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## Medical Policy



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**\*Current Policy Effective Date: 11/1/24**  
(See policy history boxes for previous effective dates)

### **Title: ALTERNATIVE PHYSICAL THERAPY MODALITIES- EXPERIMENTAL/INVESTIGATIONAL**

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#### **Description/Background**

Physical therapy (PT) uses specific activities or methods to treat disabilities when there is a loss of function; these modalities are represented by established physical therapy/occupational therapy (OT) CPT codes. This policy does not address established PT/OT therapy modalities.

#### **Definitions**

Typically physical therapy is the treatment of a physical dysfunction or injury by the use of therapeutic exercise and the application of modalities intended to restore or facilitate normal function or development.

Physical therapy modalities are physical agents that produce a specific therapeutic response. The most commonly used physical modalities include heat, cold, sound, electricity, mechanical forces and light. These modalities are used to augment the physical therapy program to help individuals regain normal functional mobility.

However there are other therapies and programs that are used in the PT/OT realm that are considered alternative to established care routines, those alternative are discussed below.

#### **The Interactive Metronome Program**

The Interactive Metronome (IM) program is designed for processing speed, focus, as well as coordination. Trainees wear headphones and hear a fixed, repeating reference beat; they press against a hand or foot sensor to try to match it, while receiving visual and auditory feedback. The IM program has been promoted as a treatment for children with attention-deficit hyperactivity disorder (ADHD) and for other special needs children to increase concentration, focus, and coordination. It has also been promoted to improve athletic performance, to assess and improve academic performance of normal children, and to improve children's performance in the arts (e.g., dance, music, theater, creative arts). Furthermore, the IM program has also

been implemented as part of a therapy program for patients with balance disorders, cerebrovascular accident, limb amputation, multiple sclerosis, Parkinson's disease, and traumatic brain injury.

### **Augmented Soft Tissue Mobilization**

Augmented soft tissue mobilization (ASTM), a non-invasive mobilization technique, is used by chiropractors as well as massage, occupational, and physical therapists to treat chronic musculoskeletal disorders that result from scarring and fibrosis. It entails the use of hand-held tools made from bone or stone or metal and a lubricant on the skin to scrape and mobilize scar tissue. Scraping is done to promote circulation, thus, promoting healing. Manual and other treatments may also be used with exercise to guide the healing process. Treatments with ASTM are often administered on non-consecutive days, 1 to 2 times per week. A typical 30-min session usually includes 15 mins of treatment and 15 mins of exercise and assessment. Less severe conditions reportedly can respond well in 2 to 4 sessions whereas difficult chronic cases may require 8 to 16 sessions.

### **Kinesio Taping/McConnell Taping/Taping**

Kinesio taping is a method of taping utilizing a specialized type of tape. It differs from traditional white athletic tape in the sense that it is elastic and can be stretched to 140 % of its original length before being applied to the skin. It subsequently provides a constant pulling (shear) force to the skin over which it is applied unlike traditional white athletic tape. The fabric of this specialized tape is air permeable and water resistant and can be worn for repetitive days. Kinesio tape is being used immediately following injury and during the rehabilitation process.

### **Dynamic Method for Kinetic Stimulation (MEDEK) Therapy**

MEDEK, a form of physiotherapy, refers to Metodo Dinamico de Estimulacion Kinesica or Dynamic Method for Kinetic Stimulation. It was developed by a Chilean physical therapist in the 1970s. MEDEK is used for developing gross motor skills in children with physical disabilities and movement disorders (e.g., cerebral palsy, Down syndrome, hypotonia, muscular dystrophy, and developmental motor delay). It does not focus on modifying muscle tone, primitive reflexes or abnormal patterns of movement. It focuses on training movements leading to sitting, standing, and walking. Muscles are trained in postural and functional tasks rather than in isolation.

### **Hands-Free Ultrasound and Low-Frequency Sound (Infrasound)**

The "hands-free" ultrasound (US) device was recently introduced by Rich-Ma, Inc. This unit allows the clinician to choose the mode of US delivery, using either a hand-held (manual) transducer or a hands-free device that pulses the US beam through the transducer.

### **Hivamat Therapy (Deep Oscillation Therapy)**

Hivamat therapy (deep oscillation therapy) utilizes an intermittent electrostatic field via a Hivamat machine. It supposedly penetrates deeper into the body tissue than manual methods, allowing previously "untreatable" injuries to be manipulated with a minimum of physical pressure. Electrostatic waves create a kneading effect deep within the damaged tissues, restoring flexibility and blood supply to the affected area.

### **Applied Functional Science**

Applied Functional Science (AFS) combines physical sciences, biological sciences, and

behavioral sciences to create a system for functional assessment, rehabilitation, training and conditioning, as well as injury prevention. The advocates of AFS note that these principles, integrated with neuromusculoskeletal Chain Reaction biomechanics, lead to strategies that guide the decision-making process.

### **McKenzie Method of Mechanical Diagnosis and Therapy**

The McKenzie Method is a biopsychosocial system of musculoskeletal care emphasizing patient empowerment and self-treatment. This system of diagnosis and patient management applies to acute, subacute and chronic conditions of the spine and extremities. It supposedly offers a reliable and practical approach that focuses on what patients need and not on what therapists choose to do.

### **Intensive Model of Constraint-Induced Movement Therapy (CIMT)**

CIMT is a specialized approach used to increase the use of a limb affected or weakened as the result of a stroke or brain injury. CIMT aims at decreasing the effects of learned non-use. This therapy is based on a task-oriented approach to improve functional use and control of an affected extremity.

### **Intensive Model of Therapy (IMOT) Programs (e.g., Neurosuit, TheraSuit™, Adeli Suit, TheraTogs™)**

Developed in Poland, IMOT is a unique therapeutic approach to treating children with cerebral palsy and other neurological disorders. This therapy involves performing exercises over an extended period of time — 5 days a week for 4 hours a day. An important part of the therapy is the use of the NeuroSuit. The Neurosuit frames the body providing support and resistance simultaneously. It is postulated that the Neurosuit improves and changes proprioception (pressure from the joints, ligaments, muscles), reduces a patient's undesired reflexes, facilitates proper movement and provides additional weight bearing distributed strategically throughout the body. This additional weight bearing may provide strong feedback to the brain which may help create new improved patterns of movement such as when walking while the body is maintaining a more upright, correct posture.

### **Dry Hydrotherapy/Aquamassage/Hydromassage**

Dry hydrotherapy, also referred to as aquamassage, water massage, or hydromassage, is a treatment that incorporates water with the intent of providing therapeutic massage. The treatment is generally provided in chiropractor or physical therapy offices. Proponents of dry hydrotherapy maintain that it can be used in lieu of certain conventional physical medicine therapeutic modalities and procedures, such as heat packs, wet hydrotherapy, massage, and soft tissue manipulation.

### **Non-Invasive Interactive Neurostimulation (e.g., InterX®)**

Non-invasive, Interactive Neurostimulation (NIN) (e.g., InterX®) is used for the treatment of acute and chronic pain using high amplitude, high density stimulation to the cutaneous nerves, activating the natural pain relieving mechanisms of the body (segmental and descending inhibition).

### **Compression Band Therapy (Voodoo Flossing)**

Compression band therapy (also known as flossing or voodoo flossing) is a tool that may be used to improve joint mobility, reduce soft tissue stiffness and improve pain. Compression band therapy involves wrapping floss tape around the affected limb, muscle or joint from

proximal to distal area and moving the affected joint or muscle through active or passive range of motion.

There are two possible mechanisms of action:

- Compressing the area improves local blood flow by temporarily restricting blood flow to the area. When the band is taken off, blood rushes into the area to aid in healing and recovery.
- Compression the area creates fascial shear which breaks up adhesions in the tissues caused by injury or lack of movement.

### **IntraDiscNutrosis®**

A non-surgical therapeutic intervention for patients with bulging, herniated, degenerative discs, and other discogenic disorders. This noninvasive therapy purportedly treats the problem of “why” the disc is degenerating instead of treating the conditions or symptoms that manifest from a degenerating disc. This therapy is said to activate self-healing mechanisms by incorporating manipulative procedures with nutrition therapy and home traction therapy.

### **Hako-Med Horizontal Therapy**

Hako-Med Horizontal Therapy is a new form of pain therapy that uses bioelectricity for pain management as well as circulatory disorders. This form of therapy uses different electrical signals to influence the body in order to treat a wide range of ailments with little or no negative side effects. Mild tingling to the affected area after therapy can be expected. The manufacturer asserts a proprietary concept called Horizontal® Therapy which claims can treat both bioelectrical and biochemical cellular communication components in one treatment session by holding the bioelectric intensity constant while changing the frequency. This therapy uses the PRO ElectDT 2000 muscle stimulation device.

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## **Regulatory Status**

The practice of physical therapy is legally regulated at the state level. In Michigan, the Public Health Code is state law. The Administrative Rules written by the Michigan Board of Physical Therapy provide details and interpretation of legislative intent, and are as binding as state law. Compliance with both is required for all settings and patients at all times. Violations of state law can result in sanctions against your license.

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## **Medical Policy Statement**

The therapies listed in this policy have been determined to be Investigational/Experimental. They are not a covered benefit for all contracts that exclude reimbursement for investigational services.

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## **Inclusionary and Exclusionary Guidelines**

N/A

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**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

**Established codes:**

N/A

**Other codes (investigational, not medically necessary, etc.):**

97039                      97139                      97799

*Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.*

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**Rationale**

**The Interactive Metronome Program**

In a case report, Bartscherer and Dole (2005) described the use of the IM program for improving timing and coordination in a 9-year old boy who had difficulties in attention and developmental delay of unspecified origin.<sup>1</sup> The subject underwent a 7-week training with the program. Before, during, and after training, timing accuracy was evaluated with testing procedures consistent with the IM training protocol. Before and after training, the subject's gross and fine motor skills were examined with the Bruininiks-Oseretsky Test of Motor Proficiency (BOTMP). The child exhibited marked change in scores on both timing accuracy and several BOTMP subtests. Additionally his mother relayed anecdotal reports of changes in behavior at home. This child's participation in a new intervention for improving timing and coordination was associated with changes in timing accuracy, gross and fine motor abilities, and parent reported behaviors. The authors noted that these findings warrant further study.

Cosper et al (2009) examined the effectiveness of IM (Interactive Metronome, Sunrise, FL) training in a group of children with mixed attentional and motor coordination disorders to further explore which subcomponents of attentional control and motor functioning the training influences.<sup>2</sup> A total of 12 children who had been diagnosed with ADHD, in conjunction with either developmental coordination disorder (n = 10) or pervasive developmental disorder (n = 2), underwent 15 1-hr sessions of IM training over a 15-week period. Each child was assessed before and after the treatment using measures of attention, coordination, and motor control to determine the effectiveness of training on these cognitive and behavioral realms. As a group, the children made significant improvements in complex visual choice reaction time and visuomotor control after the training. There were, however, no significant changes in sustained attention or inhibitory control over inappropriate motor responses after treatment. These results suggested IM training may address deficits in visuomotor control and speed, but appears to have little effect on sustained attention or motor inhibition.

In a review on autism, Levy and colleagues (2009) stated that popular biologically based treatments include anti-infectives, chelation medications, gastrointestinal medications, hyperbaric oxygen therapy, and intravenous immunoglobulins.<sup>3</sup> Non-biologically based

treatments include auditory integration therapy, chiropractic therapy, cranio-sacral manipulation, facilitated communication, IM, and transcranial stimulation. However, few studies have addressed the safety and effectiveness of most of these treatments.

### **Section Summary: Interactive Metronome Program**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of the IM program. Randomized controlled studies are needed to establish the clinical value of this program.

### **Augmented Soft Tissue Mobilization**

In a case report, Melham et al (1998) described their finding on the use of ASTM in the treatment of excessive scar tissue around an athlete's injured ankle.<sup>4</sup> Surgery and several months of conventional physical therapy failed to alleviate the athlete's symptoms. As a final resort, ASTM was administered. It used ergonomically designed instruments that assist therapists in the rapid localization and effective treatment of areas exhibiting excessive soft tissue fibrosis; followed by a stretching and strengthening program. Upon the completion of 6 weeks of ASTM, the athlete had no pain and had regained full range of motion and function.

### **Section Summary: Augmented Soft Tissue Mobilization**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this program. Randomized controlled studies are needed to establish the clinical value of this program.

### **Kinesio Taping/McConnell Taping/Taping**

Halseth et al (2004) examined if Kinesio taping the anterior and lateral portion of the ankle would enhance ankle proprioception compared to the untaped ankle.<sup>5</sup> A total of 30 subjects (15 men, 15 women, aged 18 to 30 years) participated in this study. Exclusion criteria: included ankle injury less than 6 months prior to testing, significant ligament laxity as determined through clinical evaluation, or any severe foot abnormality. Experiment utilized a single group, pre-test and post-test. Plantar flexion and inversion with 20° of plantar flexion reproduction of joint position sense (RJPS) was determined using an ankle RJPS apparatus. Subjects were barefooted, blind-folded, and equipped with headphones playing white noise to eliminate auditory cues. They had 5 trials in both plantar flexion and inversion with 20° plantar flexion before and after application of the Kinesio tape to the anterior/lateral portion of the ankle. Constant error and absolute error were determined from the difference between the target angle and the trial angle produced by the subject. The treatment group (Kinesio taped subjects) showed no change in constant and absolute error for ankle RJPS in plantar flexion and 20° of plantar flexion with inversion when compared to the untaped results using the same motions. The application of Kinesio tape does not appear to enhance proprioception (in terms of RJPS) in healthy individuals as determined by measures of RJPS at the ankle in the motions of plantar flexion and 20° of plantar flexion with inversion. The authors stated that in order to fully understand the effect of Kinesio tape on proprioception, further research needs to be conducted on other joints, on the method of application of Kinesio tape, and the health of the subject to whom it is applied. In addition, further research should provide vital information about a possible benefit of Kinesio taping during the acute and sub-acute phases of rehabilitation, thus facilitating earlier return to activity participation.

In a pilot study, Yasukawa and colleagues (2006) described the use of the Kinesio taping method for the upper extremity in enhancing functional motor skills in children admitted into an

acute rehabilitation program.<sup>6</sup> A total of 15 children (10 females and 5 males; 4 to 16 years of age), who were receiving rehabilitation services at the Rehabilitation Institute of Chicago participated in this study. For 13 of the inpatients, this was the initial rehabilitation following an acquired disability, which included encephalitis, brain tumor, cerebral vascular accident, traumatic brain injury, and spinal cord injury. The Melbourne Assessment of Unilateral Upper Limb Function (Melbourne Assessment) was used to measure upper-limb functional change prior to use of Kinesio tape, immediately after application of the tape, and 3 days after wearing tape. Children's upper-limb function was compared over the three assessments using analysis of variance. The improvement from pre- to post-taping was statistically significant,  $F(1, 14) = 18.9$ ;  $p < 0.02$ . The authors concluded that these results suggested that Kinesio tape may be associated with improvement in upper-extremity control and function in the acute pediatric rehabilitation setting. The use of Kinesio Tape as an adjunct to treatment could possibly assist with the goal-focused occupational therapy treatment during the child's inpatient stay. However, further study is recommended to test the effectiveness of this method and to determine the lasting effects on motor skills and functional performance once the tape is removed.

In a pilot study, Fu and associates (2008) examined the possible immediate and delayed effects of Kinesio taping on muscle strength in quadriceps and hamstring when taping is applied to the anterior thigh of healthy young athletes.<sup>7</sup> A total of 14 healthy young athletes (7 males and 7 females) free of knee problems were enrolled in this study. Muscle strength of the subject was assessed by the isokinetic dynamometer under three conditions: (i) without taping; (ii) immediately after taping; (iii) 12 hours after taping with the tape remaining in situ. The result revealed no significant difference in muscle power among the three conditions. Kinesio taping on the anterior thigh neither decreased nor increased muscle strength in healthy non-injured young athletes.

In a prospective, randomized, double-blinded, clinical study using a repeated-measures design, Thelen et al (2008) determined the short-term clinical efficacy of Kinesio tape when applied to college students with shoulder pain, as compared to a sham tape application.<sup>8</sup> A total of 42 subjects with clinically diagnosed rotator cuff tendonitis and/or impingement were randomly assigned to 1 of 2 groups: therapeutic Kinesio tape group or sham Kinesio tape group. Subjects wore the tape for 2 consecutive 3-day intervals. Self-reported pain and disability and pain-free active ranges of motion (ROM) were measured at multiple intervals to evaluate for differences between groups. The therapeutic Kinesio tape group showed immediate improvement in pain-free shoulder abduction (mean +/- SD increase, 16.9 degrees +/- 23.2 degrees ;  $p = 0.005$ ) after tape application. No other differences between groups regarding ROM, pain, or disability scores at any time interval were found. The authors concluded that Kinesio tape may be of some assistance to clinicians in improving pain-free active ROM immediately after tape application for patients with shoulder pain. Utilization of Kinesio tape for decreasing pain intensity or disability for young patients with suspected shoulder tendonitis/impingement is not supported.

McConnell (2002) noted that the management of chronic low back pain (LBP) and leg pain has always provided a challenge for therapists.<sup>9</sup> This researcher examined the influence of a repetitive movement such as walking as a possible causative factor of chronic LBP. Diminished shock absorption as well as limited hip extension and external rotation are hypothesized to affect the mobility of the lumbar spine resulting in lumbar spine dysfunction. Treatment must therefore be directed not only at increasing the mobility of the hips and

thoracic spine, but also the stability of the lumbar spine. However, the symptoms can sometimes be exacerbated by treatment, so the neural tissue needs to be unloaded to optimize the treatment outcome. This can be achieved by taping the buttock and down the leg following the dermatome to shorten the inflamed tissue.

The role of taping in the management of musculoskeletal pain and injuries and its use in the management of LBP has not been established. In a review of LBP in athletes, Baker and Patel (2005) stated that most of the adult population experiences LBP at some time in life. Athletes may be at increased risk, but outcomes are good.<sup>10</sup> The majority of LBP in adult athletes is mechanical in nature. Herniated discs, spinal stenosis, sacrolitis, and sacral stress fractures can also cause LBP in these individuals. Low back conditions mentioned above may be treated with rest, medication, as well as specific exercise programs. Surgery is indicated for severe spinal stenosis, pain with evidence of neurological compromise, and some painful deformities. Newer treatments for back pain are emerging, but few controlled clinical trials are available. Taping was not mentioned as an option for managing individuals with LBP. Additionally, in a review of current concepts in the diagnosis and treatment of spondylolysis, McCleary and Congeni (2007) noted that treatment usually consists of rest and/or bracing to allow healing to occur, followed by rehabilitation that includes core strengthening.<sup>11</sup> They stated that more large-scale controlled studies are needed to clarify the most effective diagnostic and therapeutic protocols.

Greig et al (2008) noted that greater thoracic kyphosis is associated with increased biomechanical loading of the spine which is potentially problematic in individuals with osteoporotic vertebral fractures.<sup>12</sup> Conservative interventions that reduce thoracic kyphosis warrant further investigation. These researchers examined the effects of therapeutic postural taping on thoracic posture. Secondary aims explored the effects of taping on trunk muscle activity and balance. A total of 15 women with osteoporotic vertebral fractures participated in this within-participant design study. Three taping conditions were randomly applied: (i) therapeutic taping, (ii) control taping, and (iii) no taping. Angle of thoracic kyphosis was measured after each condition. Force plate-derived balance parameters and trunk muscle electromyographic activity (EMG) were recorded during 3 static standing tasks of 40-second duration. There was a significant main effect of postural taping on thoracic kyphosis ( $p = 0.026$ ), with a greater reduction in thoracic kyphosis after taping compared with both control tape and no tape. There were no effects of taping on EMG or balance parameters. The authors concluded that these findings showed that the application of postural therapeutic tape in a population with osteoporotic vertebral fractures could induce an immediate reduction in thoracic kyphosis. They stated that further research is needed to investigate the underlying mechanisms associated with this decrease in kyphosis.

### **Section Summary: Kinesio Taping/McConnell Taping**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this therapy. However, durability of outcomes has not been shown nor significant changes in disability score as compared to placebo/sham groups.

### **MEDEK Therapy**

There were no clinical studies identified addressing this form of therapy. Well-designed clinical studies are needed to determine the effectiveness of MEDEK physical therapy.



### **Hands-Free Ultrasound and Low-Frequency Sound (Infrasound)**

Gulick (2010) examined the effectiveness of tissue heating with a hands-free US technique compared to a hand-held US transducer using the Rich-Mar AutoSound unit.<sup>13</sup> A total of 40 volunteers over 18 years of age participated. Treatment was provided at a 3-MHz US frequency. Muscle temperature was measured with 26-gauge, 4-cm Physiotemp thermistors placed in the triceps surae muscle. The depth of thermistor placement was at 1-cm and 2-cm deep. One calf was treated with a manual transducer (5-cm(2) US head at 3 times the effective radiating area [ERA]), and one calf was treated with the hands-free transducer (14-cm(2) [ERA]). Both methods used a 1.5 W/cm(2) intensity for 10 mins. The manual technique used an overlapping circular method at 4 cm/sec, and the hands-free method used a sequential pulsing at 4 cm/sec. Tissue temperatures were recorded at baseline and every 30 seconds. The hands-free technique resulted in a tissue temperature increase from 33.68 to 38.7 degrees C and an increase from 33.45 to 40.1 degrees C using the manual technique at 1-cm depth. The tissue temperature increase at the 2-cm depth was from 34.95 to 35.44 degrees C for the hands-free device and 34.44 to 38.42 degrees C for the manual device. Thus, there was a significant difference between the hands-free and the manual mode of US delivery for the 3-MHz frequency (5.02 degrees C versus 6.65 degrees C at 1 cm and 1.49 degrees C versus 3.98 degrees C at 2 cm). In this study, the "hands-free" device did not result in the same level of tissue heating as the manual technique. The hands-free device may have the advantage of not needing a clinician present to deliver the modality but a therapeutic level of heating was not achieved at the 2-cm tissue depth. Thus, the effectiveness of the "hands-free" treatment is in question.

### **Section Summary: Hands Free Ultrasound/Low Frequency Sound**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this therapy. Randomized controlled studies are needed to establish the clinical value of this therapy.

### **Hivamat Therapy (Deep Oscillation Therapy)**

Aliyev (2009) noted that in Germany approximately 2 million sports injuries occur per year. Most common are distortions and ligamentous injury going along with post-traumatic lymphedema.<sup>14</sup> Deep oscillation therapy provided very good results in lymph drainage and in other indications. The purpose of this experimental study was the evaluation of the effects of deep oscillation therapy in immediate therapy and after-care of different sports injuries in addition to usual care (complex physical and medical therapy). Two soccer teams were supported by a sports medicine section of a rehabilitation hospital. In n = 14 people (mean age 23.9 years) 49 sports injuries of different kind were treated. Subjective rating of the symptoms by VAS improved significant ( $p = 0.001$ ) from 8.7 (baseline) to 2.1 points (post-treatment). Objective rating by the attending physician according to different clinically relevant parameters lead to "very good" or "good" results in 90% of the patients. The authors concluded that therapy method deep oscillation is an easy to use and comparably cost effective adjuvant therapy option. In general there were no side effects; patients were highly compliant.

### **Section Summary: Hivamat Therapy**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this therapy. Randomized controlled studies are needed to establish the clinical value of this therapy.

## **Applied Functional Science**

There were no clinical studies identified addressing this form of therapy. Well-designed clinical studies are needed to determine the effectiveness of applied functional science therapy.

### **McKenzie Method of Mechanical Diagnosis and Therapy**

Flavell et al (2016) noted that physiotherapists use musculoskeletal classification systems for patient assessment.<sup>15</sup> Since its early development, the McKenzie lumbar spine assessment (MK) has been incorporated into examination algorithms and combined with a series of pathoanatomical diagnostic tests. No previous studies have used a MK and a combined examination (MK-C) to provide a detailed profile of patients, report and compare the classification characteristics of a chronic LBP (CLBP) population. In a prospective, cross-sectional study, these investigators reported the classification characteristics of a CLBP population using MK and MK-C examinations, and conducted inter-classification comparison of the MK-C for demographics, the Oswestry Disability Index (ODI), Roland Morris Disability Index (RM), Modified Somatic Perceptions Questionnaire (MSPQ), symptom duration and intensity. Results were obtained in 150 patients. Using MK, 31% (n = 47) of participants were classified as inconclusive. Following MK-C only 6 % of participants remained inconclusive (n = 9). The most frequent MK-C classification was facet joint syndrome (FJS) (49%). Participants with FJS were significantly older than those classified as discogenic (p < 0.001; 95 % CI: 3.96– to 19.74), or mixed (p < 0.001; 95% CI: 5.98–to 36.41). Participants classified as discogenic had significantly higher RM (p = 0.022) and MSPQ (p = 0.005) scores than FJS. The authors concluded that results indicated that 94% of CLBP patients could be classified using a MK-C. The most common presentation in CLBP was facet joint syndrome. Age, RM and MSPQ appeared to be distinguishing characteristics of this population. Moreover, they stated that future studies should be conducted to establish the validity and reliability of the MK-C.

Hosseiniifar et al (2013) compared the effectiveness of stabilization and McKenzie exercises on pain, disability, and thickness of the transverse abdominis and multifidus muscles in patients with non-specific chronic LBP.<sup>16</sup> A total of 30 patients were randomly assigned into 2 groups: (i) the McKenzie and (ii) stabilization exercise groups. Before and after intervention, pain, disability, and thickness of the transverse abdominis and multifidus muscles were evaluated by visual analog scale (VAS), functional rating index, and sonography, respectively. The training program was 18 scheduled sessions of individual training for both groups. After interventions, the pain score decreased in both groups. The disability score decreased only in the stabilization group. The thickness of the left multifidus was significantly increased during resting and contracting states in the stabilization group. The thickness of the right transverse abdominis during the abdominal draw-in maneuver, and thickness of the left transverse abdominis during the active straight leg raising maneuver were significantly increased in the stabilization group. The intensity of pain, disability score, thickness of the right transverse abdominis during the abdominal draw-in maneuver, and thickness of the left transverse abdominis during active straight leg raising in the stabilization group were greater than those on the Mackenzie. The authors concluded that stabilization exercises were more effective than McKenzie exercises in improving the intensity of pain and function score and in increasing the thickness of the transverse abdominis muscle.

Werneke et al (2014) examined the association between therapists' level of formal precredential McKenzie post-graduate training and agreement on the following McKenzie classification variables for patients with LBP: main McKenzie syndromes, presence of lateral shift, derangement reducibility, directional preference, and centralization.<sup>17</sup> Raters (n = 47)

completed multiple sets of 2 independent successive examinations at 3 different stages of McKenzie post-graduate training (levels parts A and B, part C, and part D). Agreement was assessed with  $\kappa$  coefficients and associated 95 % CIs. A minimum  $\kappa$  threshold of 0.60 was used as a pre-determined criterion for level of agreement acceptable for clinical use. Raters examined 1,662 patients (mean age of  $51 \pm 15$ ; range of 18 to 91; females, 57 %). Data distributions were not even and were highly skewed for all classification variables. No training level studied had acceptable agreement for any McKenzie classification variable. Agreements for all levels of McKenzie post-graduate training were higher than expected by chance for most of the classification variables except parts A and B training level for judging lateral shift and centralization and part D training level for judging reducibility. Agreement between training levels parts A and B, part C, and part D were similar with overlapping 95 % CIs. The authors concluded that results indicated that level of inter-rater chance-corrected agreement of McKenzie classification system was not acceptable for therapists at any level of formal McKenzie post-graduate training. They stated that this finding raised concerns about the clinical utility of the McKenzie classification system at these training levels. They stated that additional studies are needed to assess agreement levels for therapists who receive additional training or experience at the McKenzie credentialed or diploma levels.

Garcia et al (2015) noted that although the McKenzie method has been compared with several other interventions, it is not yet known whether this method is superior to placebo in patients with chronic LBP.<sup>18</sup> This proposed trial will evaluate the effectiveness of the McKenzie method in patients with chronic non-specific LBP. It is an assessor-blinded, 2-arm, randomized, placebo-controlled trial. The participants will be 148 patients seeking care for chronic non-specific LBP. Participants will be randomly allocated to 1 of 2 treatment groups: (i) McKenzie method, or (ii) placebo therapy (detuned ultrasound and shortwave therapy). Each group will receive 10 sessions of 30 minutes each (2 sessions per week over 5 weeks). The clinical outcomes will be obtained at the completion of treatment (5 weeks) and at 3, 6, and 12 months after randomization. The primary outcomes will be pain intensity (measured with the Pain Numerical Rating Scale) and disability (measured with the Roland-Morris Disability Questionnaire) at the completion of treatment. The secondary outcomes will be pain intensity; disability and function; kinesiophobia and global perceived effect at 3, 6, and 12 months after randomization; and kinesiophobia and global perceived effect at completion of treatment. The data will be collected by a blinded assessor. The authors stated that this will be the 1<sup>st</sup> trial to compare the McKenzie method with placebo therapy in patients with chronic non-specific LBP.

### **Section Summary: McKenzie Method of Mechanical Diagnosis and Therapy**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this program. Randomized controlled studies are needed to establish the clinical value of this program.

### **Intensive Model of Constraint-Induced Movement Therapy (CIMT)**

Rafiei et al (2019) investigated the extent to which individual characteristics before treatment predict improved use of the more affected arm following Constraint-induced therapy (CI).<sup>19</sup> This study was a retrospective analysis of 47 people who had chronic (> 6 months) mild to moderate upper extremity hemiparesis and were consecutively enrolled in 2 CI therapy randomized controlled trials. An enhanced probabilistic neural network model predicted whether individuals showed a low, medium, or high response to CI therapy, as measured with the Motor Activity Log, on the basis of the following baseline assessments: Wolf Motor

Function Test, Semmes-Weinstein Monofilament Test of touch threshold, Motor Activity Log, and Montreal Cognitive Assessment. Then, a neural dynamic classification algorithm was applied to improve prognostic accuracy using the most accurate combination obtained in the previous step. Motor ability and tactile sense predicted improvement in arm use for daily activities following intensive upper extremity rehabilitation with an accuracy of nearly 100%. Complex patterns of interaction among these predictors were observed. The fact that this study was a retrospective analysis with a moderate sample size was a limitation.

Simon-Martinez et al (2018) described a randomized controlled trial (RCT) protocol investigating the effects of an intensive treatment model, combining CIMT and Action-Observation Training (AOT) compared to CIMT alone on UL function in children with unilateral cerebral palsy (uCP).<sup>20</sup> Additionally, the role of neurological factors as potential biomarkers of treatment response will be analyzed. An evaluator-blinded RCT will be conducted in 42 children aged between 6 and 12 years. Before randomization, children will be stratified according to their House Functional Classification Scale, age and type of corticospinal tract wiring. A 2-week day-camp will be set up in which children receive intensive CIMT therapy for 6 hours a day on 9 out of 11 consecutive days (54 h) including AOT or control condition (15 h). During AOT, these children watch video sequences showing goal-directed actions and subsequently execute the observed actions with the more impaired UL. The control group performs the same actions after watching computer games without human motion. The primary outcome measure will be the Assisting Hand Assessment. Secondary outcomes comprise clinical assessments across body function, activity and participation level of the International Classification of Function, Disability and Health. Furthermore, to quantitatively evaluate UL movement patterns, a three-dimensional motion analysis will be conducted. UL function will be assessed at baseline, immediately before and after intervention and at 6 months follow up. Brain imaging comprising structural and functional connectivity measures as well as Transcranial Magnetic Stimulation (TMS) to evaluate corticospinal tract wiring would be acquired before the intervention. No result of this clinical trial have been published as of July 2020.

### **Section Summary: Intensive Model of Constraint-Induced Movement Therapy**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this program. Results from RCT studies are pending.

### **Intensive Model of Therapy (IMOT) Programs**

There were no clinical studies identified addressing this form of therapy. Well-designed clinical studies are needed to determine the effectiveness of IMOT programs.

### **Dry Hydrotherapy/Aquamassage/Hydromassage**

According to a report on manipulative and body-based practices by the National Institute of Health's National Center for Complementary and Alternative Medicine (NCCAM) (2004), there are numerous published reports of clinical trials evaluating the effects of various types of massage for a variety of medical conditions (most with positive results).<sup>21</sup> However, these trials are almost all small, poorly designed, inadequately controlled, or lacking adequate statistical analyses. Many trials include co-interventions that make it impossible to evaluate the specific effects of massage, while others evaluate massage delivered by individuals who are not fully trained massage therapists or follow treatment protocols that do not reflect common (or adequate) massage practice.

Furlan et al (2008) assessed the effects of massage therapy for non-specific low back pain. The authors searched MEDLINE, EMBASE, CINAHL from their beginning to May 2008.<sup>22</sup> We also searched the Cochrane Central Register of Controlled Trials (The Cochrane Library 2006, issue 3), HealthSTAR and Dissertation abstracts up to 2006. There were no language restrictions. References in the included studies and in reviews of the literature were screened. The studies had to be randomized or quasi-randomized trials investigating the use of any type of massage (using the hands or a mechanical device) as a treatment for non-specific low-back pain. Thirteen randomized trials were included. Eight had a high risk and five had a low risk of bias. One study was published in German and the rest in English. Massage was compared to an inert therapy (sham treatment) in two studies that showed that massage was superior for pain and function on both short and long-term follow-ups. In eight studies, massage was compared to other active treatments. They showed that massage was similar to exercises, and massage was superior to joint mobilization, relaxation therapy, physical therapy, acupuncture and self-care education. One study showed that reflexology on the feet had no effect on pain and functioning. The beneficial effects of massage in patients with chronic low-back pain lasted at least one year after the end of the treatment. Two studies compared two different techniques of massage. One concluded that acupuncture massage produces better results than classic (Swedish) massage and another concluded that Thai massage produces similar results to classic (Swedish) massage. The evidence suggests that acupuncture massage is more effective than classic massage, but this needs confirmation. More studies are needed to confirm these conclusions, to assess the impact of massage on return-to-work, and to determine cost-effectiveness of massage as an intervention for low-back pain.

### **Section Summary: Dry Hydrotherapy/Aquamassage/Hydromassage**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this therapy. The clinical utility of this intervention has yet to be proven when compared to standard therapy.

### **Non-Invasive Interactive Neurostimulation (e.g., InterX®)**

Biggs et al (2012) compared the hypoalgesic effect of non-invasive interactive neurostimulation with transcutaneous electrical nerve stimulation (TENS).<sup>23</sup> A repeated measures parallel group study on healthy human volunteers randomized to receive strong non-painful TENS or non-invasive interactive neurostimulation for 21 min on the forearm (N= 10/group). Pressure algometry was used to determine blunt pressure pain threshold at baseline, 10, and 20 min during stimulation, and 5 min post stimulation. Low impedance sites were found in half of the participants receiving noninvasive interactive neurostimulation. ANOVA found no effects for intervention ( $p= 0.923$ ), time  $\times$  intervention interaction ( $p= 0.21$ ), or time ( $p= 0.094$ ). Given the limited power of this study, the results show that there were no significant differences in hypoalgesia between non-invasive interactive neurostimulation and TENS. Unlike previous studies there was a failure to detect a change pain threshold during TENS.

Nigam et al (2011) evaluated the potential clinical benefit of the InterX neurostimulation device on pain reduction and rehabilitative outcome.<sup>24</sup> A clinical trial under the Hywel Dda Clinical Audit Committee to validate the clinical benefit of Non-invasive Interactive Neurostimulation (NIN) therapy using the InterX device was performed in patients undergoing TKR. Sixty-one patients were randomized to treatment groups in blocks of two from the Theatre Operation List. The control group received the standard hospital course of pain medication and rehabilitation twice daily for 3 post-op days. The experimental group received 8 sessions of NIN therapy over 3 post-op days in addition to the standard course received by the Control group. Pain and

range of motion were collected as the primary study measures. Sixty one subjects were enrolled and randomized, but 2 subjects (one/group) were excluded due to missing data at Baseline/Final; one subject in the InterX group was excluded due to pre-existing rheumatoid pain conditions confounding the analysis. The experimental group pre- to post-session Verbal Rating Scale for pain (VRS) showed that NIN therapy consistently reduced the pain scores by a mean of 2.3 points (SE 0.11). The NIN pre-treatment score at Final was used for the primary ANCOVA comparison, demonstrating a significantly greater cumulative treatment effect of a mean 2.2 (SE 0.49) points pain reduction ( $p = 0.002$ ). Control subjects only experienced a mean 0.34 (SE 0.49) point decrease in pain. Ninety degrees ROM was required to discharge the patient and this was attained as an average despite the greater Baseline deficit in the InterX group. Eight control patients and three experimental patients did not achieve this ROM. The results may show the clinical benefit of NIN therapy as a supplement to the standard rehabilitation protocol.

### **Section Summary: Non-Invasive Interactive Neurostimulation**

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this therapy. However results from available from the one RCT study are based on a small number of subjects and there are no further studies that substantiate positive outcomes.

### **Compression Band Therapy (Voodoo Flossing)**

Borda et al (2017) describes a case report of a 14 year old patient with achilles tendinopathy.<sup>25</sup> The purpose of this study case was to describe the use of compression tack and flossing with lacrosse ball massage. The patient presented with 8/10 left posterior ankle pain during activity and scored 66/80 on the Lower Extremity Functional Scale. The outcomes of interest were the lower extremity function scale (LEFS) and the ability to participate in sport without pain. The authors concluded that the patient's outcomes improved after therapy; however further research, including controlled clinical trials and long-term outcome data are needed.

Driller et al (2017) evaluated the effect of band Flossing on ankle ROM and jump performance.<sup>26</sup> In a crossover design, 52 participants performed a number of tests pre and post the application of a floss band to one ankle (FLOSS) with the counter ankle acting as the control (CON). Pre and post measures included a weight-bearing lunge test (WLBT), ankle dorsiflexion (DF) and plantarflexion (PF) ROM, and single leg vertical jump height and velocity. The authors concluded that floss bands applied to the ankle may increase dorsiflexion and plantarflexion ROM and may improve single-leg jump performance in recreational athletes. The results from this study may suggest that floss bands could be used for injury prevention and athletic performance.

Prill et al (2019) studied tissue flossing and whether its post-exercise application can reduce the extent of perceived delayed-onset muscle soreness (DOMS).<sup>27</sup> Participants (N=17) without any musculoskeletal injuries were recruited from university students. Participants performed an exercise protocol and obtained the intervention subsequently on one of both arms. Participants had to return for a second day to perform the whole procedure again, this time receiving the flossing intervention on the other arm. At both timepoints, their opposite arms served as the control. The primary outcome measure was a patient-reported score on a 100-mm Visual Analogue Scale. The mean value of DOMS of the flossed arm was 42 mm compared to the non-flossed arm was 48 mm. Differences were found to be statistically significant at 24 hours ( $P=0.036$ ;  $\alpha=0.05$ ), as well as at 48 hours postintervention ( $P=0.035$ ;  $\alpha=0.05$ ). Effect sizes

were  $d_z=0.408$  at 24 hours-and  $d_z=0.411$  at 48 hours post-intervention. The clean language effect size was 0.66. The authors concluded that tissue flossing appears to be a slightly less effective but much more practicable method for treating DOMS than the standard treatment.

### Section Summary: Compression Band Therapy (Voodoo Flossing)

Currently, there is insufficient evidence in the peer-reviewed medical literature to support the effectiveness of this therapy. Randomized controlled studies are needed to establish the clinical value of this program.

### IntraDiscNutrosis

There are no peer reviewed studies establishing the safety and/or effectiveness of this treatment.<sup>28</sup>

### Hako-Med Horizontal Therapy

There are no peer reviewed studies establishing the safety and/or effectiveness of this treatment.<sup>29</sup>

### Summary of Evidence

For some of the above physical therapy modalities, the evidence may include one or more of the following: case reports, pilot studies, retrospective analysis or a review of literature. In some of the above physical therapy modalities there were no clinical studies or literature identified for the therapy modality. Although the above physical therapy modalities may be safe, their effectiveness on health outcomes has not been scientifically determined.

### Ongoing and/or Unpublished Clinical Trials

A search of ClinicalTrials.gov identified the following ongoing trials in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT06461858	Effects of Cuevas Medek Exercises on Trunk Control and Balance in Children With Down Syndrome	32	Oct 2024
NCT06522451	Effects of Conventional Physical Therapy With and Without Cuevas Medek Exercises in Developmental Delay	24	Aug 2025
<b>Unpublished</b>			
NCT05678140	The effect of instrument assisted soft tissue mobilization in adhesive capsulitis treatment	28	Dec 2023
NCT04873778	Comparing effects of kinesio and dynamic tapings in postpartum women with pelvic girdle pain	63	Dec 2023
NCT05476718	Kinesio taping in patients after lumbar disc surgery	80	Jun 2023
NCT05811299	Effects of abdominal exercises and kinesio taping on abdominal strength in females with diastasis recti	46	Aug 2023
NCT05531851	Effects of instrument assisted soft tissue mobilization on delayed onset muscle soreness	40	Sep 2022
NCT05356624	Mobilization with movement versus soft tissue mobilization in patients with De Quervain tenosynovitis	30	Sep 2022
NCT04425980	The efficacy of two models of intensive upper limb training on quality of life in children with congenital hemiplegia	30	Feb 2020

NCT03256357	Constraint-induced movement therapy and action observation training in children with unilateral cerebral palsy	44	Feb 2018
NCT03302871	Integrated management enhances functional gains in children with cerebral palsy treated by BoNT-A and CIMT	40	Apr 2020
NCT02875054	Camp high 5: evaluation of the effect on upper limb function	10	Jan 2017
NCT01643109	Constraint induced movement therapy-neuroimaging predictors of positive response to constraint (OBI_CIMT)	26	Jun 2015

## Government Regulations

### National:

There are no NCD for these therapies.

### Local:

There is no LCD for these therapies.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

## Related Policies

Low Level Laser Therapy

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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, the date the research was completed.*

### Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/20	8/18/20		Joint policy established
11/1/21	8/17/21		Background section language clarified. Routine policy maintenance, no change in policy status.
9/1/22	6/21/22		Added IntraDisc Nutrosis as E/I to policy, routine policy maintenance, no change in policy status.
3/1/23	12/20/22		Added Hako-Med Horizontal Therapy as E/I to policy, no specific code to therapy.
11/1/23	8/15/23		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
11/1/24	8/20/24		Routine policy maintenance, no change in status. Vendor managed: N/A (ds)

Next Review Date:                    3<sup>rd</sup> Qtr. 2025

### Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

**BLUE CARE NETWORK BENEFIT COVERAGE  
POLICY: PHYSICAL THERAPY MODALITIES-  
EXPERIMENTAL/INVESTIGATIONAL**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	Not covered
<b>BCNA (Medicare Advantage)</b>	See government section
<b>BCN65 (Medicare Complementary)</b>	Coinsurance covered if primary Medicare covers the service.

**II. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.