

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

4 **Date of Implementation:** **April 20, 2017**

6 **Product:** **Specialty**

8	Related Policies:
9	CPG 87: Non-Motorized Flexion Distraction Technique
10	CPG 119 Spinal Manipulative Therapy for Non-Musculoskeletal and Related Disorders
11	CPG 120: Spinal Manipulative Therapy for Treatment of Children
12	CPG 121: Passive Physiotherapy Modalities
13	CPG 132: Spinal Manipulative Therapy for Treatment of Children with Non-Musculoskeletal and Related Disorders
14	CPG 135: Physical Therapy Medical Policy/Guideline
15	CPG 155: Occupational Therapy Medical Policy/Guideline
16	CPG 175: Extra-Spinal Manipulation/Mobilization for the Treatment of Upper Extremity Musculoskeletal Conditions
17	CPG 177: Extra-Spinal Manipulation / Mobilization for the Treatment of Lower Extremity Musculoskeletal Conditions
18	CPG 278: Chiropractic Services Medical Policy/Guideline

21 **GUIDELINES**

22 American Specialty Health, Inc. (ASH) considers Spinal Manipulation (or Grade V
23 Mobilization) to be medically necessary when both of the following criteria are met:

- 24 • There is adequate documentation that the member has a symptomatic (acute,
25 subacute or chronic; with or without radicular components) Musculoskeletal or
26 Related Disorder attributable to a mechanical, structural, or functional disorder of
27 the sacroiliac, lumbosacral; lumbar, thoracic and/or cervical spine or headache
28 disorders including tension-type headache and migraine headache; and
- 29 • There is an absence of contraindications to manipulation/mobilization or diagnostic
30 red flags suggesting a possible organic disorder (e.g., tumor, infection, fracture,
31 etc.).

33 For the purposes of this policy, Musculoskeletal and Related Disorders are defined as
34 conditions with signs and symptoms related to the nervous, muscular, and/or skeletal
35 systems. Musculoskeletal or Related Disorders are conditions typically categorized as:
36 structural, degenerative, or inflammatory disorders; or biomechanical dysfunction of the
37 joints of the body and/or related components of the muscle or skeletal systems (muscles,
38 tendons, fascia, nerves, ligaments/capsules, discs and synovial structures) and related
39 manifestations or conditions.

1 Such spinal disorders may be acute, sub-acute, or chronic and may or may not include
2 radicular components.

3
4 Signs and symptoms of a musculoskeletal or related disorder may include:

- 5 • Pain/tenderness;
- 6 • Stiffness and/or limited motion;
- 7 • Tone or texture changes in the adjacent muscles and soft tissues including muscle
8 tightness or weakness;
- 9 • Asymmetry or malalignment between adjacent spinal segments;
- 10 • Headache disorders (including tension-type headache and migraine headache); and
- 11 • Numbness/tingling or other paresthesia, weakness, loss of deep tendon reflexes, or
12 other signs of nerve or nerve root compression or irritation.

13
14 Note: The populations of members eligible for spinal manipulation includes all ages, co-
15 morbid conditions and other demographic variables as long as the documentation
16 establishes a valid diagnosis and symptomatic status and satisfies the above criteria.

17
18 II. Spinal manipulation is considered **not** medically necessary when:

- 19 • The above criteria are not met; or
- 20 • The patient has become asymptomatic; or
- 21 • There is no progress toward the resolution of symptoms within a reasonable and
22 predictable period of time; or
- 23 • Maximum therapeutic benefit has been achieved; or
- 24 • The primary aim is to prevent future episodes.

25
26 III. Spinal manipulation is considered not medical necessary for the treatment of
27 conditions not directly related to the spine including, but not limited to:

- 28
29 • Asthma
- 30 • Infantile colic
- 31 • Irritable bowel syndrome
- 32 • Dysmenorrhea

33
34 See the *Spinal Manipulative Therapy for Non-Musculoskeletal Conditions and Related*
35 *Disorders (CPG 119 – S)* clinical practice guideline for more specific information.

36
37 ASH considers use of manual devices (i.e., those that are hand-held with the thrust of the
38 force of the device being controlled manually) by chiropractors in performing manual
39 manipulation of the spine or the extremities as a reasonable alternative to high velocity,
40 low amplitude manipulation when the medical necessity criteria above is met. Use of these

1 devices may also be considered a possible alternative when high velocity low amplitude
 2 manipulation (HVLA) may be contraindicated.

3
 4 ASH does not support the use of any examination and/or diagnostic method associated with
 5 manual devices. Moreover, ASH does not support claims of benefit(s) associated with
 6 instrument assisted methods of assessment. CPT coding does not change with the use of
 7 these devices.
 8

9 **CPT CODES AND DESCRIPTIONS**

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

10
 11 **EVIDENCE AND RESEARCH**

12 **Low Back Pain**

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

20
 21 Rubinstein et al. performed a systematic review of the effectiveness of spinal manipulative
 22 therapy (SMT) for chronic low back pain first in 2009 and followed with an update in 2013.
 23 The authors defined chronic low back pain as pain lasting longer than 12 weeks and SMT
 24 as any ‘hands on’ treatment, including both spinal manipulation and mobilization. A total
 25 of 26 randomized controlled trials were included in this review, 9 of which were considered
 26 as having a low risk of bias. Studies were included if they were designed to examine the
 27 unique contribution of SMT alone. Comparison therapies were grouped as inert
 28 interventions, sham SMT, all other interventions, and SMT in addition to any intervention
 29 versus that intervention alone. Primary outcomes included pain from a self-reported scale

1 (VAS or NRS), functional status reported on a back pain specific scale (Roland-Morris
2 Disability Questionnaire or Oswestry Disability Index), and global improvement (number
3 of patients reported to be recovered or nearly recovered). The primary technique used was
4 a high-velocity low-amplitude SMT thrust, followed by Maitland mobilization, flexion-
5 distraction mobilization, unspecified mobilization, and unspecified technique. About 1/3
6 of the studies reported on adverse events, which were limited to muscle soreness, stiffness,
7 and/or other transient increase in pain. Professions included in these studies were bone-
8 setters, chiropractors, and manual/physical therapists. Combinations of these professions
9 were also included. Generally speaking, there is high quality evidence that SMT has a
10 statistically significant effect on short-term pain and functional status, but the effect size is
11 small and clinically insignificant. Therefore, SMT is neither superior nor inferior to other
12 low back pain treatments. The authors discuss several possibilities for their results,
13 including how well investigators were able to successfully blind their participants from
14 knowing if they had the sham treatment. Another discussion item was that the patients all
15 had non-specific low back pain, which may be too broad of a category to consider for
16 treatment comparisons. The authors suggest future studies of SMT examine cost-
17 effectiveness. If SMT is as effective as other treatments and has demonstrated its safety as
18 a treatment it makes sense to utilize SMT more often if shown to be a cost-effective form
19 of treatment.

20
21 In an attempt to look at the effectiveness of spinal manipulation in a more pragmatic setting,
22 in 2011 Walker et al. examined 12 randomized controlled studies that combined
23 chiropractic, or spinal manipulation (SM), with additional therapies. Objectives evaluated
24 included pain, disability, back-related function, overall improvement, and patient
25 satisfaction. Studies that were included had a defined region of low back pain and specified
26 duration as acute (less than 6 weeks), subacute (6 to 12 weeks), or chronic (12 weeks or
27 more). Interventions included combinations of therapies such as SM and massage,
28 thermotherapies, electrotherapies, mechanical devices, exercise programs, nutritional
29 advice, orthotics, lifestyle modification, and patient education. The authors evaluated the
30 evidence of the studies with the GRADE approach and assessed the risk of bias based on
31 those results. Only 3 of the 12 studies were classified as having a low risk of bias. Using
32 the VAS, Oswestry Disability Index and the Roland Morris Disability Questionnaire as
33 outcome measures, none of the studies provided a clinically significant difference for
34 combined chiropractic interventions. Individuals with acute and subacute low back pain
35 did experience pain relief after combined chiropractic, rather than spinal manipulation
36 alone. Although this was statistically significant, the effect sizes were small and not
37 considered clinically significant. The authors' suggestions for future research include
38 careful planning and reporting of studies to reduce bias as well as examination of frequency
39 or dosing effect of treatment visits. In 2012, Goertz et al. performed a systematic review
40 that included 38 articles examining the effectiveness of high-velocity, low-amplitude
41 (HVLA) spinal manipulation for the treatment of low back pain. The authors reviewed
42 randomized controlled trials that focused on patient-centered outcomes of pain and

1 functional health status. The most commonly used pain ratings were the Visual Analogue
2 Scale (VAS) and the Numerical Rating Scale (NRS), while the most commonly used
3 functional health status tools were the Roland Morris Disability Questionnaire (RM) and
4 the Oswestry Low Back Pain Disability Index (OSW). While the authors agreed with
5 previous studies that there is moderate evidence that spinal manipulation is an effective
6 treatment option for both acute and chronic low back pain, they also share concerns that
7 there is high variation in the quality of studies as well as high variation in reported
8 outcomes. The authors concluded that the variation is most likely due to a combination of
9 heterogeneity of low back pain patients, variations in the spinal manipulation itself, and
10 inadequate reporting of trial methodology. Finally, to aid in the ability to adequately
11 compare spinal manipulation trials, the authors recommend adoption of standards for
12 classification of low back pain, reporting of patient outcome data, and content of
13 randomized controlled trials.

14
15 A meta-analysis of efficacy, cost-effectiveness, and safety of complementary and
16 alternative medicine (CAM) therapies such as acupuncture, manipulation, mobilization,
17 and massage for neck and low back pain in adults was conducted in 2012 by Furlan et al.
18 Studies were included if they reported efficacy and/or economic data of CAM therapies in
19 comparison with no treatment, placebo, or other active treatments in adults with low back,
20 neck, or thoracic pain. Pain intensity and disability were the primary patient outcomes of
21 interest for efficacy and for cost-effectiveness analysis, data was extracted related to costs
22 to the health care sector, production loss, costs in other sectors, patient and family costs,
23 and total costs. In total, 147 studies were included in this meta-analysis; of the studies that
24 examined low back pain 13 analyzed manipulation, 13 analyzed mobilization, 5 analyzed
25 manipulation and mobilization, and 7 analyzed economic impact. In participants with
26 acute/subacute and mixed duration nonspecific low back pain, manipulation was
27 significantly more effective than placebo or no treatment in reducing pain intensity
28 immediately after treatment. In participants with chronic nonspecific low back pain,
29 manipulation was significantly more effective than placebo in reducing pain intensity
30 (VAS score) immediately after treatment. Manipulation was significantly better or no
31 different than pain medication in improving pain intensity but did not differ from pain
32 medication in reducing pain intensity at follow up after treatment. Participants with
33 acute/subacute and chronic nonspecific low back pain who received mobilization
34 experienced significantly improved pain intensity (VAS score) compared to subjects not
35 receiving any treatment. Results regarding participant-reported disability (RMDQ,
36 Oswestry) were inconsistent, showing either a significant difference favoring mobilization
37 or showing no difference between mobilization and no treatment. Participants with
38 acute/subacute nonspecific low back pain receiving manipulation plus mobilization were
39 not significantly better than those who received a double placebo (sham manipulation and
40 placebo analgesic). Manipulation plus mobilization was significantly better in reducing
41 pain than physiotherapy (e.g., exercise, massage, heat, electrotherapy, ultrasound) in
42 participants with mixed duration low back pain. However, there was no difference between

1 manipulation plus mobilization and usual care (analgesics, muscle relaxants, instruction in
2 proper back care, life-style recommendations, and exercise) in participants with mixed
3 duration of nonspecific low back pain. Unfortunately, due to the small number of studies
4 reporting on economic impact, inconsistencies in methods reported and differences in
5 health care calculations by country, the authors were unable to draw conclusions regarding
6 cost effectiveness. The authors also noted the evidence is inconclusive for treatment of low
7 back pain as the majority of the studies cited were of low quality and recommend a
8 concerted effort to improve study quality in future reporting of CAM studies for
9 musculoskeletal conditions.

10
11 Osteopathic approaches to the effectiveness of manipulation for low back pain were
12 investigated by Orrock and Myers in 2013. Articles were searched for spinal manipulative
13 therapy as well as osteopathic manipulative therapy but were only included in the review
14 if they included a form of osteopathy. The authors chose to focus their review on
15 osteopathic manual interventions performed by osteopathic clinicians in chronic, non-
16 specific lower back pain in adults. Articles were also evaluated for risk of bias based on
17 the Systematic Review Guidelines of the Cochrane Back Review Group. The authors
18 searched many data bases but only found 2 articles that met the inclusion criteria and had
19 a low risk of bias. One of the studies concluded the osteopathic intervention was similar in
20 effect to a sham intervention while the other study suggested osteopathic intervention was
21 similar to that of exercise and physiotherapy. The authors note that although both studies
22 had a low risk of bias neither the participants nor the clinicians in the studies were blinded.
23 The authors felt this could have an effect on the study outcomes. Therefore, the authors
24 conclude that more research is needed, ideally with appropriate controls and use of
25 interventions that reflect actual practice, before determining if osteopathic manipulation is
26 effective in treatment of chronic low back pain in adults.

27
28 In 2014 Merepeza examined the effectiveness of spinal manipulation versus prescribed
29 exercises for chronic low back pain. Studies included in the review were those with
30 participants with low back pain of over 12 weeks duration, spinal manipulation performed
31 by a health care provider, exercises prescribed by a health care provider, and a measurable
32 outcome for reducing pain, disability, or improving function. Studies were excluded if
33 participants were diagnosed with spinal stenosis, spondylolisthesis (2nd degree or more),
34 lumbar scoliosis (>20° or more), previous vertebral fractures, systemic causes of CLBP
35 (rheumatoid arthritis), or psychiatric or cognitive co-morbidities. Three studies were found
36 that met the author's inclusion criteria and were evaluated for risk of bias with the PEDro
37 scale. While all 3 studies had a fairly low risk of bias, none of the studies blinded the
38 subjects and the administrators of the treatment therapy. Another bias present in all three
39 (3) studies is that the outcomes were self-reported in a subjective manner. One study
40 showed spinal manipulation was more effective than individual physiotherapy for pain
41 reduction and improved function. A different study found that spinal manipulation therapy
42 and motor control exercise were better at reducing pain and disability than general exercise

1 in the short term but not in the long term. Finally, another study found that spinal
2 stabilization exercises were more effective than manual therapy in reducing pain intensity
3 and disability and dysfunction. Merepeza (2014) concludes that first, chronic low back pain
4 may itself pose a challenge to study because of the heterogeneity of the condition. Second,
5 Merepeza (2014) acknowledges that there are many components to exercise and manual
6 therapy as treatments and more evidence is needed to determine what is considered an
7 effective treatment.

8
9 Hidalgo et al. performed a systematic review in 2014 focused specifically on different
10 manual therapies for different stages of low back pain. Randomized controlled trials were
11 included only if they had a low risk of bias, appropriate randomization methods,
12 appropriate blinding, and low back pain was treated with manual therapy. The authors used
13 a combination of duration and location of symptoms to specify the population included;
14 participants were classified as having duration of acute-subacute (0-12 weeks) or chronic
15 (>12 weeks). Participants were also categorized as having low back pain defined by the
16 Quebec-Task-Force (QTF) regarding presence and location of leg pain, with or without
17 neurological deficit. Participants with nerve root pain with neurologic deficit were not
18 included. Manual therapy techniques were categorized into 3 types; high-velocity, low-
19 amplitude thrust with cavitation, mobilization and soft tissue techniques, or a combination.
20 Control groups received no treatment, placebo, usual medical care, or exercise. The authors
21 found 11 studies that met their inclusion criteria that had not previously been reported; 5
22 were considered to be of high level of evidence and 6 were considered to be of moderate
23 quality of evidence. In contrast with what other systematic reviews have reported, the
24 authors concluded that there is moderate to strong evidence for the benefits of high-
25 velocity, low-amplitude manual therapy in comparison to sham manual therapy for pain
26 relief, functional improvement, and overall health for short term follow up for all durations
27 of low back pain. The authors also concluded that there was moderate evidence to support
28 high-velocity, low-amplitude manual therapy and combination manual therapy with usual
29 medical care in comparison to usual medical care alone for pain, function, and overall
30 quality of life. Additionally, for chronic low back pain, the authors found moderate
31 evidence in support of combination manual therapy with exercises or usual medical care
32 compared to usual medical care alone for pain and function. The authors recommend future
33 research focus on pragmatic, high quality randomized controlled trials, specific types of
34 manual therapy classification, and classification of participants.

35
36 A 2014 systematic review of complementary and alternative medicine (CAM) for low back
37 pain was performed by Kizhakkeveetil et al. The authors were specifically interested in
38 examining the effects of an integrative approach to treating low back pain instead of
39 isolating a single therapy. Studies were included in the review if they had at least 1 outcome
40 measure for pain or disability as well as at least 1 treatment group receiving integrated
41 therapy that included at least 1 CAM therapy. The authors found 21 articles that met their
42 search criteria (13 of which included spinal manipulative therapy) and used the Cochrane

1 Back Review Group scale to determine risk of bias. Integrated CAM therapy with active
2 care appeared to be effective for treatment, while adding passive care to CAM therapy was
3 generally ineffective. The authors found this surprising as it is common to have the
4 combination of CAM therapy with passive care (such as heat or ice) as a standard treatment
5 for low back pain. Even though the authors support integrated therapies, they acknowledge
6 that it may be difficult in a real-world setting to coordinate care between practitioners. The
7 authors also acknowledge that some interventions for low back pain appear to be
8 ineffective in the short term but may actually help prevent chronicity and disability. Finally,
9 the authors state the need for more high-quality research that examines integration of spinal
10 manipulative therapy with exercise, acupuncture, and conventional care rather than single
11 therapies of any type along with reporting appropriate cost effectiveness data.

12
13 In 2014 Tsertsvadze et al. evaluated the cost effectiveness of manual therapies relative to
14 other alternative therapies for management of musculoskeletal conditions. Studies
15 considered for review were classified by which area of the body was being treated (spinal,
16 upper extremity and lower extremity). Twenty-five publications from 11 different trials
17 were included for review that reported specific economic factors for analysis. The risk of
18 bias was rated as low for 7 of the 11 trials and high for 4 of the 11 trials. Of the trials
19 included, 4 reported information regarding low back pain. The first trial found individual
20 physiotherapy more effective and ‘marginally more costly’ than spinal stabilization
21 therapy. The second trial found a combination of manual therapy, stabilization exercise
22 and physician consultation more effective than physician consultation alone at 24-month
23 follow up. The third study evaluated manipulation alone, exercise alone, and manipulation
24 and exercise to general practitioner care. The addition of manipulation had better
25 participant outcomes and lower overall cost. The last study compared manual
26 physiotherapy with a brief pain management program for participants with acute low back
27 pain. Although the manual physiotherapy group had more improvement in disability and
28 was more cost effective, the results were not statistically significant between the groups.

29
30 In 2014 Menke performed a comparative effectiveness meta-analysis of manual therapies,
31 including spinal manipulative therapy (SMT), for the treatment of low back pain. Menke
32 searched the literature and found 56 studies from 1974-2010 for a total of 257 study arms.
33 The study arms were then classified into treatment types such as SMT, exercise,
34 physiotherapy modalities, usual medical care, and control groups. The treatment types were
35 then divided into acute and chronic low back pain for short- and long-term effects.
36 Treatments for acute pain levels were no better than the course of natural history while
37 treatment for chronic pain showed a weak response to SMT. Additionally, study quality
38 measurements were taken to measure levels of evidential support. Menke found that overall
39 SMT study quality improved 1.2% each year from 1974. Menke proposes that the reason
40 SMT has had success was not because of the treatment, but because of the psychosocial
41 support received during treatment and encouraged future research to examine this
42 component of SMT.

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

36
37 In 2016 Chou, et al. published (under the auspices of the Agency for Healthcare Research
38 and Quality (AHRQ) and currently archived) a systematic review—*Noninvasive Treatment*
39 *for Low Back Pain*. This review included both pharmacological and non-pharmacological
40 treatments. The latter included spinal manipulation, acupuncture, exercise, low-level laser,
41 heat, yoga, relaxation techniques, cognitive behavioral therapy (CBT), and electrical

1 stimulation of various types, ultrasound, lumbar supports and traction. Findings for SMT
2 included:

- 3 • For acute low back pain, two trials (one included in a systematic review) found
4 spinal manipulation associated with better effects on function versus sham
5 manipulation (statistically significant in one trial); in one trial effects on pain
6 favored manipulation but were small and not statistically significant (strength of
7 evidence (SOE): low for function, insufficient for pain).
- 8 • For chronic low back pain, a systematic review found spinal manipulation
9 associated with small, statistically nonsignificant effects versus sham manipulation
10 on pain at 1 month; one trial reported similar results for function; one trial not
11 included in the systematic review reported generally consistent results (SOE: low
12 for pain, insufficient for function).
- 13 • For acute low back pain, a systematic review found no differences between spinal
14 manipulation versus and inert treatment in pain relief at 1 week, though one trial
15 found SMT associated with better longer-term pain relief; there were no differences
16 in function at 1 week or at 3 months (SOE: low for pain and function).
- 17 • For chronic low back pain, one high-quality trial found spinal manipulation
18 associated with greater improvement in the “main complaint” versus an inert
19 treatment; results from three low risk of bias trials and three additional trials not
20 included in the systematic review were somewhat inconsistent, though some trials
21 reported effects that favored manipulation (SOE: low).
- 22 • For acute low back pain, a systematic review found no difference between spinal
23 manipulation versus other active interventions in pain relief at 1 week, 1 month, 3
24 to 6 months, or 1 year. Findings were similar for function, with no differences
25 observed at any time point. A subsequent trial of patients with acute or subacute
26 low back pain found spinal manipulation associated with moderate effects versus
27 usual care on pain and small effects on function at short-term follow-up, but effects
28 were smaller and no longer statistically significant at 3 and 6 months (SOE:
29 moderate for pain and function).
- 30 • For chronic low back pain, a systematic review found spinal manipulation
31 associated with better short-term pain relief versus other active interventions at 1
32 month and 6 months, though the magnitude of effects was below the small/slight
33 threshold. There was no difference at 12 months. Manipulation was also associated
34 with greater function improvement in function versus other active interventions at
35 1 month; effects were smaller and no longer statistically significant at 6 and 12
36 months. Three trials not included in the systematic reviews reported results
37 consistent with these findings (SOE: moderate for pain and function).
- 38 • For acute low back pain, four trials in a systematic review found spinal
39 manipulation plus either exercise or advice associated with greater improvement in
40 function at 1 week versus exercise or advice alone, but there were no differences at
41 1 month or 3 months (SOE: low).

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

14
15 Chou et al. (2017) also published a systematic review on nonpharmacologic therapies for
16 low back pain for an American College of Physicians Clinical Practice Guideline. Results
17 were consistent with the conclusion stated previously from the AHRQ publication (Chou
18 et al., 2017). Similar findings were noted within the Veteran’s Administration/Department
19 of Defense guidelines for treatment of low back pain. They suggest offering spinal
20 mobilization/manipulation as part of a multimodal program for patients with acute or
21 chronic low back pain (VA/DoD, 2017). Clinical Guidelines Committee of the American
22 College of Physicians published a Clinical Practice Guideline from the American College
23 of Physicians on noninvasive treatments for acute, subacute, and chronic low back pain.
24 This guideline states that for patients with acute or chronic low back pain, SMT is
25 recommended as one of several nonpharmacologic initial treatment options (Qaseem et al.,
26 2017). Paige et al. (2017) systematically reviewed studies of the effectiveness and harms
27 of SMT for acute (≤ 6 weeks) low back pain. Of 26 eligible RCTs identified, 15 RCTs (1711
28 patients) provided moderate-quality evidence that SMT has a statistically significant
29 association with improvements in pain. Twelve RCTs (1381 patients) produced moderate-
30 quality evidence that SMT has a statistically significant association with improvements in
31 function. Heterogeneity was not explained by type of clinician performing SMT, type of
32 manipulation, study quality, or whether SMT was given alone or as part of a package of
33 therapies. No RCT reported any serious adverse event. Minor transient adverse events such
34 as increased pain, muscle stiffness, and headache were reported 50% to 67% of the time in
35 large case series of patients treated with SMT. Authors concluded that among patients with
36 acute low back pain, spinal manipulative therapy was associated with modest
37 improvements in pain and function at up to 6 weeks, with transient minor musculoskeletal
38 harms. However, heterogeneity in study results was large.

39
40 Skelly et al. (2018) reports in a review on chronic pain non-invasive non-pharmacological
41 treatments that at short and intermediate terms, spinal manipulation, was associated with
42 slight improvements in function compared with usual care or inactive controls. Skelly et

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

26
27 Evans et al. (2018) conducted a multicenter randomized trial comparing 12 weeks of spinal
28 manipulative therapy (SMT) combined with exercise therapy (ET) to ET alone.
29 Participants were 185 adolescents aged 12 to 18 years with chronic LBP. The primary
30 outcome was LBP severity at 12, 26, and 52 weeks. Secondary outcomes included
31 disability, quality of life, medication use, patient- and caregiver-rated improvement, and
32 satisfaction. Outcomes were analyzed using longitudinal linear mixed effect models. An
33 omnibus test assessing differences in individual outcomes over the entire year controlled
34 for multiplicity. Of the 185 enrolled patients, 179 (97%) provided data at 12 weeks and
35 174 (94%) at 26 and 52 weeks. Adding SMT to ET resulted in a larger reduction in LBP
36 severity over the course of 1 year ($P = 0.007$). The group difference in LBP severity (0-10
37 scale) was small at the end of treatment (mean difference = 0.5; $P = 0.08$) but was larger at
38 weeks 26 (mean difference = 1.1; $P = 0.001$) and 52 (mean difference = 0.8; $P = 0.009$). At
39 26 weeks, SMT with ET performed better than ET alone for disability ($P = 0.04$) and
40 improvement ($P = 0.02$). The SMT with ET group reported significantly greater satisfaction
41 with care at all time points ($P \leq 0.02$). There were no serious treatment-related adverse
42 events. For adolescents with chronic LBP, spinal manipulation combined with exercise was

1 more effective than exercise alone over a 1-year period, with the largest differences
2 occurring at 6 months. These findings warrant replication and evaluation of cost
3 effectiveness.

4
5 Rubenstein et al. (2019) assessed the benefits and harms of spinal manipulative therapy
6 (SMT) for the treatment of chronic low back pain. Forty-seven randomized controlled trials
7 including a total of 9211 participants were identified, who were on average middle aged
8 (35-60 years). Most trials compared SMT with recommended therapies. Moderate quality
9 evidence suggested that SMT has similar effects to other recommended therapies for short
10 term pain relief and a small, clinically better improvement in function. According to
11 authors, high quality evidence suggested that compared with non-recommended therapies
12 SMT results in small, not clinically better effects for short term pain relief and small to
13 moderate clinically better improvement in function. In general, these results were similar
14 for the intermediate and long-term outcomes as were the effects of SMT as an adjuvant
15 therapy. Most of the observed adverse events reported were musculoskeletal related,
16 transient in nature, and of mild to moderate severity. Authors concluded that SMT produces
17 similar effects to recommended therapies for chronic low back pain, whereas SMT seems
18 to be better than non-recommended interventions for improvement in function in the short
19 term. Clinicians should inform their patients of the potential risks of adverse events
20 associated with SMT.

21
22 Thomas et al. (2020) evaluated the comparative effectiveness of spinal manipulation and
23 spinal mobilization at reducing pain and disability compared with a placebo control group
24 (sham cold laser) in a cohort of young adults with chronic LBP. Participants received 6
25 treatment sessions of (1) spinal manipulation, (2) spinal mobilization, or (3) sham cold
26 laser therapy (placebo) during a 3-week period. Main outcomes and measures: Coprimary
27 outcome measures were the change from baseline in Numerical Pain Rating Scale (NPRS)
28 score over the last 7 days and the change in disability assessed with the Roland-Morris
29 Disability Questionnaire (scores range from 0 to 24, with higher scores indicating greater
30 disability) 48 to 72 hours after completion of the 6 treatments. A total of 162 participants
31 (mean [SD] age, 25.0 [6.2] years; 92 women [57%]) with chronic LBP (mean [SD] NPRS
32 score, 4.3 [2.6] on a 1-10 scale, with higher scores indicating greater pain) were
33 randomized. Fifty-four participants were randomized to the spinal manipulation group, 54
34 to the spinal mobilization group, and 54 to the placebo group. There were no significant
35 group differences for sex, age, body mass index, duration of LBP symptoms, depression,
36 fear avoidance, current pain, average pain over the last 7 days, and self-reported disability.
37 At the primary end point, there was no significant difference in change in pain scores
38 between spinal manipulation and spinal mobilization, spinal manipulation and placebo, or
39 spinal mobilization and placebo. There was no significant difference in change in self-
40 reported disability scores between spinal manipulation and spinal mobilization, spinal
41 manipulation and placebo or spinal mobilization and placebo. Authors concluded that in
42 this randomized clinical trial, neither spinal manipulation nor spinal mobilization appeared

1 to be effective treatments for mild to moderate chronic LBP. According to Flynn (2020) in
2 a review of treatments for chronic musculoskeletal pain, spinal manipulation leads to a
3 small benefit for chronic neck and low back pain.

4
5 Hawk et al. (2020) developed an evidence-based clinical practice guideline (CPG) through
6 a broad-based consensus process on best practices for chiropractic management of patients
7 with chronic musculoskeletal (MSK) pain. Delphi process was conducted January-
8 February 2020. The 62-member Delphi panel reached consensus on chiropractic
9 management of five common chronic MSK pain conditions: low-back pain (LBP), neck
10 pain, tension headache, osteoarthritis (knee and hip), and fibromyalgia. Recommendations
11 were made for nonpharmacological treatments, including acupuncture, spinal
12 manipulation/mobilization, and other manual therapy; modalities such as low-level laser
13 and interferential current; exercise, including yoga; mind-body interventions, including
14 mindfulness meditation and cognitive behavior therapy; and lifestyle modifications such
15 as diet and tobacco cessation. Authors concluded that clinicians should consider multiple
16 approaches. Both active and passive, and both physical and mind-body interventions
17 should be considered in the management plan. Spinal manipulation/mobilization was
18 included in this recommendation low back pain.

19
20 Chou et al. (2020) evaluated the effectiveness and comparative effectiveness of opioid,
21 nonopioid pharmacologic, and nonpharmacologic therapy in patients with specific types of
22 acute pain, including effects on pain, function, quality of life, adverse events, and long-
23 term use of opioids. One hundred eighty-three RCTs on the comparative effectiveness of
24 therapies for acute pain were included. Findings noted that spinal manipulation might be
25 effective for acute back pain with radiculopathy. Most studies had methodological
26 limitations. Effect sizes were primarily small to moderate for pain, the most commonly
27 evaluated outcome.

28
29 Thornton et al. (2021) summarized the evidence for non-pharmacological management of
30 low back pain (LBP) in athletes, a common problem in sport that can negatively impact
31 performance and contribute to early retirement. Among 1629 references, 14 randomized
32 controlled trials (RCTs) involving 541 athletes were included. Treatments included
33 exercise, biomechanical modifications, and manual therapy. Exercise was the most
34 frequently investigated treatment. There was a reduction in pain and disability reported
35 after all treatments. Authors concluded that while several treatments for LBP in athletes
36 improved pain and function, it was unclear what the most effective treatments were, and
37 for whom. Exercise approaches generally reduced pain and improved function in athletes
38 with LBP. No conclusions regarding the value of manual therapy (massage, spinal
39 manipulation) or biomechanical modifications alone could be drawn because of
40 insufficient evidence. High-quality RCTs are urgently needed to determine the effect of
41 commonly used interventions in treating LBP in athletes.

1 Compared to traditional aggregate analyses individual participant data (IPD) meta-analyses
2 allows for a more precise estimate of the treatment effect. Given this, de Zoete et al. (2021)
3 assessed the effect of SMT on pain and function for chronic LBP in a IPD meta-analysis.
4 Of the 42 RCTs fulfilling the inclusion criteria, they obtained IPD from 21 (n=4223). Most
5 trials (s=12, n=2249) compared SMT to recommended interventions. There is moderate
6 quality evidence that SMT vs recommended interventions resulted in similar outcomes on
7 pain and functional status at one month. Effects at other follow-up measurements were
8 similar. Results for other comparisons (SMT vs non-recommended interventions; SMT as
9 adjuvant therapy; mobilization vs manipulation) showed similar findings. Authors
10 concluded that sufficient evidence suggest that SMT provides similar outcomes to
11 recommended interventions, for pain relief and improvement of functional status. SMT
12 would appear to be a good option for the treatment of chronic LBP. Study design:
13 Individual participant data (IPD) meta-analysis. In another study, de Zoete et al. (2021)
14 aimed to identify which participant characteristics moderate the effect of spinal
15 manipulative therapy (SMT) on pain and functioning in chronic LBP. IPD were requested
16 from randomized controlled trials (RCTs) examining the effect of SMT in adults with
17 chronic LBP for pain and function compared to various other therapies (stratified by
18 comparison). Potential patient moderators (n = 23) were a priori based on their clinical
19 relevance. They received IPD from 21 of 46 RCTs (n = 4223). The majority (12 RCTs, n
20 = 2249) compared SMT to recommended interventions. The duration of LBP, baseline pain
21 (confirmatory), smoking, and previous exposure to SMT (exploratory) had a small
22 moderating effect across outcomes and follow-up points; these estimates did not represent
23 minimally relevant differences in effects. No other moderators demonstrated a consistent
24 pattern across time and outcomes. Few moderator analyses were conducted for the other
25 comparisons because of too few data. Authors state they did not identify any moderators
26 that enable clinicians to identify which patients are likely to benefit more from SMT
27 compared to other treatments.

28
29 Jenks et al. (2022) assessed the effects of SMT on pain and function in older adults with
30 chronic LBP in an individual participant data (IPD) meta-analysis. Randomized controlled
31 trials (RCTs) which examined the effects of SMT in adults with chronic LBP compared to
32 interventions recommended in international LBP guidelines were included. Pain and
33 functional status were examined at 4, 13, 26, and 52 weeks. 10 studies were retrieved,
34 including 786 individuals, of which 261 were between 65 and 91 years of age. There is
35 moderate-quality evidence that SMT results in similar outcomes at 4 weeks. Second-stage
36 and sensitivity analysis confirmed these findings. Authors concluded that SMT provides
37 similar outcomes to recommended interventions for pain and functional status in the older
38 adult with chronic LBP. SMT should be considered a treatment for this patient population.
39 Trager et al. (2022) examined the relationship between chiropractic spinal manipulative
40 therapy (CSMT) and lumbar discectomy are both used for lumbar disc herniation (LDH)
41 and lumbosacral radiculopathy (LSR). Adults age 18-49 with newly diagnosed LDH/LSR
42 (first date of diagnosis) were included. Exclusions were prior lumbar surgery, absolute

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

12
13 Trager et al. (2022) examined the relationship between chiropractic spinal manipulative
14 therapy (CSMT) and prescription benzodiazepines for radicular low back pain (rLBP).
15 Adults aged 18-49 with an index diagnosis of rLBP were included. Serious aetiologies of
16 low back pain, structural deformities, alternative neurological lesions and absolute
17 benzodiazepine contraindications were excluded. Patients were assigned to cohorts
18 according to CSMT receipt or absence. Propensity score matching was used to control for
19 covariates that could influence the likelihood of benzodiazepine utilization. After
20 matching, there were 9206 patients (mean (SD) age, 37.6 (8.3) years, 54% male) per cohort.
21 Odds of receiving a benzodiazepine prescription were significantly lower in the CSMT
22 cohort over all follow-up windows prematching and postmatching. Authors suggest that
23 receiving CSMT for newly diagnosed rLBP is associated with reduced odds of receiving a
24 benzodiazepine prescription during follow-up. These results provide real-world evidence
25 of practice guideline-concordance among patients entering this care pathway.

26 27 **Neck Pain**

28 A review conducted by Walser et al. (2009) assessing the effectiveness of thoracic spinal
29 manipulation (TSM) in managing musculoskeletal conditions. Thirteen studies were
30 included in the review with 9 investigating the use of TSM for the treatment of neck pain.
31 Four high-quality and 1 fair-quality studies reported significant improvement in pain in
32 participants who received TSM over a comparison group. Two studies with fair to poor
33 quality found significant within-group increases in cervical rotation. The authors
34 concluded there is satisfactory evidence to support TSM as a treatment for certain patients
35 with neck pain in the short-term. The efficacy of thoracic spinal manipulation (TSM) alone
36 or in combination with other conservative interventions for the management of patients
37 with non-specific neck pain was assessed by Huisman et al. (2013). Ten studies met the
38 criteria for inclusion, with a range in methodological quality from “average” to “good.”
39 The authors concluded that overall, there was insufficient evidence to support or refute
40 TSM as a more effective treatment than control treatments in reducing pain and disability.
41 However, the results of the review showed evidence that combining TSM with other
42 treatments such as exercise, spinal mobilization, electro-thermal therapy, infrared radiation

1 therapy, and education was more effective than any of those treatments delivered without
2 TSM.

3
4 D'Sylva et al. (2010) published a systematic review assessing the effectiveness of
5 combination therapy approaches on neck pain with multiple outcomes including pain,
6 function, disability, and patient satisfaction. The combination therapies were defined as
7 manipulation and mobilization; manipulation, mobilization and soft tissue work; and
8 manual therapy and physical medicine modalities. The authors selected 19 trials, 37%
9 (7/19) of which had a low risk of bias. Most of the methodological weaknesses found
10 pertained to allocation concealment and blinding procedures. However, the authors noted
11 that when performing manual treatments, blinding the patient is difficult and blinding the
12 provider is impossible. Regarding an ideal combined treatment approach, using
13 manipulation and mobilization alone provide short-term (but not long-term) pain relief.
14 Manipulation, mobilization and soft tissue work were also shown to relieve pain and
15 increase patient satisfaction in the short-term. Combining manual therapy and exercise
16 seems to produce longer-term improvements across multiple outcomes.

17
18 The literature on the efficacy of manual therapies alone or with exercises in patients with
19 nonspecific neck pain was reviewed by Vincent et al. The authors divided the studies into
20 3 groups based on symptom duration: acute (defined as <3 months), chronic (>3 months)
21 and neck pain of variable duration. The selection criteria rendered 27 RCTs of which 9
22 were determined to be low quality and 18 high quality. In general, the evidence suggests
23 that manual therapy contributes to improvements in pain and function, especially when
24 used in combination with other therapies. For patients with acute neck pain, manipulation
25 produced better short-term results than electro-thermal therapy and better long-term results
26 than anti-inflammatory or analgesic medications (with varied treatment protocols).
27 Multimodal management that included manual therapy was favored over passive
28 interventions such as a cervical collar or rest, and contradictory results were found when
29 cervical and thoracic manipulation was compared. For chronic neck pain, regardless of
30 follow-up duration, manual therapy combined with exercise provided better improvements
31 in pain and function than did manual therapy or exercise alone. In the short-term, results
32 were better with manipulation than with medications or acupuncture; however, in the long-
33 term, no differences were found between these groups. For patients with a varied duration
34 of neck pain, the combination of manipulation and mobilization or exercise and
35 mobilization was better than exercise alone, medications and passive interventions.
36 Cervical manipulation combined with laser therapy was more effective than either
37 treatment performed alone.

38
39 Miller et al. (2010) reviewed the evidence for trials investigating the effectiveness of
40 manual therapy, which included manipulation and mobilization, and exercise for neck pain
41 in adults with neck pain. Seventeen studies were included in the review and examined
42 acute, subacute, chronic, and mixed durations of pain. The range in risk of bias was low (5

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

18
19 Martel et al. (2011) hypothesized that participants with chronic neck pain who received
20 preventative SMT in combination with a home exercise program would experience
21 improvements in pain, disability and function compared to a group receiving only SMT or
22 no treatment. The authors performed a 2-phase RCT in which the first phase (symptomatic)
23 consisted of 10-15 treatments that were provided over a 5- to 6-week period. The results of
24 this phase revealed a clinically and statistically significant average decrease of 1.1 cm on
25 the VAS (Visual Analog Scale) for pain and 6.5 points on the BQ (Bournemouth
26 Questionnaire) for disability. Function (measured by ROM) significantly improved as well,
27 except for lateral flexion. Participants were randomized into a SMT, SMT with exercise or
28 an attention-controlled group (no treatment, but self-management such as applying ice was
29 allowed and discussed condition at each visit) during the second phase (preventative). This
30 phase entailed 10 months of treatment at approximately 1x/month for the active groups and
31 every 2 months for the inactive. Significant group differences were not found for outcomes
32 in this phase, however; a majority of the participants in each group retained a level of pain
33 below clinically acceptable (2-point difference from baseline symptomatic phase VAS).
34 Therefore, results indicated no additional benefit to participants receiving monthly
35 preventative SMT or SMT with home exercise compared with a consultation visit to a
36 chiropractor every other month and the hypothesis was rejected. This suggests by simply
37 managing a patient for neck pain may decrease recurrence of incidents, and that strategies
38 for treatment vs. those for prevention need further investigation and delineation.

39
40 In a randomized controlled trial by Casanova-Mendez et al., (2014) two different thoracic
41 spinal manipulative techniques were compared for immediate and short-term effects on
42 patients with chronic neck pain. Sixty-four participants were allocated, received a single

1 active treatment, and completed the study. The intervention for the Dog-technique group
2 (DTG) was described as directing the patient to assume a supine position with their arms
3 folded across their chest. The right hand of the therapist was positioned to contact the T4
4 vertebrae; the other hand was placed on the participant's elbows to add flexion, reduce
5 slack and deliver a HVLA thrust in the anteroposterior direction. The other intervention,
6 toggle-recoil (TR), was described as the therapist contacting the T4 transverse processes
7 with the pisiforms in crossed-hand set-up on a participant lying prone. A posterior-anterior
8 HVLA thrust was delivered. Outcomes measured were PPT, ROM and self-reported pain,
9 and all outcomes improved using both techniques. The TR group results were superior,
10 showing statistical significance in all outcomes, however; there were no clinical differences
11 between the groups except for slightly better effects from TR on left rotation, extension,
12 and right lateral flexion.

13
14 Low-force mobilization was examined against high-force mobilization and placebo in a
15 RCT conducted by Snodgrass et al. (2014) to add to the evidence regarding optimal dosing
16 for chronic neck pain treatment. The primary outcome was pain pressure threshold (PPT),
17 and resting pain, ROM and spinal stiffness measured as secondary outcomes immediately
18 following treatment and at a 4-day follow-up session. Sixty-four participants were
19 randomized into 1 of the 3 groups receiving a single session of treatment. In the low-force
20 group, the average mean force applied was 30.8 N and 88.6 N for the high-force group
21 during 3 sets of 1-minute PA mobilization applied to the most painful spinous process. The
22 placebo treatment consisted of detuned laser for 3 sets of 1 minute. No differences were
23 found between groups in PPT or ROM at immediate or follow-up measurements. The high-
24 force group fared better than placebo in spinal stiffness at follow-up but was not
25 significantly different from the low-force group. However, regarding pain, participants in
26 the high-force group reported significant pain reduction at follow-up over the low-force
27 group (not over placebo).

28
29 Young et al. (2014) performed a review examining the effects of thoracic spinal
30 manipulation (TSM) for the treatment of mechanical neck pain. The quality of evidence
31 overall was determined to be fair (measured with the PEDro scale), and the authors'
32 inclusion criteria rendered 14 studies. This review aimed to focus on literature comparing
33 the effectiveness of TSM versus mobilization, however; only 1 study was found that
34 directly compared these treatments. Additionally, only short-term outcomes were collected
35 in all trials. Results showed that TSM was superior to mobilization, placebo, modalities,
36 and no treatment. These results prompted the authors to conclude that the evidence is scarce
37 and of questionable methodological quality regarding the use of thoracic mobilization, but
38 a considerable amount of varied quality evidence exists supporting TSM as an intervention
39 for improvements in pain, disability and range of motion (ROM) in the short-term.

40
41 A systematic review was conducted by Tsertsvadze et al. (2014) of trial-based economic
42 evaluations of manual therapy compared to other alternative treatments. Two trials out of

1 the included 25 reported results of the effectiveness of manual therapy in treating neck
2 pain. One trial found that spinal mobilization, defined as low velocity passive movements
3 within or at the limit of joint ROM, had significantly lower costs and slightly better effects
4 compared to either physiotherapy or GP care at 1-year follow-up. Clinical outcomes
5 showed manual therapy provided a faster recovery rate than physiotherapy and GP care
6 after 7 weeks, with respective rates at 68%, 51% and 36%. Another trial evaluated manual
7 therapy, defined as manipulation and mobilization, against a behavioral graded activity
8 (BGA) program. The authors concluded that their cost-effective analyses showed that BGA
9 is not cost-effective in comparison with manual therapy in measures of recovery and
10 quality of life.

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

26
27 Lopez-Lopez et al. (2015) investigated the differences in effectiveness between
28 manipulation, mobilization and sustained natural apophyseal glide (SNAG) techniques and
29 their relationship to psychological factors in the treatment of chronic neck pain. The
30 primary outcome was pain, and ROM and pressure pain threshold (PPT) were secondary
31 outcomes measured immediately following a single treatment. The group assigned to
32 manipulation received a high-velocity low-amplitude supine technique, the mobilization
33 group received a unilateral posteroanterior (PA) grade III passive oscillatory technique in
34 the prone position, and the SNAG technique was performed on a seated patient while they
35 simultaneously moved their head from a standardized position. The mean difference in pain
36 at rest was 3.08 ($P < 0.01$) in the HVLA group, 1.51 ($P < 0.05$) in the mobilization group,
37 and 0.26 (not significant) in the SNAG group. However, in pain and functional
38 measurements with movement and PPT, there were no differences between the groups
39 overall as all significantly improved. Concerning psychological factors, better outcomes
40 were shown with mobilization if the participant had high levels of anxiety. If anxiety was
41 low, the manipulation and SNAG techniques produced better results.

1 A Cochrane review was conducted by Gross et al. in 2015 as an update of 2 previous
2 reviews (performed in 2004 and 2010) assessing the effects of manipulation or
3 mobilization alone compared to a control or another treatment on pain and other outcomes
4 in adults with neck pain. The review included 51 randomized controlled trials with a total
5 of 2920 participants, and 80% (41/51) of the studies were of low or very low quality.
6 Eighteen of the trials compared manipulation/mobilization to a control, 34 compared
7 manipulation/mobilization to another treatment, and 1 trial had two comparisons.
8 Manipulation was evaluated for both the cervical and thoracic spinal regions. For subacute
9 or chronic neck pain, a single session of cervical manipulation provided temporary pain
10 relief when compared to an inactive control. Multiple treatments produced conflicting
11 evidence at short-term follow-up. However, multiple sessions of thoracic spinal
12 manipulation were shown to reduce pain at short-term and intermediate-term follow-up in
13 patients with acute or subacute neck pain and improve function in patients with acute to
14 chronic neck pain when compared to control. Cervical manipulation for acute to subacute
15 neck pain was more effective for improving pain and function than various combinations
16 of analgesics, muscle relaxants and non-steroidal anti-inflammatory medications.

17
18 For the conservative treatment of cervical radiculopathy, Zhu et al. (2015) examined the
19 evidence for the effectiveness and safety of using cervical spine manipulation. Three
20 studies, published in Chinese, met the criteria for inclusion in the systematic review, and
21 the analysis represented a total of 502 patients with a diagnosis of degenerative cervical
22 radiculopathy. Each was a two-arm RCT comparing manipulation to cervical computer
23 traction (serving as a control group) where active treatment frequency was approximately
24 2x/ week and inactive frequency varied from 3-7x/week. The duration of the treatments in
25 2 of the trials was 2 weeks (1 including a 4-week follow-up), and 4 weeks in the other.
26 Mean differences in pain measured by VAS showed statistically significant improvements
27 in the active groups in all 3 studies. Overall, the authors deemed the level of evidence to
28 be of moderate quality due to statistical heterogeneity ($I^2 >50\%$). They used the PEDro
29 scale to determine methodological quality; a score of 5 or above (out of a possible 10) was
30 considered acceptable and indicated low risk of bias. Two of the 3 studies scored a 5, and
31 1 scored a 6. The items related to blinding considerations were not met in all 3 of the
32 studies, and the authors echoed the opinions of many other authors regarding the limitations
33 or difficulties in blinding during trials involving spinal manipulation. However, other
34 methods of more concern were a lack of detail regarding sample size calculations,
35 randomization, allocation concealment, and intention-to-treat analyses. Additionally,
36 adverse event reporting was not prevalent, leading to inconclusive safety results.

37
38 In a revised clinical practice guideline linked to the International Classification of
39 Functioning, Disability and Health From the Orthopaedic Section of the American Physical
40 Therapy Association, Blanpied et al. (2017) reports that for acute neck pain with mobility
41 deficits, clinicians should provide thoracic manipulation, a program of neck ROM
42 exercises, and scapulothoracic and upper extremity strengthening to enhance program

1 adherence and clinicians may provide cervical manipulation and/or mobilization. For
2 subacute neck pain with mobility deficits included whiplash associated disorders,
3 clinicians may provide thoracic manipulation and cervical manipulation and/or
4 mobilization. For chronic neck pain with mobility deficits, clinicians should provide a
5 multimodal approach of the following:

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

10
11 For patients with subacute or chronic neck pain with headache, clinicians should provide
12 cervical manipulations or mobilizations. For patients with chronic neck pain with radiating
13 pain, clinicians should provide mechanical intermittent cervical traction, combined with
14 other interventions such as stretching and strengthening exercise plus cervical and thoracic
15 mobilization/manipulation.

16
17 Griswold et al. (2018) compared the clinical effectiveness of concordant cervical and
18 thoracic non-thrust manipulation (NTM) and thrust manipulation I for patients with
19 mechanical neck pain. The Neck Disability Index (NDI) was the primary outcome.
20 Secondary outcomes included the Patient-Specific Functional Scale (PSFS), numeric pain-
21 rating scale (NPRS), deep cervical flexion endurance (DCF), global rating of change
22 (GROC), number of visits, and duration of care. Outcomes were collected at baseline, visit
23 2, and discharge. Patients were randomly assigned to receive either NTM or TM directed
24 at the cervical and thoracic spines. Techniques and dosages were selected pragmatically
25 and applied to the most symptomatic level. One hundred three patients were included in
26 the analyses (NTM, n = 55 and TM, n = 48). The between-group analyses revealed no
27 differences in outcomes on all outcome measures, number of visits and duration of care.
28 Authors concluded that NTM and TM produce equivalent outcomes for patients with
29 mechanical neck pain.

30
31 Masaracchio et al. (2019) investigated the role of thoracic spine manipulation (TSM) on
32 pain and disability in the management of mechanical neck pain (MNP). Across the included
33 studies, there was increased risk of bias for inadequate provider and participant blinding.
34 The GRADE approach demonstrated an overall level of evidence ranging from very low
35 to moderate. Meta-analysis that compared TSM to thoracic or cervical mobilization
36 revealed a significant effect favoring the TSM group for pain and disability. Meta-analysis
37 that compared TSM to standard care revealed a significant effect favoring the TSM group
38 for pain and disability at short-term follow-up, and a significant effect for disability at long-
39 term follow-up. Meta-analysis that compared TSM to cervical spine manipulation revealed
40 a non-significant for pain without a distinction between immediate and short-term follow-
41 up. Limitations include heterogeneity among the studies making it difficult to assess the
42 true clinical benefit, as well as the overall level of quality of evidence. Authors conclude

1 that TSM has been shown to be more beneficial than thoracic mobilization, cervical
2 mobilization, and standard care in the short-term, but no better than cervical manipulation
3 or placebo thoracic spine manipulation to improve pain and disability. Coulter et al. (2019)
4 sought to determine the efficacy, effectiveness, and safety of various mobilization and
5 manipulation therapies for treatment of chronic nonspecific neck pain. A total of 47
6 randomized trials were included in the systematic review and included a total of 4,460
7 patients with nonspecific chronic neck pain who were being treated by a practitioner using
8 various types of manipulation and/or mobilization interventions. A total of 37 trials were
9 categorized as unimodal approaches and involved thrust or non-thrust compared with
10 sham, no treatment, or other active comparators. Of these, only 6 trials with similar
11 intervention styles, comparators, and outcome measures/timepoints were pooled for meta-
12 analysis at 1, 3, and 6 months, showing a small effect in favor of thrust plus exercise
13 compared to an exercise regimen alone for a reduction in pain and disability. Multimodal
14 approaches appeared to be effective at reducing pain and improving function from the 10
15 studies evaluated. Authors concluded that studies provide low-moderate quality evidence
16 that various types of manipulation and/or mobilization will reduce pain and improve
17 function for chronic nonspecific neck pain compared to other interventions. It appears that
18 multimodal approaches, in which multiple treatment approaches are integrated, might have
19 the greatest potential impact. According to the published trials reviewed, manipulation and
20 mobilization appear safe.

21
22 Bernal-Utrera et al. (2020) compared the effects of two experimental treatments based on
23 manual therapy and therapeutic exercise. The short-term and mid-term changes produced
24 by different therapies on subjects (n=69) with non-specific chronic neck pain were studied.
25 The sample was randomized divided into three groups: manual therapy, therapeutic
26 exercise, and placebo. No statistically significant differences (P 0.05) were obtained
27 between the experimental groups, if they exist against the control group. Nonetheless, they
28 found that manual therapy improved perceived pain before than therapeutic exercise, while
29 therapeutic exercise reduced cervical disability before than manual therapy. Authors
30 concluded that there were no differences between groups in short and medium terms.
31 Manual therapy achieves a faster reduction in pain perception than therapeutic exercise.
32 Therapeutic exercise reduces disability faster than manual therapy. Clinical improvement
33 could potentially be influenced by central processes.

34
35 Hawk et al. (2020) developed an evidence-based clinical practice guideline (CPG) through
36 a broad-based consensus process on best practices for chiropractic management of patients
37 with chronic musculoskeletal (MSK) pain. Delphi process was conducted January-
38 February 2020. The 62-member Delphi panel reached consensus on chiropractic
39 management of five common chronic MSK pain conditions: low-back pain (LBP), neck
40 pain, tension headache, osteoarthritis (knee and hip), and fibromyalgia. Recommendations
41 were made for nonpharmacological treatments, including acupuncture, spinal
42 manipulation/mobilization, and other manual therapy; modalities such as low-level laser

1 and interferential current; exercise, including yoga; mind-body interventions, including
 2 mindfulness meditation and cognitive behavior therapy; and lifestyle modifications such
 3 as diet and tobacco cessation. Authors concluded that clinicians should consider multiple
 4 approaches for neck pain. Both active and passive, and both physical and mind-body
 5 interventions should be considered in the management plan. Spinal
 6 manipulation/mobilization was included in this recommendation neck pain.

7
 8 Chaibi et al. (2021) reviewed original randomized controlled trials (RCTs) assessing the
 9 effect of spinal manipulative therapy (SMT) for acute neck pain. Six studies were included.
 10 The overall pooled effect size for neck pain was very large -1.37 favoring treatments with
 11 SMT compared with controls. Minor transient adverse events reported included increased
 12 pain and headache, while no serious AEs were reported. Authors concluded that SMT alone
 13 or in combination with other modalities was effective for patients with acute neck pain.
 14 However, limited quantity and quality, pragmatic design, and high heterogeneity limit the
 15 findings. Bakken et al. (2021) investigated the combination of home stretching exercises
 16 and spinal manipulative therapy in a multicenter randomized controlled clinical trial,
 17 carried out in multidisciplinary primary care clinics. The treatment modalities utilized were
 18 spinal manipulative therapy and home stretching exercises compared to home stretching
 19 exercises alone. Both groups received 4 treatments for 2 weeks. The primary outcome was
 20 pain, where the subjective pain experience was investigated by assessing pain intensity
 21 (NRS - 11) and the quality of pain (McGill Pain Questionnaire). Neck disability and health
 22 status were secondary outcomes, measured using the Neck Disability Index the EQ-5D,
 23 respectively. One hundred thirty-one adult subjects were randomized to one of the two
 24 treatment groups. All subjects had experienced persistent or recurrent neck pain the
 25 previous 6 months and were blinded to the other group intervention. The clinicians
 26 provided treatment for subjects in both group and could not be blinded. The researchers
 27 collecting data were blinded to treatment allocation, as was the statistician performing data
 28 analyses. An intention-to-treat analysis was used. Sixty-six subjects were randomized to
 29 the intervention group, and sixty-five to the control group. Authors concluded that based
 30 on their findings, there is no additional treatment effect from adding spinal manipulative
 31 therapy to neck stretching exercises over 2 weeks for patients with persistent or recurrent
 32 neck pain.

33 34 **Thoracic Spine Pain**

35 Spinal manipulation has not been studied in any systematic way (e.g., through RCTs) for
 36 the treatment of pain in the mid-back region. Some studies cited above have included
 37 thoracic spine manipulation as part of a treatment package for neck pain, but none of these
 38 studies have looked at pain in the thoracic spine itself as an outcome. Indeed, there are
 39 virtually no experimental studies that have evaluated the treatment of thoracic spine pain
 40 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
 15 Thoomes et al. (2022) aimed to establish consensus on effective nonsurgical treatment
 16 modalities at different stages (ie, acute, subacute, or chronic) of cervical radiculopathy
 17 (CR) using the Delphi method approach. Through an iterative multistage process, experts
 18 within the field rated their agreement with a list of proposed treatment modalities according
 19 to the stage of CR and could suggest missing treatment modalities. Agreement was
 20 measured using a 5-point Likert scale. Descriptive statistics were used to measure
 21 agreement (median, interquartile ranges, and percentage of agreement). Consensus criteria
 22 were defined a priori for each round. Consensus for Round 3 was based on ≥ 2 of the
 23 following: a median Likert scale value of ≥ 4 , interquartile range value of ≤ 1 , and/or a
 24 percentage of agreement $\geq 70\%$. Data analysis produced a consensus list of effective
 25 treatment modalities in different stages of recovery. According to experts, the focus of
 26 multimodal management in the acute stage should consist of patient education and spinal
 27 manipulative therapy, specific (foraminal opening) exercises, and sustained pain-relieving
 28 positions. In the subacute stage, increasing individualized physical activity including
 29 supervised motor control, specific exercises, and/or neurodynamic mobilization could be
 30 added. In the chronic stage, focus should shift to include general aerobic exercise as well
 31 as focused strength training. Postural education and vocational ergonomic assessment
 32 should also be considered. Authors conclude that multimodal conservative management of
 33 individuals with CR should take the stage of the condition into consideration. The focus of
 34 therapeutic interventions should shift from passive pain-relieving intervention in the acute
 35 stage to increasingly more individualized physical activity and self-management in the
 36 chronic stage.

37
 38 Núñez-Cabaleiro et al. (2022) aimed to identify the manual therapy (MT) methods and
 39 techniques that have been evaluated for the treatment of cervicogenic headache (CH) and
 40 their effectiveness. Of a total of 14 articles selected, 11 were randomized control trials and
 41 three were quasi-experimental studies. The techniques studied were: spinal manipulative
 42 therapy, Mulligan's Sustained Natural Apophyseal Glides, muscle techniques, and

1 translatory vertebral mobilization. In the short-term, the Jones technique on the trapezius
 2 and ischemic compression on the sternocleidomastoid achieved immediate improvements,
 3 whereas adding spinal manipulative therapy to the treatment can maintain long-term
 4 results. Authors concluded that manual therapy techniques could be effective in the
 5 treatment of patients with CH. The combined use of MT techniques improved the results
 6 compared with using them separately. This review has methodological limitations, such as
 7 the inclusion of quasi-experimental studies and studies with small sample sizes that
 8 reduced the generalizability of the results obtained.

9 Chronic Headache

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

38
 39
 40 Posadzki and Ernst (2012) performed a review of SMT for TTH and found favorable results
 41 for the treatment, but could not pool data due to the statistical and clinical heterogeneity of
 42 the included studies. The results of this meta-analysis found a moderate effect size

1 supporting MT and suggest that it is more effective than medication in the short term for
2 patients with TTH. Chaibi and Russell (2012) conducted a systematic review assessing the
3 efficacy of MT for the treatment of primary chronic headache. The search terms contained
4 various headache conditions combined with MT terms including ‘manipulative therapy,’
5 ‘spinal manipulative therapy,’ and ‘chiropractic treatment.’ Out of the six studies that met
6 the review criteria, 1 evaluated massage therapy and 5 evaluated physical therapy for
7 treatment effects for chronic TTH. The physical therapy interventions consisted of soft
8 tissue therapy, exercises, stretching, TENS, postural correction and mobilization; therefore,
9 spinal manipulative therapy (SMT) was not evaluated. However, the results showed that
10 MT was equal in efficacy to prophylactic medication with tricyclic antidepressant. The
11 massage group had significant reduction in headache intensity when compared to detuned
12 ultrasound. In 3 of the physical therapy trials, 54-85% of participants had $\geq 50\%$ reduction
13 in headache frequency post-treatment, and 2 of the studies reported a maintained effect at
14 a 6-month follow-up.

15
16 Racicki et al. (2013) conducted a study with the aim of assessing the effectiveness of
17 various non-invasive treatments for cervicogenic headaches. The conservative
18 interventions included were MT or exercise. Six studies were included in the review, and
19 all were determined to have good methodological quality scores on the PEDro scale. One
20 of the most common methodological weaknesses involved blinding. The therapists were
21 not blinded in all 6 studies, but as is the case with all MT studies, the intervention that is
22 delivered must be known. Three of the trials did not blind the participants. Three studies
23 had weaknesses associated with not offering point measures or measures of variability for
24 1 key outcome and intention to treat analysis. Some conflicting evidence was found among
25 the studies; 4 concluded that manipulative therapy had a significant effect, but 2 showed
26 no clinically or statistically significant differences (1 of which was conducted with
27 participants aged 7-15 years). Five studies evaluated manipulation (1 included cervico-
28 scapular strengthening exercises and mobilization) and 1 evaluated mobilization only. The
29 cervical spine was the main region where the interventions were applied, but 1 study also
30 incorporated upper thoracic SMT. After calculating effect sizes and reviewing all results,
31 the authors found improvements in headache intensity, frequency and in neck pain when
32 utilizing cervical manipulation, mobilization and exercise. These findings echoed those of
33 2 previous reviews.

34
35 Chaibi and Russell (2014) also performed a systematic review to assess efficacy of manual
36 therapies for the treatment of cervicogenic headache. The authors identified 7 studies that
37 met the inclusion criteria with 6 involving a cervical SMT intervention. The authors
38 deemed all studies to have at least good methodological quality based on scores of over 50
39 out of 100, and 1 study with excellent quality scoring 81. The most common
40 methodological issues were related to blinding and the number of participants. Two studies
41 reported a statistically significant reduction in NSAID consumption from pre- to post-
42 treatment in the cervical SMT group, but no statistically significant difference in

1 consumption between cervical SMT and control groups. Another trial found a 50%
2 reduction in the frequency of participant's headaches in the exercise group (76%), cervical
3 SMT group (71%), combined exercise and SMT group (81%) and control (29%) and 100%
4 reduction in 31, 33, 42 and 4% of the groups respectively. The combined group also showed
5 significantly reduced durations of headaches immediately post-treatment ($P<0.05$) and at
6 12-month follow-up ($P<0.05$). Dose response was evaluated in 2 of the studies. One
7 reported percentages of improvement in headache intensity and frequency that increased
8 as treatment incidence increased; however, significant reductions in intensity were shown
9 in the SMT 4x/week group compared to 1x/week at 4-week follow-up and in the SMT 3
10 and 4x/week compared to 1x/week at 12-week follow-up. The other study compared 1 and
11 2x/week SMT and light massage control groups and found more improvement in the
12 treatment groups over the controls, but significant improvement was found specifically in
13 the 2x/week SMT group ($P<0.05$) compared the control group at 4, 12 and 24-week follow-
14 up concerning headache intensity. Based on 1 treatment, another study showed significant
15 reductions in headache days from baseline to 2-month follow-up in both the cervical SMT
16 ($P<0.01$) and sham ($P<0.03$) groups but no statistically significant change in either group
17 regarding headache frequency, total duration and intensity. The authors concluded that the
18 results were difficult to evaluate due to only 1 study incorporating a control group, but
19 SMT may be an effective treatment for cervicogenic headache. A very similar systematic
20 review was published by Posadzki and Ernst (2011), who concluded that evidence for the
21 effectiveness of SMT for cervicogenic headaches is inconclusive.

22
23 Espi-Lopez et al. (2014) designed a study to determine the effectiveness of delivering one
24 MT technique versus a combination of MT techniques in patients with TTH. Patients were
25 randomized into one of the 3 active treatment groups or the control (4th group) at 19 per
26 group. The treatment plan for each group consisted of 4 visits at 7-day intervals. The active
27 treatments were either a suboccipital soft tissue inhibition therapy (SI); manipulation of the
28 occiput, atlas and axis (OAA); or combined SI + OAA. Outcomes measured varying factors
29 of headache disability including the Headache Disability Inventory (assesses an overall
30 score and subscales of pain severity, frequency, function, and emotions) and presence of
31 associated symptoms such as photo/phonophobia and pericranial tenderness). Both the
32 OAA and combined groups showed significant reductions in headache frequency and
33 differences in functional and emotional subsets of HDI score ($P<0.05$). No change in
34 frequency was observed in the SI or control groups. In all 3 active groups, headache
35 severity was significantly reduced ($P<0.05$) where no change was noted for the control.
36 Only participants receiving the combined treatment reported significantly less frequency
37 of photo/phonophobia and pericranial tenderness. Regarding between-group differences,
38 results favored the OAA and combined groups. The authors concluded that individual
39 techniques have different effects, but that manipulative OAA alone was effective for
40 reducing severity, frequency, and functional and emotional features of disability related to
41 TTH.

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

24
25 In a pragmatic RCT, Vernon et al. (2015) studied patients with TTH and cervicogenic
26 headaches. They compared one group who received 5 weeks of usual chiropractic treatment
27 to another group who received the same treatment in addition to 4 weeks of a self-
28 acupressure pillow. Usual chiropractic treatment consisted of SMT to the cervical and
29 upper thoracic spine, and could include mobilizations, soft tissue therapy or postural
30 exercises, and the groups received nearly the same levels of all interventions. The pillow
31 was prescribed to be used 2x/day for 5 minutes and during a headache episode up to
32 3x/episode. Although a true comparison between the groups could not be made due to a
33 failure in randomization, post hoc analysis revealed statistically and clinically significant
34 reductions in headache frequency (>40% reduction) in the chiropractic-only group (71%).

35
36 Dunning et al. (2016) compared the effects of manipulation to mobilization and exercise
37 in individuals with cervicogenic headache (CH). One hundred and ten participants (n =
38 110) with CH were randomized to receive both cervical and thoracic manipulation (n = 58)
39 or mobilization and exercise (n = 52). The primary outcome was headache intensity as
40 measured by the Numeric Pain Rating Scale (NPRS). Secondary outcomes included
41 headache frequency, headache duration, disability as measured by the Neck Disability
42 Index (NDI), medication intake, and the Global Rating of Change (GRC). The treatment

1 period was 4 weeks with follow-up assessment at 1 week, 4 weeks, and 3 months after
2 initial treatment session. Results demonstrated that individuals with CH who received both
3 cervical and thoracic manipulation experienced significantly greater reductions in
4 headache intensity ($p < 0.001$) and disability ($p < 0.001$) than those who received
5 mobilization and exercise at a 3-month follow-up. Individuals in the upper cervical and
6 upper thoracic manipulation group also experienced less frequent headaches and shorter
7 duration of headaches at each follow-up period ($p < 0.001$ for all). Additionally, patient
8 perceived improvement was significantly greater at 1 and 4-week follow-up periods in
9 favor of the manipulation group ($p < 0.001$). Authors concluded that six to eight sessions
10 of upper cervical and upper thoracic manipulation were shown to be more effective than
11 mobilization and exercise in patients with CH, and the effects were maintained at 3 months.

12
13 Côté et al. (2019) developed an evidence-based guideline for the non-pharmacological
14 management of persistent headaches associated with neck pain (i.e., tension-type or
15 cervicogenic). Authors concluded that when managing patients with headaches associated
16 with neck pain, clinicians should (a) rule out major structural or other pathologies, or
17 migraine as the cause of headaches; (b) classify headaches associated with neck pain as
18 tension-type headache or cervicogenic headache once other sources of headache pathology
19 has been ruled out; (c) provide care in partnership with the patient and involve the patient
20 in care planning and decision making; (d) provide care in addition to structured patient
21 education; (e) consider low-load endurance craniocervical and cervicoscapular exercises
22 for tension-type headaches (episodic or chronic) or cervicogenic headaches >3 months
23 duration; (f) consider general exercise, multimodal care (spinal mobilization,
24 craniocervical exercise and postural correction) or clinical massage for chronic tension-
25 type headaches; (g) do not offer manipulation of the cervical spine as the sole form of
26 treatment for episodic or chronic tension-type headaches; (h) consider manual therapy
27 (manipulation with or without mobilization) to the cervical and thoracic spine for
28 cervicogenic headaches >3 months duration. However, there is no added benefit in
29 combining spinal manipulation, spinal mobilization and exercises; and (i) reassess the
30 patient at every visit to assess outcomes and determine whether a referral is indicated. Neck
31 pain and headaches are very common comorbidities in the population. Authors Tension-
32 type and cervicogenic headaches can be treated effectively with specific exercises. Manual
33 therapy can be considered as an adjunct therapy to exercise to treat patients with
34 cervicogenic headaches. The management of tension-type and cervicogenic headaches
35 should be patient-centered.

36
37 Fernandez et al. (2020) evaluated the effectiveness of SMT for cervicogenic headache
38 (CGHA). Seven trials were eligible. At short-term follow-up, there was a significant, small
39 effect favoring SMT for pain intensity and small effects for pain frequency. There was no
40 effect for pain duration. There was a significant, small effect favoring SMT for disability.
41 At intermediate follow-up, there was no significant effects for pain intensity and a
42 significant, small effect favoring SMT for pain frequency. At long-term follow-up, there

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

19
20 McDevitt et al. (2022) sought to determine if thoracic spine manipulation (TSM) improves
21 pain and disability in individuals with cervicogenic headache (CeH). A randomized
22 controlled crossover trial was conducted on 48 participants (mean age: 34.4 years) with
23 CeH symptoms. Participants were randomized to 6 sessions of TSM or no treatment (Hold)
24 and after 4-weeks, groups crossed over. Outcomes were collected at 4, 8 and 12 weeks and
25 included: headache disability inventory (HDI), neck disability index (NDI), and the global
26 rating of change (GRC). Scores at 4 weeks represent the only timepoint where 1 group is
27 fully treated and other group has not received any treatment. Comparing hold to active
28 treatment, HDI were not significantly different between groups at any timepoint; the NDI
29 was significant at 4 weeks. Odds of achieving the +4 MCID on the GRC favored TSM at
30 4 weeks. Authors concluded that TSM had no effect on headache-related disability but
31 resulted in significant improvements in neck-related disability and participant reported
32 perceived improvement

33 34 **SAFETY**

35 A recent RCT by Maiers et al. (2015) collected data on adverse events that occurred as a
36 result of cervical SMT and exercise interventions in a senior population. Of those who
37 received SMT with home exercise, 74 out of 78 reported non-serious adverse events that
38 were mostly musculoskeletal in nature such as muscle soreness, stiffness, headache and
39 joint pain. Aggravated neck pain was the most reported symptom. It was noted that no
40 subjects withdrew from study participation due to these events. Also, in this group, three
41 serious adverse events were reported but deemed as likely unrelated due to the nature and

1 absence of a temporal association. These included bradycardia and arrhythmia (n=2) and
2 myocardial infarction (n=1).

3
4 Overall, no causal relationship between SMT and cervical artery dissection or stroke has
5 been established. Cervical artery dissection is a rare event in itself and has been associated
6 with SMT, other treatments disparate from any manual therapy, and general movements of
7 the neck. Prior to delivering an intervention such as SMT, clinicians are advised to attempt
8 to identify a potential arterial or ischemic event in progress. The primary appropriate
9 screening method seems to be taking an effective history to recognize conjunctive features.

10
11 Chu et al. (2022) examined the incidence and severity of adverse events (AEs) of patients
12 receiving chiropractic spinal manipulative therapy (SMT), with the hypothesis that < 1 per
13 100,000 SMT sessions results in a grade ≥ 3 (severe) AE. A secondary objective was to
14 examine independent predictors of grade ≥ 3 AEs. They identified patients with SMT-
15 related AEs from January 2017 through August 2022 across 30 chiropractic clinics in Hong
16 Kong. AE data were extracted from a complaint log, including solicited patient surveys,
17 complaints, and clinician reports, and corroborated by medical records. AEs were
18 independently graded 1-5 based on severity (1-mild, 2-moderate, 3-severe, 4-life-
19 threatening, 5-death). Among 960,140 SMT sessions for 54,846 patients, 39 AEs were
20 identified, two were grade 3, both of which were rib fractures occurring in women age >
21 60 with osteoporosis, while none were grade ≥ 4 , yielding an incidence of grade ≥ 3 AEs
22 of 0.21 per 100,000 SMT sessions (95% CI 0.00, 0.56 per 100,000). There were no AEs
23 related to stroke or cauda equina syndrome. The sample size was insufficient to identify
24 predictors of grade ≥ 3 AEs using multiple logistic regression. In this study, severe SMT-
25 related AEs were reassuringly very rare.

26
27 Whedon et al. (2022) evaluated the association between cervical spinal manipulation and
28 cervical artery dissection among older Medicare beneficiaries in the United States. The
29 primary exposure was cervical spinal manipulation; the secondary exposure was a clinical
30 encounter for evaluation and management for neck pain or headache. They created a 3-
31 level categorical variable, (1) any cervical spinal manipulation, 2) evaluation and
32 management but no cervical spinal manipulation and (3) neither cervical spinal
33 manipulation nor evaluation and management. The primary outcomes were occurrence of
34 cervical artery dissection, either (1) vertebral artery dissection or (2) carotid artery
35 dissection. The cases had a new primary diagnosis on at least one inpatient hospital claim
36 or primary/secondary diagnosis for outpatient claims on at least two separate days. Cases
37 were compared to 3 different control groups: (1) matched population controls having at
38 least one claim in the same year as the case; (2) ischemic stroke controls without cervical
39 artery dissection; and (3) case-crossover analysis comparing cases to themselves in the time
40 period 6-7 months prior to their cervical artery dissection. Comparison across three
41 different time frames occurred: up to (1) 7 days; (2) 14 days; and (3) 30 days prior to index
42 event. The odds of cervical spinal manipulation versus evaluation and management did not

1 significantly differ between vertebral artery dissection cases and any of the control groups
 2 at any of the timepoints (ORs 0.84 to 1.88; $p > 0.05$). Results for carotid artery dissection
 3 cases were similar. Authors concluded that among Medicare beneficiaries aged 65 and
 4 older who received cervical spinal manipulation, the risk of cervical artery dissection is no
 5 greater than that among control groups.

6 7 **PRACTITIONER SCOPE AND TRAINING**

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

13
 14 It is best practice for the practitioner to appropriately render services to a member only if
 15 they are trained, equally skilled, and adequately competent to deliver a service compared
 16 to others trained to perform the same procedure. If the service would be most competently
 17 delivered by another health care practitioner who has more skill and training, it would be
 18 best practice to refer the member to the more expert practitioner.

19
 20 Best practice can be defined as a clinical, scientific, or professional technique, method, or
 21 process that is typically evidence-based and consensus driven and is recognized by a
 22 majority of professionals in a particular field as more effective at delivering a particular
 23 outcome than any other practice (Joint Commission International Accreditation Standards
 24 for Hospitals, 2020).

25
 26 Depending on the practitioner's scope of practice, training, and experience, a member's
 27 condition and/or symptoms during examination or the course of treatment may indicate the
 28 need for referral to another practitioner or even emergency care. In such cases it is prudent
 29 for the practitioner to refer the member for appropriate co-management (e.g., to their
 30 primary care physician) or if immediate emergency care is warranted, to contact 911 as
 31 appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practices
 32 guideline for information.

33 34 ***Low Back References***

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