of adverse events in the abstract has increased ($n=29$, 30.9%) while reporting in the results section has decreased ($n=83$, 88.3%) over the past 6 years. Spinal manipulation was delivered to 7,518 participants in the included studies. No serious adverse events were reported in any of these studies. Authors concluded that while the current level of reporting of adverse events associated with spinal manipulation in RCTs has increased since the 2016 publication on the same topic, the level remains low and inconsistent with established standards.

Pankrath et al. (2024) extracted available information from RCTs to synthesize the comparative risk of AEs following cervical manipulation to that of various control interventions in a systematic review and meta-analysis due to the unclear risk level of AEs associated with high-velocity, low-amplitude (HVLA) cervical manipulation. Studies finding an association between cervical manipulation and serious AEs such as artery dissections are mainly case control studies or case reports. These study designs are not appropriate for investigating incidences and therefore do not imply causal relationships.

Randomized controlled trials (RCTs) are considered the gold standard study designs for assessing the unconfounded effects of benefits and harms, such as AEs, associated with therapies. Fourteen articles were included in the systematic review and meta-analysis. The pooled IRR indicates no statistically significant differences between the manipulation and control groups. All the reported AEs were classified as mild, and none of the AEs reported were serious or moderate. In summary, HVLA manipulation does not impose an increased risk of mild or moderate AEs compared to various control interventions. However, these results must be interpreted with caution, since RCTs are not appropriate for detecting the rare serious AEs. In addition, future RCTs should follow a standardized protocol for reporting AEs in clinical trials.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practices guideline for information.

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