Medical Policy:
Osteopathic Manipulative Treatment (Commercial)

POLICY NUMBER	EFFECTIVE DATE	APPROVED BY
M20190007	**06/21/2020**	MPC (Medical Policy Committee)

IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:

 The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies(LMRP). All coding and web site links are accurate at time of publication.

Overview:

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

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

The diagnosis of somatic dysfunction is made by determining the presence of one or more findings, known as T.A.R.T. (Tenderness, Asymmetry, Restriction of Motion and Tissue Abnormality). Osteopathic manipulative treatment includes thrust (active correction), muscle energy, high velocity-low amplitude, articulation, counterstrain, myofascial release, and visceral and craniosacral techniques. The chosen treatment will vary depending on patient's age and clinical condition.

Somatic dysfunction in one region can create compensatory somatic dysfunction in other regions. Osteopathic manipulative treatment can also be used to treat the somatic component of visceral disease and any organ system. This component can manifest as changes in the skeletal, arthrodial and myofascial tissues. Normalizing musculoskeletal activity (relaxing tense muscles, etc.) can normalize outflows through sympathetic or parasympathetic autonomic nervous systems to visceral systems, resulting in more normal visceral and any organ system function.

Musculoskeletal Disorders: For the purposes of this policy, Musculoskeletal Disorders (MSDs) are injuries or conditions originating from joints, muscles, ligaments, discs, or other soft tissues in the spine or limbs, and produce clinically relevant symptoms (e.g., pain, numbness, etc.) and functional limitations (e.g., ability to perform daily activities).

Policy:

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

The medical record should support the medical necessity of osteopathic manipulative treatment as taught in the United States Osteopathic Medical Schools and made available to ConnectiCare, Inc. upon request.

Documentation of examination findings of somatic dysfunction should describe pathology in the areas of the skeletal, arthroidal and myofascial structures as well as related vascular, lymphatic and neuroelements.

Functional improvement or decline is determined by the treating physician and may be cause for further interventions and/or procedures based upon the evaluation and management services and the presence or absence of medical necessity.

Criteria:

For coverage to apply all criteria below must be documented:

- The diagnosis is established by a Doctor of Osteopathic Medicine which services and supports utilization of the therapy; AND
- There is documentation of objective physical and functional [strength, range of motion (ROM), mobility, and/or activities of daily living (ADL)] limitations; AND
- There is an individualized plan of care that includes treatment services that are expected to result in improvement of these limitations in a reasonable and generally predictable period of time. The amount, frequency and duration of services must be reasonable; AND
- The services are one-to-one; AND

- The services are skilled. The services must be of a level of complexity and sophistication, or the condition of the patient must be such that the services required can be safely and effectively performed only by a qualified, licensed provider; AND
- Documented by the person rendering the services; AND
- The services must not duplicate services provided by any other therapy.

Utilization Guidelines:

- The number of regions treated during any one session will depend upon the history, examination and medical decision-making utilized to determine medical necessity of the most appropriate intervention.
- The type, frequency and duration of services must be reasonable and consistent with the standards of practice in the medical community.

Treatment Guidelines:

- Treatments, acute or chronic, should generally not exceed 1-2x/month
- Only one OMT service should be billed per day, based on the description of the procedure code.
    - Body regions included are head, cervical thoracic, lumbar, sacral, pelvic, extremities, rib cage, abdomen, and viscera.
- Treatment beyond six months should be limited to cases of chronic incurable illness (e.g., postpolio, ALS, post CVA, etc.)

Limitations and Exclusions:

Osteopathic Manipulative Treatment is not covered when the indication of Coverage is not met, and conventional documentation of somatic dysfunction is not present in the patient's medical record.

Osteopathic manipulative treatment (OMT) is unproven and not medically necessary for the following due to insufficient evidence of efficacy:

- Non-Musculoskeletal Disorders (e.g., asthma, otitis media, infantile colic, etc.)
- Prevention/maintenance/custodial care
- Internal organ disorders (e.g., gallbladder, spleen, intestinal, kidney, or lung disorders)
- Temporomandibular joint (TMJ) disorder
- Scoliosis
- Craniosacral therapy (cranial manipulation/Upledger technique) or manipulative services that utilize nonstandard techniques including but not limited to applied kinesiology, National Upper Cervical Chiropractic Association (NUCCA), and neural organizational technique.

Osteopathic manipulative treatment (OMT) is unproven and not medically necessary when ANY of the following apply:

- The member’s condition has returned to the pre-symptom state
- Little or no improvement is demonstrated within 30 days of the initial visit despite modification of the treatment plan

- Concurrent manipulative therapy, for the same or similar condition, provided by another health professional whether or not the healthcare professional is in the same professional discipline

Note: Osteopathic Manipulative Treatment specifically encompasses only the procedure itself. Evaluation and management (E&M) services are covered, as a separate and distinct service when medically necessary and appropriately documented. No E&M service is warranted for previously planned follow-up OMT treatments unless a new condition occurs, or the patient's condition has changed substantially, necessitating an overall reassessment.

Applicable Coding:

CPT Code	Description
98925	Osteopathic manipulative treatment (OMT); 1-2 body regions involved
98926	Osteopathic manipulative treatment (OMT); 3-4 body regions involved
98927	Osteopathic manipulative treatment (OMT); 5-6 body regions involved
98928	Osteopathic manipulative treatment (OMT); 7-8 body regions involved
98929	Osteopathic manipulative treatment (OMT); 9-10 body regions involved

Clinical Evidence:

Osteopathic manipulative treatment (OMT), also known as Manipulative treatment, mobilization therapy or "adjustment," refers to manual therapy employed to soft or osseous tissues for therapeutic purposes. This term encompasses a wide variety of physical manipulations, including rhythmic stretching, deep pressure and traction, and spinal adjustments. Spinal manipulation involves manual and mechanical interventions that may be high or low velocity; short or long lever; high or low amplitude; with or without recoil. Most often, manipulation is performed by applying a controlled force into a joint or joints of the spinal column to reduce or correct a specific derangement. Depending on the provider specialty, a joint derangement may be listed as a subluxation, vertebral subluxation complex, osteopathic lesion, somatic dysfunction or a mechanical dysfunction.

Craniosacral therapy (CST) is a noninvasive osteopathic technique that involves the therapist touching the individual to detect pulsations and rhythms of flow of cerebrospinal fluid (CSF). The therapist then gently works with the skull and spine, with the goal to effect release of potential restrictions to the flow of CSF, without the use of forceful physical manipulation (Hayes, 2018). It is considered a treatment for a variety of conditions, such as multiple sclerosis, asthma, pelvic pain, fibromyalgia, and tension-type and migraine headaches. Many of these disease states are associated with acute and chronic pain.

A variety of non-standard manipulative therapy techniques exist such as applied kinesiology, National Upper Cervical Chiropractic Association (NUCCA), and neural organizational technique.

Applied kinesiology, also known as muscle strength testing, is a method of diagnosis and treatment based on the belief that various muscles are linked to particular organs and glands, and that specific muscle weakness can signal distant internal problems such as nerve damage, reduced blood supply, chemical imbalances or other organ or gland problems.

The NUCCA technique is a variation of chiropractic care with the goal to improve structural and sustained postural balance that leads to improved spinal stability along with balanced mobility.

The neural organizational technique attempts to treat the cause, the whole person, and work with what the body communicates is out of balance.

Non-Musculoskeletal Disorders (e.g., Asthma, Otitis Media, Infantile Colic, etc.)

Numerous systematic literature reviews have investigated manipulative therapies for a range of non-musculoskeletal disorders. Relevant systematic reviews address the treatment of respiratory disorders such as asthma (Alcantara et al., 2012; Hondras et al., 2005, Kaminskyj et al., 2010; Pepino et al., 2013) cystic fibrosis, bronchiolitis, recurrent infections (Pepino et al., 2013); pneumonia (Yang et al., 2013); and chronic pulmonary obstructive disease (Heneghan et al., 2013).

Four systematic reviews examined the use of manipulation for the management of gastrointestinal disorders affecting infants e.g., infantile colic (Alcantara et al., 2011; Dobson et al., 2012), adults for irritable bowel syndrome (Müller et al., 2013), gastroesophageal reflux, and duodenal ulcers (Ernst, 2011).

Three systematic reviews reported on the efficacy of manual therapy for the treatment of otitis media (Carr and Nahata, 2006; Leighton, 2009; Pohlman, 2012).

Single systematic reviews of manipulation as part of manual therapy interventions were identified for the treatment of attention deficit hyperactivity disorder [ADHD] (Karpouzis et al., 2010), hypertension (Mangum et al., 2012), nocturnal enuresis (Huang et al., 2011), insomnia (Kingston et al., 2010), and lower urinary tract symptoms [LUTS] (Franke and Hoesele, 2013).

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 including manipulation for the treatment of non-musculoskeletal disorders.
Additional systematic reviews that included a wide range of non-musculoskeletal disorders found the evidence lacking, inconclusive or unproven in assessing the effectiveness of manual therapy interventions including manipulative therapy for the treatment of non-musculoskeletal disorders (Clar et al., 2014; Posadzki et al., 2013; Gleberzon et al., 2012; Gotlib and Rupert, 2008; Ferrance and Miller, 2010; Cole and Reed, 2010).

Osteopathic manipulative treatment (OMT) with Non-Standard Techniques Published peer-reviewed literature was not identified for non-standard manipulative therapy techniques such as

applied kinesiology, National Upper Cervical Chiropractic Association (NUCCA), and neural organizational technique (NOT).

Scoliosis

In a systematic review to evaluate the current body of literature on chiropractic treatment of IS, Morningstar et al. (2017b) identified 15 case reports, 10 case series, 1 prospective cohort, and 1 RCT. Of the 27 studies, only 2 described their outcomes as recommended in a 2014 SOSORT and the SRS Non-Operative Management Committee consensus paper. The consensus paper details the format and types of outcomes they collectively believe are the most important and relevant to the patient. Among the chiropractic studies located in this review, 2 described outcomes consistent with how SOSORT recommends they be reported. Given that these consensus papers form the basis for nonoperative treatment recommendations and outcome reporting, future chiropractic studies should seek to report their outcomes as recommended by these papers. This may allow for better interprofessional collaboration and methodologic comparison.

Czaprowski (2016) conducted a systematic review to assess the efficacy of non-specific manual therapy (manual therapy, chiropractic, osteopathy) used in the treatment of children and adolescents with IS. Results of these studies are contradictory, ranging from Cobb angle reduction to no treatment effects whatsoever. The papers analyzed are characterized by poor methodological quality, small group sizes, incomplete descriptions of the study groups, and no follow-up or control groups.

Additional systematic reviews reported on manual therapy for the treatment of idiopathic scoliosis (Everett and Patel, 2007; Romano and Negrini, 2008; Gleberzon et al., 2012; Posadzki et al., 2013). All of the reviews arrived at similar conclusions; there is a lack of evidence, which does not permit conclusions on the efficacy of manual therapy including spinal manipulation for the treatment of adolescent and adult idiopathic scoliosis.

Temporomandibular Joint (TMJ) Disorders (TMD)

Four of the systematic reviews had one or more critical flaws along with other methodologic weaknesses and could not be relied on to provide an accurate and comprehensive summary of the available studies. Adelizzi, et al. (2016) was rated as being of critically low quality due to limitations in reporting the research questions and inclusion criteria for the review, uncertainty about the comprehensiveness of the literature search strategy, and methods used to assess RoB in non-randomized studies of interventions (NRSI). Calixtre, et al. (2016) was judged to be of low quality due to a critical flaw regarding the accuracy of the results. The analysis (Tables 4 and 5) reported absolute changes incorrectly, as effect sizes, and further compounded the error by interpreting the magnitude of results using Cohen's d criteria. Non-critical weaknesses were identified increasing the risk of selection and funding bias. The systematic review authored by De Castro, et al. (2018) contained several critical methodologic flaws relating to the development of the review, the approach used to identify and extract study data, and the failure to incorporate the role of study bias into the analysis. A systematic review with meta-analysis (Martins, et al; 2016) was deemed to be of critically low quality. There were critical flaws pertaining to the literature search strategy and the statistical methods used to interpret the meta-analytic results, which likely over-estimated the effects of manipulative therapy for pain intensity and MMO.

The systematic review and meta-analysis conducted by Armijo-Olivo, et al. (2016) was rated as moderate overall quality. A detailed assessment of the review showed that for pain intensity MT interventions including manipulative therapy, when used as a monotherapy, did not achieve

clinically relevant outcomes. Further, it was not possible to distinguish the effects on pain intensity of MT when combined with exercise interventions. Over the short-term, MT demonstrated potentially clinically meaningful benefit concerning MMO. MT-alone (6 RCTs) showed mixed results for individuals diagnosed as having mixed (arthrogenous and myogenous) TMD.

A RCT conducted by Corum, et al; 2018 was not included in any of the evidence syntheses. As with previous trials on the topic, the study had a high RoB due to significant flaws concerning treatment allocation, blinding and failure to include all participants in the analysis. Also, there were concerns about the potential for bias due to compliance with the intervention and avoidance of co-interventions. Further, the treatment arms did not permit conclusions about the discreet effects of MT on pain and MMO. Additionally, the statistical approach did not allow for judgments about clinical relevance and precision.

Another RCT that was not assessed in the included reviews was performed by Brochado, et al. (2018). The authors investigated the comparative effectiveness of photobiomodulation (laser therapy) and MT, alone or combined. Outcomes measured included pain intensity, MMO, psychosocial aspects, and anxiety symptoms of TMD patients. While all groups improved across the measured outcomes, the change in mean scores did not differ significantly between groups during the 90-day evaluation time.

In summary, the current body of evidence regarding the efficacy of MT for TMD consists of generally promising results across patient-important outcomes. However, confidence in the estimates of effect is limited by the low quality of evidence, uncertainty about clinical relevance, and durability of outcomes.

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Revision history

DATE	REVISION
05/08/2020	• New Policy