Clinical Practice Guideline: **Spinal Manipulative Therapy for Treatment of Children and Infants**

Date of Implementation: **July 16, 2009**

Product: **Specialty**

Related Policies:
CPG 119: Spinal Manipulative Therapy for Non-Musculoskeletal and Related Disorders for more specific information.
CPG 135: Physical Therapy Medical Policy/Guideline
CPG 155: Occupational Therapy Medical Policy/Guideline
CPG 278: Chiropractic Services
CPG 285: Spinal Manipulative Therapy (SMT) for Musculoskeletal and Related Disorders

GUIDELINES

American Specialty Health, Inc. (ASH) considers Spinal Manipulation or Mobilization for the treatment of children and infants (age 14 and under) to be medically necessary when the documentation establishes a valid diagnosis and symptomatic status and satisfies the criteria outlined in the *Spinal Manipulative Therapy (SMT) for Musculoskeletal and Related Disorders (CPG 285-S)* clinical practice guideline.

While the literature is insufficient to conclude spinal manipulative therapy in children with spinal pain is either clinically effective or ineffective as the evidence is generally very limited and low quality; it may be reasonable to infer from the literature supporting SMT for low back pain and neck pain in adults that there is a similar benefit in children. To the extent to which children are physiologically and bio-mechanically different from adults, there may be an impact of those differences on the benefit: risk profile. It is likely that these differences are greater in infants and children than in adolescents, thus additional caution should be considered prior to performing SMT on infants and children.

Spinal manipulation is considered not medically necessary when the above criteria are not met.

Spinal manipulation is considered not medically necessary for non-musculoskeletal and related disorders (e.g., asthma, infantile colic, nocturnal enuresis, or otitis media) in children. Moreover, ASH clinical committees have determined that SMT for non-musculoskeletal and related disorders in children poses a health and safety risk through substitution harm. See the *Spinal Manipulative Therapy for Non-Musculoskeletal*

Conditions and Related Disorders (CPG 119-S) clinical practice guideline for more specific information.

EVIDENCE AND RESEARCH

The literature on spinal manipulation in children shows potential beneficial effects in a few conditions, though the evidence is generally very limited and of low quality. The evidence base for the provision of SMT in children for spine pain is largest in the treatment of adolescent idiopathic scoliosis, and low back pain. However, for both of these conditions, there is insufficient evidence to support a conclusion regarding the effectiveness of SMT.

SMT for low back pain was the focus of a study by Hayden et al. (2003). The study involved a prospective cohort of 54 consecutive 4- to 18-year-old low-back-pain patients from 15 randomly selected chiropractors in Calgary, Alberta, and Toronto, Ontario, Canada. Patients presented primarily with uncomplicated mechanical low-back pain of less than three months duration, had a median of five visits (interquartile range three [3] to eight [8]) over a median treatment period of 22 days (interquartile range seven [7] to 56) and were treated most commonly with SMT (95.2%) and/or passive manual therapy (42.9%). Over the course of treatment, 90.7% of patients improved; 81.4% improved by more than 20% on the pediatric visual analogue scale (VAS), and 53.7% had "important" improvement (defined as the median change on the VAS in 78.9% of patients who reported that they were "much improved.") 92.3% of patients reported improvement of some kind. Those with pain for more than 12 weeks at the beginning of treatment were less likely to improve within the first five visits (RR = 2.1; 95% CI = 1.1, 4.3), whereas those with restricted range of motion at baseline were more likely to improve (RR = 0.39; 95% CI = 0.21, 0.75). No complications or adverse events were reported. Because the study lacked a comparison group, no conclusions can be drawn about the efficacy or relative effectiveness of SMT for pediatric patients with low-back pain. A systematic review by Vaughn et al. (2012) only identified two RCTs and two prospective cohort studies in their literature search. They did not include any research studying SMT and excessive spinal curvatures. Authors concluded that given the paucity of data in the literature to support or refute using SMT for pediatric patients with spinal conditions, further research is necessary to recommend the use of this intervention in children. For a discussion of the research supporting SMT in adults for the treatment of low back pain and neck pain, see the *Spinal Manipulative Therapy (SMT) for Musculoskeletal and Related Disorders (CPG 285-S)* clinical practice guideline.

Evans et al. (2018) conducted a multicenter randomized trial comparing 12 weeks of spinal manipulative therapy (SMT) combined with exercise therapy (ET) to ET alone for low back pain. Participants were 185 adolescents aged 12 to 18 years with chronic LBP. The primary outcome was LBP severity at 12, 26, and 52 weeks. Secondary outcomes included disability, quality of life, medication use, patient- and caregiver-rated improvement, and satisfaction. Of the 185 enrolled patients, 179 (97%) provided data at 12 weeks and 174

(94%) at 26 and 52 weeks. Adding SMT to ET resulted in a significantly larger reduction in LBP severity over the course of 1 year. The group difference in LBP severity (0-10 scale) was small at the end of treatment but was larger at weeks 26 and 52. At 26 weeks, SMT with ET performed better than ET alone for disability and improvement. The SMT with ET group reported significantly greater satisfaction with care at all time points. There were no serious treatment-related adverse events. For adolescents with chronic LBP, spinal manipulation combined with exercise was more effective than exercise alone over a 1-year period, with the largest differences occurring at 6 months. These findings warrant replication and evaluation of cost effectiveness. Dissing et al. (2018) investigated the effectiveness of adding manipulative therapy to other conservative care for spinal pain in a school-based cohort of Danish children aged 9-15 years. A text message system and clinical examinations were used for data collection. Interventions included either (1) advice, exercises and soft-tissue treatment or (2) advice, exercises and soft-tissue treatment plus manipulative therapy. The primary outcome was number of recurrences of spinal pain. Secondary outcomes were duration of spinal pain, change in pain intensity and Global Perceived Effect. Authors found no significant difference between groups in the primary outcome and intervention group 2. Children in the group receiving manipulative therapy reported a higher Global Perceived Effect. No adverse events were reported. Main limitations are the potential discrepancy between parental and child reporting and that the study population may not be comparable to a normal care-seeking population. Authors concluded that adding manipulative therapy to other conservative care in school children with spinal pain did not result in fewer recurrent episodes. The choice of treatment-if any-for spinal pain in children therefore relies on personal preferences, and could include conservative care with and without manipulative therapy. Participants in this trial may differ from a normal care-seeking population. Dissing et al. (2019) acknowledged that interventions may be more effective for subgroups of those affected with low back pain and completed a secondary analysis to investigate this. In this secondary analysis of data from a randomized clinical trial, they tested whether five indicators of a potential increased need for treatment might act as effect modifiers for manipulative therapy in the treatment of spinal pain in children. Investigators hypothesized that the most severely affected children would benefit more from manipulative therapy. To explore potential effect modification, various types of regression models were used depending on the type of outcome, including interaction tests. Authors found that children with long duration of spinal pain or co-occurring musculoskeletal pain prior to inclusion as well as low quality of life at baseline tended to benefit from manipulative therapy over non-manipulative therapy, whereas the opposite was seen for children reporting high intensity of pain. However, most results were statistically insignificant. Authors concluded that this secondary analysis indicated that children more effected by certain baseline characteristics, but not pain intensity, have a greater chance to benefit from treatment that include manipulative therapy. However, these analyses were both secondary and underpowered, and therefore merely exploratory. The results underline the need for a careful choice of inclusion criteria in future investigations of manipulative therapy in children.

Driehuis et al. (2019) conducted a systematic review of the evidence for effectiveness and harms of specific SMT techniques for infants, children and adolescents. Of the 1,236 identified studies, 26 studies were eligible. Infants and children/adolescents were treated for various (non-)musculoskeletal indications, hypothesized to be related to spinal joint dysfunction. Studies examining the same population, indication and treatment comparison were scarce. Due to very low-quality evidence, it is uncertain whether gentle, low-velocity mobilizations reduce complaints in infants with colic or torticollis, and whether high-velocity, low-amplitude manipulations reduce complaints in children/adolescents with autism, asthma, nocturnal enuresis, headache or idiopathic scoliosis. Five case reports described severe harms after HVLA manipulations in four infants and one child. Authors found the evidence was of very low-quality that prevented drawing any conclusions about the effectiveness of specific SMT techniques in infants, children and adolescents.

Parnell Prevost et al. (2019) evaluated the use of manual therapy (MT) for clinical conditions in the pediatric population, assessed the methodological quality of the studies found, and synthesized findings based on health condition within a systematic review. They also assessed the reporting of adverse events within the included studies and compared the conclusions to those of the UK Update report. Six databases were searched using the following inclusion criteria: children under the age of 18 years old; treatment using manual therapy; any type of healthcare profession; published between 2001 and March 31, 2018; and English. Case reports were excluded. Of the 3563 articles identified, 165 full articles were screened, and 50 studies met the inclusion criteria. Twenty-six articles were included in prior reviews with 24 new studies identified. Eighteen studies were judged to be of high quality. Conditions evaluated were: attention deficit hyperactivity disorder (ADHD), autism, asthma, cerebral palsy, clubfoot, constipation, cranial asymmetry, cuboid syndrome, headache, infantile colic, low back pain, obstructive apnea, otitis media, pediatric dysfunctional voiding, pediatric nocturnal enuresis, postural asymmetry, preterm infants, pulled elbow, suboptimal infant breastfeeding, scoliosis, suboptimal infant breastfeeding, temporomandibular dysfunction, torticollis, and upper cervical dysfunction. Musculoskeletal conditions, including low back pain and headache, were evaluated in seven studies. Twenty studies reported adverse events, which were transient and mild to moderate in severity. Authors concluded that moderate-positive overall assessment was found for 3 conditions: low back pain and chiropractic manipulation, pulled elbow (MT), and premature infants (osteopathic manipulation and craniosacral techniques). Inconclusive unfavorable outcomes were found for 2 conditions: scoliosis (OMT) and torticollis (MT). All other condition's overall assessments were either inconclusive favorable or unclear for all manual therapies including SMT. Adverse events were uncommonly reported. More robust clinical trials in this area of healthcare are needed.

Lynge et al. (2021) investigated the effectiveness of chiropractic spinal manipulation versus sham manipulation in children aged 7-14 with recurrent headaches. A total of 199 children aged 7 to 14 years, with at least one episode of headache per week for the previous

6 months and at least one musculoskeletal dysfunction were identified. All participants received standard oral and written advice to reduce headaches. In addition, children in the active treatment group received chiropractic spinal manipulation and children in the control group received sham manipulation for a period of 4 months. Number and frequency of treatments were based on the chiropractor's individual evaluation in the active treatment group; the children in the control group received approximately eight visits during the treatment period. 'Number of days with headache', 'pain intensity' and 'medication' were reported weekly by text messages, and global perceived effect by text message after 4 months. 'Number of days with headache' and 'pain intensity' were chosen as equally important outcomes of highest priority, followed by global perceived effect and medication. Results demonstrated that chiropractic spinal manipulation resulted in significantly fewer days with headaches and better global perceived effect compared with a sham manipulation procedure. There was no difference between groups for pain intensity during headache episodes. Due to methodological shortcomings, no conclusions could be drawn about medication use. Authors concluded that chiropractic spinal manipulation resulted in fewer headaches and higher global perceived effect, with only minor side effects. It did not lower the intensity of the headaches. Since the treatment is easily applicable, of low cost and minor side effects, chiropractic spinal manipulation might be considered as a valuable treatment option for children with recurrent headaches.

Dice et al. (2021) sought to identify the following among physical therapists holding advanced credentials in pediatrics, neurodevelopmental treatment, or manual therapy: (1) consensus regarding effective techniques in the preadolescent population, (2) differences in opinion, and (3) perceived decision-making barriers and factors regarding use of manual therapy techniques. Credentialed physical therapists in the United States were recruited for a 3-round Delphi investigation. An electronic survey in Round 1 identified musculoskeletal and neurological impairments and the manual techniques considered effective to treat such conditions, in addition to factors and barriers. Responses were used to create the second round, during which a 4-point Likert scale was used to score each survey item. A third round of scoring established consensus. Descriptive statistics and composite scores were calculated for each manual technique by impairment. Consensus was determined for several concepts. First, neuromuscular techniques were considered effective across all impairments, and joint mobilizations (grades I-IV) were believed to be effective to treat joint and muscle and myofascial impairments. Second, visceral manipulation and craniosacral therapy were considered ineffective in treating most impairments. There was lack of consensus and clear differences of opinion regarding the use of grade V mobilizations (SMT) and dry needling. Significant barriers to use of manual therapy were: lack of knowledge, lack of evidence, and fear of litigation and harming patients. Authors summarized by stating that this study is an initial step for developing manual therapy guidelines, research, and educational opportunities regarding manual therapy in pediatric physical therapy.

Milne et al. (2022) sought to identify and map the available evidence regarding effectiveness and harms of spinal manipulation and mobilization for infants, children and adolescents with a broad range of conditions; and identify and synthesize policies, regulations, position statements and practice guidelines informing their clinical use. Infants, children and adolescents (birth to < 18 years) with any childhood disorder/condition who received an intervention of spinal manipulation and mobilization were included as participants. Eighty-seven articles were included. Methodological quality of articles varied. Spinal manipulation and mobilization may be utilized clinically to manage pediatric populations with adolescent idiopathic scoliosis (AIS), asthma, attention deficit hyperactivity disorder (ADHD), autism spectrum disorder (ASD), back/neck pain, breastfeeding difficulties, cerebral palsy (CP), dysfunctional voiding, excessive crying, headaches, infantile colic, kinetic imbalances due to suboccipital strain (KISS), nocturnal enuresis, otitis media, torticollis and plagiocephaly. This descriptive synthesis revealed: no evidence to explicitly support the effectiveness of spinal manipulation or mobilization for any condition in pediatric populations. Mild transient symptoms were commonly described in randomized controlled trials and on occasion, moderate-to-severe adverse events were reported in systematic reviews of randomized controlled trials and other lower quality studies. There was strong to very strong evidence for 'no significant effect' of spinal manipulation for managing asthma (pulmonary function), headache and nocturnal enuresis, and inconclusive or insufficient evidence for all other conditions explored. There is insufficient evidence to draw conclusions regarding spinal mobilization to treat pediatric populations with any condition. Authors concluded that their descriptive synthesis of the collective findings does not provide support for spinal manipulation or mobilization in pediatric populations for any condition. Increased reporting of adverse events is required to determine true risks. Randomized controlled trials examining effectiveness of spinal manipulation and mobilization in pediatric populations are warranted.

Franke et al. (2022) reviewed the literature to determine the effectiveness of OMT for all pediatric complaints. Forty-seven RCTs examining 37 pediatric conditions were reviewed. Twenty-three studies reported significant favorable outcomes for OMT relative to the control intervention, and 14 additional studies reported non-significant outcomes, which suggested potential favorable effects of OMT. Authors concluded that although a number of studies indicated positive results with use of OMT, few pediatric conditions have been investigated in more than one study, which results in no high-quality evidence for any condition. Additional research may change estimates of effect, and larger, high-quality RCTs focusing on a smaller range of conditions are recommended.

The literature on spinal manipulation for the treatment of non-musculoskeletal and related disorders in children is limited and of low quality. The evidence base for the provision of SMT in children is largest in the treatment of asthma, infantile colic, nocturnal enuresis, and otitis media. However, for each of these conditions there is insufficient evidence to support the use of SMT. The scientifically acceptable published evidence base for the

provision of SMT in children for the prevention or treatment of other musculoskeletal and related disorders is non-existent or non-informative. See the *Spinal Manipulative Therapy for Non-Musculoskeletal and Related Disorders (CPG 119-S)* clinical practice guideline for more specific information.

SAFETY

The potential risk of a major complication due to spinal manipulation is rare (Hurwitz et al., 1996; Todd et al., 2014). These rare, serious adverse events attributed to SMT in children included quadriplegia and death. Evidence of complications associated with SMT in children comes primarily from case reports and case series. While serious adverse events may be associated with pediatric spinal manipulation, neither causation nor incidence rates can be inferred from observational data (Vohra et al., 2007). No serious complications from SMT have been reported from any of the published randomized clinical trials or observational studies involving SMT in children. Several minor transient adverse reactions have been reported. Based on a review of the literature, both the possible harms and possible benefits of SMT in children appear to be minimal.

Corso et al. (2020) conducted a rapid review of the safety of SMT in children (< 10 years). Their aim was to 1) describe adverse events; 2) report the incidence of adverse events; and 3) determine whether SMT increases the risk of adverse events compared to other interventions. Authors found that most adverse events are mild (e.g., increased crying, soreness). One case report describes a severe adverse event (rib fracture in a 21-day-old) and another an indirect harm in a 4-month-old. The incidence of mild adverse events ranges from 0.3% to 22.22%. Whether SMT increases the risk of adverse events in children is unknown. Authors concluded that the risk of moderate and severe adverse events is unknown in children treated with SMT. It is unclear whether SMT increases the risk of adverse events in children < 10 years. Vos et al. (2021) carried out a 3- year survey on pediatric use of complementary and alternative medicine (CAM) in the Netherlands Pediatricians were asked to register cases of adverse events associated with pediatric CAM usage. In 3 years, 32 unique adverse events were registered. Twenty-two of these adverse events were indirect and not related to the specific CAM therapy but due to delaying, changing, or stopping of regular treatment, a deficient or very restrictive diet or an incorrect diagnosis by a CAM therapist. These events were associated with many different CAM therapies. Nine events were deemed direct adverse events like bodily harm or toxicity and one-third of them occurred in infants. Only supplements, manual therapies, and (Chinese) herbs were involved in these nine events. For SMT, 2 adverse events occurred: torticollis and transient nerve palsy. Relatively few cases of adverse events associated with pediatric CAM usage were found, mostly due to delaying or stopping conventional treatment. Nevertheless, parents, pediatricians and CAM providers should be vigilant for both direct and indirect adverse events in children using CAM, especially in infants.

Clinicians need to provide pediatric patients and their parents or guardians with information regarding benefits, harms, and alternatives relevant to making an informed treatment decision.

PRACTITIONER SCOPE AND TRAINING

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

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

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

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

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