



Utilization Management Policy

Manual Therapy Interventions for Non-Musculoskeletal Disorders

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Policy Statement

Optum* by OptumHealth Care Solutions, LLC considers manual therapy interventions including spinal or extraspinal manipulative/mobilization therapy to be unproven and not medically necessary for the treatment of non-musculoskeletal disorders.

The use of manual therapy interventions for the treatment of non-musculoskeletal conditions is supported by some positive published data regarding safety and/or effectiveness. However, a beneficial impact on health outcomes has not been proven for at least one of two reasons: (1) data are sparse and the level of evidence is generally low, or (2) data are inconsistent or conflicting.

Purpose

This policy serves as the criterion for utilization review decisions concerning manual therapy interventions including spinal and extraspinal manipulation/mobilization therapy for the treatment of non-musculoskeletal disorders.

The policy document describes Optum’s position concerning the evidence-basis of manual therapy interventions including manipulative/mobilization services described as high velocity/low amplitude, low velocity/high amplitude (low force), hand-held mechanically assistive manipulation, muscle energy, and soft-tissue techniques, when rendered in the treatment of non-musculoskeletal conditions.

Key Policy Question

“Is there sufficient research evidence of the efficacy and safety of manual therapy interventions including manipulative/mobilization therapy to conclude these services are proven therapeutic options for treating one or more non-musculoskeletal conditions?”

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Summary

Since the inception of this policy, there has been no substantive shift in the conclusions drawn from the body of evidence regarding manual therapy interventions for the treatment of non-musculoskeletal disorders including the results of recently published literature reviews, evidence reports and primary studies. Collectively, the direction of outcomes favored subjects receiving manual therapy interventions. However, the limited number of studies and the quality of research evidence (designs, methodologies, sample sizes, variation of interventions, and outcomes measured) do not permit confident judgments about the effectiveness and safety of manual therapy interventions for the treatment of non-musculoskeletal disorders. As a result, evidence of effectiveness is lacking, and/or inconclusive. The treatment of non-musculoskeletal disorders using manual therapy interventions is unproven.

Scope

The *scope* of this policy document is limited to those conditions that are best categorized as nonmusculoskeletal disorders. Conditions that typically present in association with musculoskeletal disorders (e.g., vertigo and headache) are *out of scope*. Further, manipulation/mobilization under anesthesia was not included as a manual therapy intervention, as this procedure is addressed in a separate policy.

Terminology

The following descriptions are applicable to this policy document:

- *Nonmusculoskeletal disorders* are those conditions that are not broadly regarded as having primary etiologies within the musculoskeletal system.
- *Manual therapy* is a non-surgical clinical approach that includes different skilled hands-on and/or instrument-assisted techniques used by qualified healthcare providers to assess and/or treat soft tissues and joint structures for the purpose of modulating pain; increasing range of motion (ROM); reducing or eliminating soft tissue inflammation; inducing relaxation; improving contractile and non-contractile tissue repair, extensibility, and/or stability; facilitating movement; and improving function.
- *Manual therapy interventions* constitute a wide variety of different techniques, which may be categorized into four major groups:
 - Manipulation (thrust manipulation)
 - Mobilization (non-thrust manipulation and soft-tissue mobilization)
 - Static stretching
 - Muscle energy techniques.

The definitions and purposes of manual therapy interventions vary across health care professionals.

- *Medical necessity* is demonstrated through prevailing peer-reviewed medical literature to be either:
 - Safe and effective for treating or diagnosing the condition for which their use is proposed or;
 - Safe with promising efficacy in a clinically controlled research setting and using a specific research protocol that meets standards equivalent to those defined by the National Institute of Health.
- A *systematic review* is a critical assessment and evaluation of all research studies that address a particular clinical issue. The researchers use an organized method of locating, assembling, and evaluating a body of literature on a particular topic using a set of specific criteria.

Background

While manual therapy interventions are widely seen as reasonable treatment options for biomechanical spinal disorders (eg, neck pain and low back pain) and certain extremity conditions, the use of manual therapy interventions to treat non-musculoskeletal complaints is controversial. The body of literature investigating the physiological evidence (eg, somato-autonomic reflexes, somato-humoral pathways, somato-visceral responses) that manual therapy (eg, spinal manipulation) can impact visceral function is not large [1]. While limited literature confirms that mechanical stimulation of the spine modulates some organ functions in some cohorts [1], there is a need for more study investigating a comprehensive neurobiological rationale before using a biomechanical treatment of the spine to address disorders of visceral [nonmusculoskeletal] function can be justified.

Notwithstanding the shortcomings of evidence supporting the biologic plausibility of manual therapy interventions for the treatment of non-musculoskeletal disorders, there is a history of anecdotal reports (suggesting clinical plausibility) and moderate interest by manual therapy practitioners [2]. Manual therapy interventions have been reportedly used to treat a wide range of non-musculoskeletal disorders [Table 1].

Previous evidence syntheses [3,4] showed there are relatively few primary studies to inform clinical practice. The body of studies is characterized mainly by case reports, small cohorts of subjects, uncontrolled trials, one time pilot experimental investigations with no subsequent follow-up, and few higher-quality randomized clinical trials. The field has been slow to adopt more rigorous study designs, using well-supported methods and validated outcomes, needed to determine the therapeutic effectiveness of manual therapy interventions for various non-musculoskeletal disorders.

Bronfort, et al [4] described the limitations in the available evidence as well as a range of topics needed in a more extensive review. Since then, there have been a number of systematic reviews that critically appraised evidence including randomized controlled/clinical trials, controlled cohort studies, nonrandomized controlled trials, and other observational designs. This revision of the policy document focuses on the evidence described in these recently published systematic reviews and reports.

Literature Review

Search Strategy:

The Cochrane Back Review Group guidance [5] for conducting a literature search was followed by the work group. Biomedical databases and commercial search engines were used to identify and retrieve relevant evidence. Hand-searches of bibliographies and non-indexed documents were included in the search strategy. Additionally, accessible professional specialty society websites were searched for research evidence. Research in-progress and protocols were identified by searching www.clinicaltrials.gov and published protocols.

Systematic literature reviews were included if they reported on the discrete effects of one or more manual therapies for one or more non-musculoskeletal disorders. While the ideal approach would have been to use only systematic reviews of RCTs, a scoping review of the literature suggested limited data available. Therefore, reviews including quasi experimental studies; non-randomised controlled trials, observational data were accepted. Studies were excluded for any of the following reasons:

- The study did not investigate the effect of at least one manual therapy for a non-musculoskeletal disorder;
- The study was not characterized as a systematic review (eg, commentaries, consensus studies, surveys, etc.);
- The study represented a previous version of an included review;
- The study reported on the effects of combined interventions (eg, whole systems research methods)

Evidence Extraction:

Seventeen systematic literature reviews were identified [Table 2]. There were five relevant systematic reviews of manual therapy interventions for the treatment of respiratory disorders including asthma [6-8]; cystic fibrosis, bronchiolitis, recurrent infections [8]; pneumonia [9]; and chronic pulmonary obstructive disease [10]. Four systematic reviews examined the use of manual therapies for the management of gastro-intestinal disorders affecting infants (infantile colic [11,12]) and adults (irritable bowel syndrome [13], gastroesophageal reflux and duodenal ulcers [14]). An additional three systematic reviews [15-17] reported on the efficacy of a range of manual therapies for the treatment of otitis media. Single systematic reviews of manual therapy interventions were identified for the treatment of attention deficit hyperactivity disorder (ADHD) [18], hypertension [19], nocturnal enuresis [20], insomnia [21], and lower urinary tract symptoms (LUTS) [22].

Additionally, data were extracted from three primary studies (experimental and observational designs) that were identified as having been conducted after the publication of relevant systematic reviews. Two small randomized clinical trials (RCTs) that investigated osteopathic manipulative treatment for pediatric non-musculoskeletal disorders were identified [23,24]. A retrospective case series reported changes in urinary incontinence following a treatment regime consisting of a range of manual therapy interventions [25].

Evidence Appraisal:

The selected systematic reviews were critically appraised for quality using the AMSTAR (A Measurement Tool to Assess Reviews) instrument [26,27]. The AMSTAR tool is comprised of 11 items that question the methodological quality of systematic reviews. It has good face and content validity. Literature reviews were rated as being methodologically strong (i.e. good quality), if the AMSTAR score was ≥ 6 . This interpretation is consistent with the approaches of other recent 'reviews of reviews' [28-30]. For the primary studies, the two experimental designs (RCTs) were assessed for risk of bias using the Cochrane Back Review Group risk of bias methodology [5]; and the appraisal scheme described by Chan and Bhandari [31] was applied to the case series in assessing risk of bias.

Twelve of the 17 included systematic reviews were recently quality appraised, as part of the methods used in a comprehensive evidence synthesis of manual therapy interventions, using the AMSTAR tool [32]. The ratings from this publication have been adopted for the purposes of this policy [Table 2]. The remaining five systematic reviews were appraised using the AMSTAR tool by the policy work group [Appendix A]. Overall, twelve of the reviews were rated as being methodologically strong (≥ 6). Both RCTs were qualitatively appraised as having a low risk of bias [Appendix B]. The single retrospective case series was assessed as having a high risk of bias [Appendix C]. This study did not describe the inclusion/exclusion criteria (eg, recent chiropractic care). Further, clinically relevant outcomes – as recommended by the International Urogynecological Association (IUGA) guidelines [33] – in the form of validated questionnaires (eg, the Urogenital Distress Inventory (UDI) for Women or the Severity Index for Urinary Incontinence in Women) and/or objective measures (eg, pad testing) were not reported.

Results/Conclusions:

The results and conclusions of the included systematic reviews have been abstracted into Table 2. Collectively, the direction of outcomes favored subjects receiving manual therapy interventions. However, the limited number of studies and the quality of research evidence (designs, methodologies, sample sizes, variation of interventions, and outcomes measured) do not permit confident judgments about the effectiveness and safety of manual therapy interventions for the treatment of non-musculoskeletal disorders. When only those reviews appraised as being of good quality (AMSTAR score ≥ 6) are considered [7-10,12-14,17-20,22], these conclusions do not change.

The findings of the limited number of new primary research evidence parrots the results and conclusions of systematic reviews. The favorable outcomes reported in pilot RCTs [23,24] for patients receiving OMT in addition to usual care require larger trials in order to make firm judgments. The single case series design [25] does not permit conclusions about effectiveness. Higher-quality study designs (eg, RCTs) using rigorous methods and validated outcomes are needed.

Other Evidence Syntheses:

In addition to systematic literature reviews and recent primary studies, at least six evidence syntheses reported on the application of manual therapy interventions for a broad range of non-musculoskeletal disorders [Table 3]. Four of the 6 syntheses [32,34-36] provided quality appraisal. Two of these [32,34] included an assessment of adverse event reporting. Two additional descriptive evidence syntheses [37,38] provided narrative summaries of the evidence for a number of non-musculoskeletal disorders.

Uniformly, the authors of these publications found the evidence lacking, inconclusive or unproven in assessing the effectiveness of manual therapy interventions for the treatment of non-musculoskeletal disorders. Consequently, none of the evidence syntheses provided a basis of support for the medical necessity of manual therapy interventions for the treatment of non-musculoskeletal disorders.

Conclusion

Potential but unproven benefit: The use of manual therapy interventions for the treatment of non-musculoskeletal conditions is supported by some positive published data regarding safety and/or effectiveness. However, a beneficial impact on health outcomes has not been proven for at least one of two reasons: (1) data are sparse and the level of evidence is generally low, or (2) data are inconsistent or conflicting [39].

Coding Information

Note: The Current Procedural Terminology (CPT) codes listed in this policy may not be all inclusive and are for reference purposes only. The listing of a service code in this policy does not imply that the service described by the code is a covered or non-covered health service. Coverage is determined by the member’s benefit document.

Code	Description
97140	Manual therapy techniques (e.g. mobilization, manipulation, manual lymphatic drainage, manual traction) one or more regions, each 15 minutes
98925	Osteopathic manipulative treatment (OMT); 1-2 body regions involved
98926	Osteopathic manipulative treatment (OMT); 3-4 body regions involved
98927	Osteopathic manipulative treatment (OMT); 5-6 body regions involved
98928	Osteopathic manipulative treatment (OMT); 7-8 body regions involved
98929	Osteopathic manipulative treatment (OMT); 9-10 body regions involved
98940	Chiropractic manipulative treatment (CMT); spinal, one to two regions
98941	Chiropractic manipulative treatment (CMT); spinal, three to four regions
98942	Chiropractic manipulative treatment (CMT); spinal, five regions
98943	Chiropractic manipulative treatment (CMT); extraspinal, one or more regions

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Tables

Table 1: Non-musculoskeletal Conditions reportedly treated using manual therapy interventions

Table 2: Reviews Included in the Evidence Summary

Table 3: Evidence Syntheses Included in the Literature Review

Table 4: What are the Policies/Positions of Other Organizations?

Appendices

Appendix A: Quality Appraisal of Systematic Reviews Not Previously Reported

Appendix B: Risk of Bias Appraisals for Selected Randomized Clinical Trials

Appendix C: Risk of Bias Appraisal for Selected Case Series

Non-musculoskeletal Conditions reportedly treated using manual therapy interventions Table 1

Conditions Addressed	
Vision/optic nerve ischemia/constricted visual fields	Infertility/amennorrhea
Asthma	ADHD/learning disabilities
Hypertension	GERD
Hypercholesterolemia	Chronic pelvic pain
Infantile colic	Dysfunctional nursing
Otitis media	Nocturnal enuresis
Dysmenorrhea/PMS/endometriosis	Constipation
Chronic obstructive pulmonary disease	Seizures/epilepsy
Visceral-related pain disorders	Pneumonia
Arrhythmia/ECG abnormalities	Parkinson's disease
Depression	Phobia/anxiety
Bowel/bladder dysfunction	Cerebral palsy
Crohn's disease/irritable bowel syndrome	Jet lag
Multiple sclerosis	Duodenal ulcer
Upper respiratory infection	Autism
Dysphonia	Eczema/psoriasis
Encopresis	Hearing loss/tinnitus
Aphasia	Cancer pain
Cystic hygroma	Diabetes
Diabetic polyneuropathy	Down syndrome
Urinary tract infection	Vertebrobasilar ischemia
Bell's palsy	Reflex sympathetic dystrophy
Tourette syndrome	AIDS-related complex
Chronic fatigue syndrome	Systemic lupus erythematosus

Adapted from Hawk, et al [3] and Budgell [40]



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Reviews Included in the Evidence Summary

Table 2

Author (Year)	Disorder	Population	Intervention	Comparator	Results	Quality Appraisal			AMSTAR Rating*
						Quality	Method	Adverse Events	
Kaminskyj (2010)	- Asthma	- Adults - Pediatric	- Any type of CMT	- Sham	Results of the eight retrieved studies indicated that chiropractic care showed improvements in subjective measures and, to a lesser degree objective measures, none of which were statistically significant. It is evident that some asthmatic patients may benefit from this treatment approach; however, at this time, the evidence suggests chiropractic care should be used as an adjunct, not a replacement, to traditional medical therapy.	Quality ratings ranged from poor to good	Down's and Black	Not reported	7.5/11
Alcantara (2012)	- Asthma	- Adults - Pediatric	- Any type of CMT with or without: - Nutritional support - Medication	- Not reported	The lower level design studies provide some measure of evidence on the effectiveness of chiropractic care for patients with asthma, while a critical appraisal of 3 RCTs revealed questionable validity of the sham SMTs involved and hence the conclusions and interpretations derived from them. The RCTs on chiropractic and asthma are arguably comparison trials rather than controlled clinical trials per se. Chiropractic may offer an alternative care approach for asthmatic patients. Future investigations of this conservative care approach for patients with asthma should pave the way for higher-level design studies such as randomized controlled clinical trials.	None	N/A	Not reported	
Pepino (2013)	- Asthma - Cystic fibrosis - Bronchiolitis - Recurrent respiratory infections	- Children and adolescents 0-17 yrs.)	- Manual therapy techniques including: - SMT - OMT - Massage	- Parental interventions eg, relaxation advice, bedtime reading - Sham - Medical care - Soft tissue technique	There is some evidence, although from low quality studies, suggesting that manual therapy has some beneficial effect on children with respiratory disease. The lack of standardized procedures and limited variety of methods used evidenced the need for more studies on the subject.	- Scores ranged from 2-7 on a scale of 0-10 (10 = lowest RoB) - Median = 5	PEDro	Not reported	
Karpouzis (2010)	- ADHD	- Children and adolescents 0-17 yrs.) - Diagnosis of ADHD consistent with DSM-III, DSM-IV, DSM-IV-TR or ICD-10 criteria - Diagnosis made by Pediatrician, Psychiatrist, Medical Doctor, Clinical or Educational Psychologist	- Any type of CMT with or without: - Dietary advice - Supplements - Exercise - Cranio-sacral therapy	None (no clinical trials met inclusion criteria)	The current finding for this systematic review has been classified as an 'empty review'. As a result, to date there is no high quality evidence to evaluate the efficacy of chiropractic care for paediatric and adolescent ADHD. The claims made by chiropractors that chiropractic care improves ADHD symptomatology for young people are only supported by low levels of scientific evidence. In the interest of paediatric and adolescent health, if chiropractic care is to continue for this clinical population, more rigorous scientific research needs to be undertaken to examine the efficacy and effectiveness of chiropractic treatment for ADHD.	Poor quality	Jadad	Not reported	8.5/11

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Mangum (2012)	- Hypertension	- Patients with hypertension	- Any type of SMT	- Effleurage massage - No treatment - Sham - Placebo - Diet intervention	Statistically significant decreases in blood pressure were not observed in clinical trials with low bias. The studies with more risk of bias showed a greater treatment effect. There is currently a lack of low bias evidence to support the use of SMT as a therapy for the treatment of hypertension.	- 2 = Low RoB - 3 = Unclear - 5 = High RoB	Cochrane guidelines	Not reported	7.5/11
Alcantara (2011)	- Infantile colic	- Children and adolescents (0-18 yrs.)	- Any type of SMT	- No treatment - Medication - Occipito-sacral decompression treatment	Chiropractic care is an alternative approach to the care of the child with colic. We encourage more research, both quantitative and qualitative, in this area of pediatric care.	None	N/A	Not reported	3.5/11
Dobson (2012)	- Infantile colic	- Infants younger than six months of age (at entry to study)	- Any type of SMT including OMT, CMT and cranio-sacral therapy	- Various controls	The studies included in this meta-analysis were generally small and methodologically prone to bias, which makes it impossible to arrive at a definitive conclusion about the effectiveness of manipulative therapies for infantile colic. The majority of the included trials appeared to indicate that the parents of infants receiving manipulative therapies reported fewer hours crying per day than parents whose infants did not, based on contemporaneous crying diaries, and this difference was statistically significant. The trials also indicate that a greater proportion of those parents reported improvements that were clinically significant. However, most studies had a high risk of performance bias due to the fact that the assessors (parents) were not blind to who had received the intervention. When combining only those trials with a low risk of such performance bias, the results did not reach statistical significance. Further research is required where those assessing the treatment outcomes do not know whether or not the infant has received a manipulative therapy.	Variable	Cochrane guidelines (GRADE)	Inadequate data	10/11
Müller (2014)	- Irritable bowel syndrome	- Adults (≥18 yrs.) - Diagnosed using Rome (I-III) criteria	- Any type of OMT	- Sham - Standard medical treatment	The current systematic review of 5 RCTs indicated favorable results for OMT compared with standard medical therapies or sham interventions in the management of IBS. Caution is required when interpreting these results, however, because of the limited number of studies available and the small sample sizes. Future studies should include VAS and a validated questionnaire in their study design so that the results of those studies could be included in future meta-analyses.	Low RoB	Cochrane guidelines	None reported	
Ernst (2011)	- Gastrointestinal problems including gastro-esophageal reflux disease and duodenal ulcers,	- Not described	- SMT with or without ischemic compression - SMT with or without conventional medical care	- Mono vs. combined therapies	There is no supportive evidence to show that chiropractic treatments [SMT and soft tissue manual therapy] are effective for gastrointestinal problems.	Poor quality	Jadad	Not reported	6.5/11

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Huang (2011)	- Nocturnal enuresis	- Children (as defined by the trialists, usually up to age 16)	- CMT	- Sham - Wait list control - Medication	There was weak evidence to support the use of chiropractic [SMT] but it was provided by 3 small trials of dubious methodological rigor. Robust randomized trials are required with efficacy, cost-effectiveness and adverse effects clearly reported.	Unclear RoB	Cochrane guidelines	Reported in a single trial. AE included: headache, stiff neck and lumbar spine pain	9/11
Leighton (2009)	- Chronic otitis media	- Children (6 mos. - 6 yrs.)	- Wide range of manual intervention techniques	- Sham - Standard medical treatment	The evidence is inconclusive as to whether chiropractic or other manual therapy protocols may benefit over placebo in the treatment of otitis media.	None	N/A	Not reported	
Pohlman (2012)	- Otitis media (acute or chronic)	- Children (6 yrs. or younger)	- Any type of SMT including CMT and OMT	- Controls not described	From the 49 studies 17 surveys/editorials/commentaries, 15 case reports, 5 case series, 8 reviews, and 4 clinical trials) found in this report, there was limited quality evidence for the use of SMT for children with OM. There are currently no evidence to support or refute using SMT for OM and no evidence to suggest that SMT produces serious adverse effects for children with OM. More rigorous studies are needed to provide evidence and a clearer picture for both practitioner and patients.	Ranged from fair to excellent based on self-established criteria Data (eg, RoB tables) were not reported	CMAJ (case reports) Yang (case series) CONSORT (clinical trials) QUORUM (review articles)	No serious AE were found; minor transient AE were noted in 1 case series article and 2 of the clinical trials.	9/11
Carr (2006)	- Otitis media (acute)	- Children (median age 1.9 yrs.)	- OMT	- Sham - Placebo	Current data are generally inadequate to support CAM for the prevention or treatment of URTI in children.	None	N/A	Not reported	
Yang (2010 rev. 2013)	- Pneumonia	- Adults (>18 yrs.) with any type of pneumonia	- OMT including: paraspinal inhibition, rib raising and myofascial release	- Placebo	OMT (versus placebo) did not: 1) improve mortality rates of adults with pneumonia; 2) increase the cure rate or chest X-ray improvement rate; and 3) reduce fever duration. OMT (versus placebo) reduced duration of intravenous (MD -2.1 days, 95% CI -3.4 to -0.9) and total antibiotic treatment (MD -1.9 days, 95% CI -3.1 to -0.7). OMT also reduced the mean duration of hospital stay by 2.0 days. In summary, chest physiotherapy [including OMT] should not be recommended as routine adjunctive treatment for pneumonia in adults.	All included studies were of poor to moderate quality	Cochrane guidelines	Transient muscle tenderness emerged after treatment in two individuals during the period of study.	9.5/11
Heneghan (2012)	- COPD	- Adults with a history of chronic obstructive airways disease, including patients described as having COPD, emphysema and chronic bronchitis. - There were no age restrictions.	- Manual therapy techniques including OMT, massage, muscle stretching, and passive movements	- Control period - Sham technique - Alternative manual therapy intervention	Evidence for manual therapies as an adjunctive management approach for COPD is lacking. More exploratory research is first required to better understand the nature and extent of changes in the musculoskeletal system in patients with COPD and their possible relationship with pulmonary function.	High RoB = 6 studies Low RoB = 1 study	Cochrane guidelines	Not reported	8/11
Kingston (2010)	- Insomnia	- Not described	- Manual therapy such as SMT or muscle relaxation techniques	- No treatment control	Some studies have noted improvement in insomnia following manual therapy; however, based on clinical trials, there is minimal evidence of support for chiropractic in insomnia. Further studies with high methodological scores need to be conducted.	None	N/A	Not reported	2.5/11

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Franke (2013)	<ul style="list-style-type: none"> - lower urinary tract symptoms (LUTS) 	<ul style="list-style-type: none"> - Female - ≥ 18 yrs. old - A diagnosed female urinary tract disorder 	<ul style="list-style-type: none"> - OMT (with or without PFMT) 	<ul style="list-style-type: none"> - No treatment control - PFMT 	<p>The quantitative analysis shows a statistically significant and clinically relevant improvement when the osteopathic intervention was compared to an untreated group. Two studies which compare OMT with the pelvic floor muscle training as a reference treatment document almost the same therapeutic effect.</p> <p>The findings of this systematic review and meta-analysis are promising and encouraging to conduct larger, rigorous osteopathic intervention studies for female urination disorders. Future studies should compare the osteopathic treatment with established standard procedures in the control group.</p>	Low RoB = All 5 studies	Cochrane guidelines	Not reported	9/11
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Legend:

ADHD = attention deficit hyperactivity disorder; AE = adverse events; CAM = complementary and alternative medicine; CMT = chiropractic manipulative treatment; CNLDO = congenital nasolacrimal duct obstruction; COPD = chronic obstructive pulmonary disease; OM = otitis media; OMT = osteopathic manipulative therapy; PFMT = Pelvic floor muscle training; RCT = randomized clinical trial; RoB = risk of bias; SMT = spinal manipulative treatment; URTI = upper respiratory tract infection

*AMSTAR ratings obtained from Clar, et al. [32]

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Evidence Syntheses Included in the Literature Review

Table 3

Author (Year)	Disorder(s)	Population	Intervention	Comparator	Results	Quality Appraisal		Adverse Events	Supports Medical Necessity
						Quality	Method		
Clar (2014)	<ul style="list-style-type: none"> - Asthma - ADHD/Learning disorders - Cancer care - Cerebral palsy - Chronic fatigue - Chronic pelvic pain - Cystic fibrosis - Dysfunctional voiding (pediatric) - Gastrointestinal - Hypertension - Infantile colic - Insomnia - Menopausal symptoms - Otitis media - Parkinson's disease - Pediatric nocturnal enuresis - Peripheral artery disease - Pneumonia / respiratory disorders - Systemic sclerosis - Dysmenorrhea - Premenstrual syndrome 	<ul style="list-style-type: none"> - Mixed - Adults - Pediatric 	<ul style="list-style-type: none"> - SMT - OMT - Cranio-sacral therapy - Chiropractic care - Massage - Myofascial release including strain / counterstrain - Distension of pelvic structures - Mobilization - Upper cervical (NUCCA) SMT - Instrument-assisted SMT - Gonstead technique - Fox's low-force OMT - Kinesiotherapy - McMennell joint manipulation 	<ul style="list-style-type: none"> - Control - Placebo - Sham - Usual care - Educational support - Exercise - Acupuncture 	<p>Both Bronfort et al. [20] and the current review considered the evidence for treating a large range of non-MSK conditions, but despite finding additional evidence in some cases, the current review was unable to change the inconclusive evidence ratings for these conditions including:</p> <ul style="list-style-type: none"> - Asthma using osteopathic manual therapy; - Paediatric nocturnal enuresis using spinal manipulation; - Infant colic using cranial osteopathic manual therapy (although new evidence appeared more favourable than that reported in the UK evidence report); - Premenstrual syndrome using spinal manipulation; - Stage 1 hypertension using upper cervical (NUCCA) spinal manipulation; - Stage 1 hypertension using instrumental assisted spinal manipulation; - Otitis media and pneumonia in elderly adults using osteopathic manual therapy; and - Pneumonia in elderly adults using osteopathic manual therapy. 	Predominantly "inconclusive" with "favorable" results	AHRQ guidelines	12 – systematic reviews 13 – primary studies	No
Posadzki (2013)	<ul style="list-style-type: none"> - Cerebral palsy - Respiratory conditions - Otitis media - ADHD - Infantile colic - CNLDO - Dysfunctional voiding 	<ul style="list-style-type: none"> - Children and adolescents (≤18 yrs.) 	<ul style="list-style-type: none"> - OMT 	<ul style="list-style-type: none"> - Any types of controls 	The effectiveness of OMT for pediatric [non-MSK] conditions is unproven	Overall quality was poor No RCT was free of major limitations	Cochrane guidelines	9 of 13 non-msk RCTs did not report on AE	No
Gleberzon (2012)	<ul style="list-style-type: none"> - Infantile colic - Asthma - Otitis media - Autism - Suboptimal breastfeeding - Enuresis - Jet lag 	<ul style="list-style-type: none"> - Children and adolescents (≤18 yrs.) 	<ul style="list-style-type: none"> - High-velocity low-amplitude (HVLA) CMT 	<ul style="list-style-type: none"> - Control - Placebo - Sham - Pharmacotherapy - Soft tissue technique 	Studies that monitored both subjective and objective outcome measures of relevance to both patients and parents tended to report the most favorable response to SMT, especially among children with asthma. Many studies reviewed suffered from several methodological limitations. Further research is clearly required in this area of chiropractic health care...	RoB not explicitly determined Quality scores ranged from 18 to 48 on a 50 point scale	Sackett	None reported	No

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Ferrance (2010)	<ul style="list-style-type: none"> - Infantile colic - Asthma - Otitis media - ADHD - Nocturnal enuresis 	<ul style="list-style-type: none"> - Children (age range not explicitly stated) 	<ul style="list-style-type: none"> - SMT - Finger pressure - OMT - Cranial manipulation 	<ul style="list-style-type: none"> - Control - Placebo - Sham - Medication 	<p>Most of the published literature centers around case reports or series. The more scientifically rigorous studies show conflicting results for colic and the crying infant, and there is little data to suggest improvement of otitis media, asthma, nocturnal enuresis or attention deficit hyperactivity disorder.</p> <p>The efficacy of chiropractic care in the treatment of non-musculoskeletal disorders has yet to be definitely proven or disproven, with the burden of proof still resting upon the chiropractic profession.</p>	None	N/A	Not reported	No
Cole (2010)	<ul style="list-style-type: none"> - Infantile colic - Asthma - Otitis media - Irritable bowel syndrome - COPD 	<ul style="list-style-type: none"> - Mixed - Adults - Pediatric 	<ul style="list-style-type: none"> - Any type of OMT 	<ul style="list-style-type: none"> - Sham - Standard medical treatment 	<p>The authors reported on a limited number of studies that showed some positive findings for OMT in the treatment of otitis media. For other conditions the summarized results were not significant or the data were deemed insufficient to make a recommendation.</p>	None	N/A	Not reported	No
Gotlib (2008)	<ul style="list-style-type: none"> - Asthma - ADHD/Learning disorders - Seizures - Sleep dysfunction - Dyslexia - Irritable baby syndrome - Constipation - GERD - Otitis media - Autism - Infantile colic - Difficulty breastfeeding - Jet lag 	<ul style="list-style-type: none"> - Children and adolescents (≤18 yrs.) 	<ul style="list-style-type: none"> - High-velocity low-amplitude (HVLA) CMT 	<ul style="list-style-type: none"> - Control - Placebo - Sham - Medication - Optimal medical management 	<p>There has been no substantive shift in this body of knowledge during the past 3 ½ years. The health claims made by chiropractors with respect to the application of manipulation as a health care intervention for pediatric health conditions continue to be supported by only low levels of scientific evidence. Chiropractors continue to treat a wide variety of pediatric health conditions. The evidence rests primarily with clinical experience, descriptive case studies and very few observational and experimental studies. The health interests of pediatric patients would be advanced if more rigorous scientific inquiry was undertaken to examine the value of manipulative therapy in the treatment of pediatric conditions.</p>	<p>Most evidence is at low levels</p> <p>RoB not assessed</p>	Levels of evidence	Not reported	No

Legend:

ADHD = attention deficit hyperactivity disorder; AE = adverse events; CAM = complementary and alternative medicine; CMT = chiropractic manipulative treatment; CNLDO = congenital nasolacrimal duct obstruction; COPD = chronic obstructive pulmonary disease; GERD = gastro-esophageal reflux disease; OM = otitis media; OMT = osteopathic manipulative therapy; PFMT = Pelvic floor muscle training; RCT = randomized clinical trial; RoB = risk of bias; SMT = spinal manipulative treatment; URTI = upper respiratory tract infection

Appendix A

Quality Appraisal of Systematic Reviews Not Previously Reported

Appraisal Methods		Quality Appraisal				
Item	Description	Alcantara (2012)	Pepino (2013)	Müller (2014)	Leighton (2009)	Carr (2006)
Was an 'a priori' design provided?	The research question and inclusion criteria should be established before the conduct of the review.	Yes	Yes	Yes	Yes	Yes
Was there duplicate study selection and data extraction?	There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.	Yes (however, the consensus process was not reported)	Yes	Yes	No	No
Was a comprehensive literature search performed?	At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.	Yes	Yes (however, supplemental searches were not reported)	Yes	Yes (however, supplemental searches were not reported)	Yes
Was the status of publication (e.g., grey literature) used as an inclusion criterion?	The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.	Yes	No	Yes	Yes	Yes
Was a list of studies (included and excluded) provided?	A list of included and excluded studies should be provided.	No	Yes (although, excluded studies were not listed)	Yes (although, excluded studies were not listed)	Yes (although, excluded studies were not listed)	No
Were the characteristics of the included studies provided?	In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.	No	Yes	Yes	Yes	No
Was the scientific quality of the included studies assessed and documented?	'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.	No	Yes	Yes	No	No
Was the scientific quality of the included studies used appropriately in formulating conclusions?	The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.	N/A	Yes	Yes	N/A	N/A
Were the methods used to combine the findings of studies appropriate?	For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I ²). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).	N/A	N/A	N/A	N/A	N/A
Was the likelihood of publication bias assessed?	An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).	No	No	No	No	No
Was the conflict of interest stated?	Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.	No	Yes	Yes	No	No
Score		4	8	9	4	3

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Appendix B

Risk of Bias (limitations in study design or implementation)

Title: Steele KM, Carreiro JE, Viola JH, et al. Effect of osteopathic manipulative treatment on middle ear effusion following acute otitis media in young children: a pilot study. *J Am Osteopath Assoc.* 2014; 114:436-447

Domain	No.	Source	Assessment	Notes
A	1	Was the method of randomization adequate?	Yes	Assigned using a web-based "randomizer"
B	2	Was the treatment allocation concealed?	Unknown	Allocation method not described
C		Was knowledge of the allocated interventions adequately prevented during the study?		
	3	Was the patient (parent) blinded to the intervention?	No	Attempts at blinding were not successful
	4	Was the care provider blinded to the intervention?	No	
	5	Was the outcome assessor blinded to the intervention?	Yes	
D		Were incomplete outcome data adequately addressed?		
	6	Was the drop-out rate described and acceptable?	Yes	17% drop-out rate
	7	Were all randomized participants analyzed in the group to which they were allocated?	Yes	
E	8	Are reports of the study free of suggestion of selective outcome reporting?	Yes	
F		Other sources of potential bias:		
	9	Were the groups similar at baseline regarding the most important prognostic indicators?	Yes	Tables 1 and 2
	10	Were co-interventions avoided or similar?	Yes	
	11	Was the compliance acceptable in all groups?	Yes	
	12	Was the timing of the outcome assessment similar in all groups?	Yes	
Total Score			9/12	Low Risk of Bias

Interpretation:

- Low risk of bias = when at least 6 of the 12 criteria have been met and the study has no serious flaws (e.g., 80% drop-out rate in 1 group).
- High risk of bias = Studies with serious flaws, or those in which fewer than 6 of the criteria are met

Reference: Furlan AD, Pennick V, Bombardier C, van Tulder M. 2009 Updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine* 2009; 34:1929-1941

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Risk of Bias (limitations in study design or implementation)

Title: Accorsi A, Lucci C, Di Mattia L, et al. Effect of osteopathic manipulative therapy in the attentive performance of children with attention-deficit/hyperactivity disorder. *J Am Osteopath Assoc.* 2014; 114:374-81

Domain	No.	Source	Assessment	Notes
A	1	Was the method of randomization adequate?	Yes	Assigned using permuted-block process and generated by the R statistical program
B	2	Was the treatment allocation concealed?	Yes	
C		Was knowledge of the allocated interventions adequately prevented during the study?		
	3	Was the patient (parent) blinded to the intervention?	No	
	4	Was the care provider blinded to the intervention?	No	
	5	Was the outcome assessor blinded to the intervention?	Unknown	
D		Were incomplete outcome data adequately addressed?		
	6	Was the drop-out rate described and acceptable?	Yes	0% drop-out rate
	7	Were all randomized participants analyzed in the group to which they were allocated?	Yes	
E	8	Are reports of the study free of suggestion of selective outcome reporting?	Yes	
F		Other sources of potential bias:		
	9	Were the groups similar at baseline regarding the most important prognostic indicators?	Yes	Table 1
	10	Were co-interventions avoided or similar?	Unknown	Participants not controlled for other psychosocial and drug treatments
	11	Was the compliance acceptable in all groups?	Yes	
	12	Was the timing of the outcome assessment similar in all groups?	Yes	
Total Score			8/12	Low Risk of Bias

Interpretation:

- Low risk of bias = when at least 6 of the 12 criteria have been met and the study has no serious flaws (e.g., 80% drop-out rate in 1 group).
- High risk of bias = Studies with serious flaws, or those in which fewer than 6 of the criteria are met

Reference: Furlan AD, Pennick V, Bombardier C, van Tulder M. 2009 Updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine* 2009; 34:1929-1941

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Appendix C

Risk of Bias (limitations in study design or implementation)

Title: Cuthbert SC, Rosner AL. Conservative chiropractic management of urinary incontinence using applied kinesiology: a retrospective case-series report. *J Chiropr Med.* 2012;11:49-57.

Clear study objective/question	Yes	The purpose of this case series is to report on the findings of chiropractic management of patients with urinary incontinence
Well-defined study protocol	Yes/No	Protocol included standardized assessment and interventions. The outcome assessment were not described
Explicit inclusion and exclusion criteria for study participants	Yes	Criteria did not account for a minimum Cobb angle or Risser sign. Two of the five subjects had baseline Cobb angles of <10 degrees. Only one subject had a baseline Cobb angle of >20 degrees.*
Specified time interval for patient recruitment	Yes	6-months
Consecutive patient enrollment	Unsure	Not reported
Clinically relevant outcomes	Unsure	Neither validated subjective assessments nor objective measures were explicitly reported
Prospective outcome data collection	No	
High follow-up rate	Yes	100%

Source: Chan K, Bhandari M. Three-minute critical appraisal of a case series article. *Indian Journal of Orthopaedics* 2011; 45:103–104

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Policy History/Revision Information

Date	Action/Description
3/07/2001	Original effective date; Title: <i>Determination of Inappropriate Therapeutic Applications</i>
11/11/2003	Policy inactivated
4/10/2008	Policy activated (approved); Policy re-titled; Literature review included; Plain Language Summary appended
11/11/2008	Policy header rebranded, "OptumHealth Care Solutions – Physical Health"
1/15/2009	Policy placed into new format
4/30/2009	Annual review and approval completed
4/08/2010	Annual review and approval completed
10/26/2010	Policy rebranded to "OptumHealth Care Solutions, Inc. (OptumHealth)"
4/07/2011	Annual review and approval completed
4/19/2012	Annual review and approval completed
4/18/2013	Annual review and approval completed
4/17/2014	Annual review and approval completed; Policy rebranded "Optum* by OptumHealth Care Solutions, Inc."
4/16/2015	Annual review completed
7/30/2015	The policy was revised using recently published systematic reviews and evidence syntheses to inform the policy statement. The policy title was changed to encompass a broader range of manual therapy interventions, which were included in the literature review.
4/21/2016	Table 4 updated; Annual review completed
4/20/2017	Table 4 updated; Annual review completed; Legal entity name changed from "OptumHealth Care Solutions, Inc." to "OptumHealth Care Solutions, LLC."
4/26/2018	Annual review completed; no significant changes made to the document
4/25/2019	Annual review completed; Deleted Table 4 (Policies of other health care organizations)
4/23/2020	Annual review completed; no significant changes made to the document

Contact Information

Please forward any commentary or feedback on Optum utilization management policies to: policy.inquiry@optumhealth.com with the word "Policy" in the subject line.

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PLAIN LANGUAGE SUMMARY***Manual Therapy Interventions for Non-musculoskeletal Disorders***

Utilization Management Policy # 342

Plain Language Summaries are a service provided by *Optum*^{*} by *OptumHealth Care Solutions, LLC* to help patients better understand the complicated and often mystifying language of modern healthcare.

Plain Language Summaries are presented to supplement the associated clinical policy or guideline. These summaries are not a substitute for advice from your own healthcare provider.

What are manual therapy interventions for non-musculoskeletal disorders and what is known about it so far?

Manual therapy interventions include hands-on treatments such as manipulation (adjustments), mobilization (a gentler version of manipulation), and different types of stretching techniques. These “interventions” have been shown to be an effective treatment option for common spinal and extremity pain of musculoskeletal origin. Clinicians such as chiropractors and physical therapists, as well as patients, have observed that manual therapy may also be helpful in the treatment of certain non-musculoskeletal disorders.

Non-musculoskeletal conditions represent a variety of ailments typically associated with body systems such as gastrointestinal, cardiovascular, pulmonary, etc. There are scientific mechanisms and theories¹ suggesting it is possible that manual therapy (usually of the spine) can help in the treatment of these types of conditions. There is little high quality research, however, to support these theories in clinical practice. The conclusions of others who evaluated the literature generally found the evidence to be insufficient to support manual therapy for the treatment of non-musculoskeletal disorders.

How was manual therapy interventions for non-musculoskeletal disorders evaluated?

A work group of clinicians was assigned to review the available research. The internet was searched for policies, guidelines, and articles about manual therapy interventions for the treatment of non-musculoskeletal disorders. Recently published literature reviews on this topic were included in the assessment of research. Additionally, the work group independently examined new research studies. Broadly accepted evidence rating scales were used to determine how confident we can be in the results of these studies.

Before it was approved, the policy was presented to a series of committees that included independent health care practitioners.

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What did the work group find?

The evidence about using manual therapy interventions for the treatment of non-musculoskeletal disorders is generally inconclusive. The number of studies are too few and of lower-quality to prove or disprove the effectiveness of manual therapy interventions for the treatment of non-musculoskeletal disorders.

What were the limitations of the information?

The research on manual therapy interventions is limited primarily to reports of individual cases and series of small numbers of cases. The large majority of these studies were of low to very low quality. Accordingly, any conclusions about the results were uncertain.

What are the conclusions?

Manual therapy interventions for the treatment of non-musculoskeletal disorders are viewed as *unproven* and not medically necessary. Further research is needed before manual therapy interventions can be considered established treatment options for any non-musculoskeletal conditions.