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Orthotics

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
DME103.002: Knee Braces

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

An orthotic device **may be considered eligible** for benefit coverage when:
- It is legislatively mandated, OR it meets contract benefit criteria for coverage and/or is not specifically excluded from coverage; **AND**
- It is considered medically necessary.

An orthotic device **may be considered medically necessary** when the device:
- Is prescribed by a physician, chiropractor, and/or other qualified provider; **AND**
- Is medically necessary for therapeutic support, protection, restoration, or function of an impaired body part; **AND**
- Meets applicable additional criteria (if any) outlined below.

Orthotic devices **are considered not medically necessary** when they**:**
- Have not been prescribed by a physician, chiropractor, and/or other qualified provider;
- Are not necessary to treat an existing medical condition;
- Are for sports-related activities (e.g., knee brace to prevent injury to the knees while playing football); **AND/OR**

- Are upgraded splints, e.g., decorative items; functionality or features beyond what is required for management of the patient's current medical condition.

Orthotic devices include, but are not limited to:

- Braces for leg, arm, neck, back, and shoulder;
- Corsets for the back or for use after special surgical procedures;
- Splints for extremities;
- Trusses (including Sykes hernia control device);
- Orthopedic shoes when either one or both shoes are an integral part of a leg brace [Legislation may apply, check each Plan];
- Foot orthotics and supportive devices [Legislation may apply, check each Plan; also see Foot Orthotic Section below];
- Oral orthotics (See specific Medical Policies for temporomandibular joint (TMJ) disorders, or sleep related breathing disorders).

Foot Orthotics (Functional and Accommodative Podiatric Appliances)

NOTE 1: Foot orthotics (podiatric appliances) may be subject to contract limitations or exclusions, and/or state legislation. Check contracts and legislation carefully for coverage and limitations.

NOTE 2: Some functional foot orthotics that are determined to be medically necessary may also have accommodative padding (e.g., for diabetic patients).

When foot orthotics are a covered benefit (i.e., orthopedic shoes, inserts, arch supports, footwear, lifts, wedges, heels, and miscellaneous shoe additions), the following criteria apply to functional and accommodative foot orthotics:

Functional foot orthotics **may be considered medically necessary for:**

- Symptomatic pediatric dysfunctional flatfoot;
- Symptomatic adult dysfunctional flatfoot;
- Symptomatic posterior tibial tendon dysfunction;
- Symptomatic peroneal spastic flatfoot with or without subtalar coalition;
- Postoperative treatment following surgical correction of foot deformities, i.e.,
    1. Hallux abducto-valgus,
    2. Hallux limitus/rigidus,
    3. Multiple hammertoes,
    4. Joint fusions,
    5. Joint or bone resections due to arthritis or infection,
    6. Partial amputations;
- Postoperative treatment following surgical treatment of congenital conditions of the foot and ankle, i.e.,
    1. Calcaneovalgus,
    2. Talipes calcaneous,

3. Talipes equinous,
4. Equino-cavovarus; and/or

- Treatment of the conditions listed in table 1 when the listed prerequisites have been determined:

Table 1. Functional Foot Orthotics Coverage Requirements

Diagnosis	Duration of symptoms	Previous failed treatments	Confirmation that patient is ambulatory
Hallux Abducto-Valgus (1st metatarsophalangeal joint [MPJ] Bunion)	>3 months	• Accommodating shoe wear • Padding • NSAIDS • Cortisone injections	Yes
Hallux Limitus/Rigidus (Degenerative 1st MPJ)	>3 months	• Accommodating shoe wear • Padding • NSAIDS • Cortisone injections	Yes
Hammertoes	>3 months	• Accommodating shoe wear • Padding • NSAIDS • Cortisone injections	Yes
Tailor's Bunions (5th MPJ Area)	>3 months	• Accommodating shoe wear • Padding • NSAIDS • Cortisone injections	Yes
Neuromas	>3 months	• Accommodating shoe wear • Padding • Over the counter (OTC) insoles • NSAIDS • Cortisone injections	Yes
Plantar Fasciitis/Heel Spur Syndrome	>3 months	• Proper shoe wear • OTC Arch supports worn > 6 weeks • Stretching/Ice Therapy • NSAIDS • Cortisone injections	Yes
Metatarsalgia	>3 months	• Proper shoe wear • Padding • OTC insoles/Arch supports • NSAIDS	Yes
Chronic Ankle Instability	>1 year	• Ankle support utilized for activities	Yes

		• OTC arch support worn > 6 weeks • NSAIDS	

Key: NSAIDS: nonsteroidal anti-inflammatory drugs; OTC: over the counter; MPJ: metatarsophalangeal joint.

Accommodative foot orthotics **are considered not medically necessary** as they do not address structural or functional abnormalities, they are primarily for comfort, and/or they are over the counter (OTC) items (with or without a prescription).

NOTE 3: Coverage of foot orthotics is defined separately (See below).

Stock Orthotics

Stock orthotics (i.e., over the counter [OTC] and/or off-the-shelf) items that do not require a physician's prescription) may be contract exclusions. Member contract benefit may vary. Check contracts for coverage eligibility.

Stock orthotics include, but are not limited to:

- Arch supports and other foot support devices and foot orthotics, including transferrable shoe inserts— Legislation may apply, check each Plan; see coverage of Foot Orthotics below;
- Elastic stockings;
- Garter belts; and/or
- Orthopedic shoes, except when either one or both shoes are an integral part of a leg brace- Legislation may apply, check each Plan.

Inversion/Eversion Correction Devices

Inversion/eversion correction devices (e.g., Agilium Freestep) **are considered experimental, investigational and/or unproven.**

Stance-Control Knee-Ankle-Foot-Orthotic

A stance-control knee-ankle-foot-orthotic (SCKAFO) with electronic or microprocessor stance control **is considered experimental, investigational and/or unproven**, including but not limited to SensorWalk™, E Mag™, FreeWalk™ and C-Brace Orthotronic Mobility System.

Energy-Storing Exoskeletal Orthoses

Energy-storing exoskeletal orthoses **are considered experimental, investigational and/or unproven**, including but not limited to Intrepid Dynamic Exoskeletal Orthosis (IDEO) brace.

Dynamic Movement Orthoses/Suit Therapy

Dynamic movement orthoses and/or suit therapy **are considered experimental, investigational and/or unproven**, including but not limited to:

- Sensory dynamic orthosis; or
- Dynamic movement brace/orthosis; and/or

- Therasuit.

Spinal Pelvic Stabilizers
Spinal pelvic stabilizers (including, but not limited to, Foot Levelers Spinal Pelvis Stabilizers, Elite™ XL Spinal Pelvic Stabilizers, etc.) **are considered experimental, investigational and/or unproven.**

AposTherapy
AposTherapy (biomechanical shoe-like device) for the management of various back, hip, and knee conditions **is considered not medical necessary**.

Policy Guidelines

For Sensor Walk, E Mag, and FreeWalk: Manufacturer advises billing with L2005 as the base code, in addition to the unlisted code L2999 with the following description: Addition to lower extremity orthosis, microprocessor stance control feature, limitless knee flexion block in stance, includes sensors, any type.

There are no specific codes for the dynamic movement brace/orthoses, sensory dynamic orthosis, suit therapy or AposTherapy.

Description

Orthotics
An orthotic (orthosis) is a rigid or semi-rigid device used to support or align body parts, prevent or correct deformities, protect a body function, improve or restore the function of movable body parts, or assist a dysfunctional joint. Orthotics may redirect or restrict motion of an impaired body part. An orthotic is used in the treatment of an illness or injury for therapeutic support, protection, restoration, or function of an impaired body part. Orthotic devices range from arm slings to corsets and finger splints. They may be made from a variety of materials, including rubber, leather, canvas, rubber synthetics, and plastic. Examples of orthotics include but are not limited to external braces, splints, immobilizers, and trusses. (1)

A foot orthosis, or foot orthotic, is a brace which is designed to correct foot, ankle, leg, knee, thigh and hip abnormalities to reduce the strain on the injured structure(s). There are two main types of prescription foot orthoses: accommodative foot orthoses and functional foot orthoses. (2)

Accommodative Foot Orthotics
Accommodative foot orthotics are used to cushion, pad or alleviate pressure from a painful or injured area on the bottom or sole of the foot (e.g., calluses, sore bones, foot ulcers etc.). An accommodative foot orthotic does not address structural or functional abnormality. Accommodative orthotics may be made of a wide range of materials including but not limited

to cork, leather, plastic foams, and rubber materials. Accommodative orthotics are usually softer and more flexible than functional foot orthotics. The disadvantages include they are typically bulky, have relatively poor durability, and often require frequent adjustments to allow them to continue working properly. (2)

Functional Foot Orthotics

Functional foot orthotics are designed for the shape of the foot to accommodate or correct abnormal function. While supporting and balancing the foot, a functional orthotic controls the way the foot works (function) for either therapeutic or preventative purposes. Functional foot orthoses are useful in the treatment of a very wide range of painful conditions of the foot and lower extremities, including toe joint pain, arch and instep pain, ankle and heel pain. Since abnormal foot function can cause abnormal leg, knee and hip function, functional foot orthoses are commonly used to treat painful tendinitis and bursitis conditions in the ankle, knee and hip, in addition to shin splints in the legs. Some types of functional foot orthoses may also be designed to accommodate painful areas on the bottoms of the foot, just like accommodative foot orthoses. Diagnosis, patient history and physician evaluation determine the therapeutic benefit of functional orthotics. Functional foot orthoses are relatively durable, infrequently require adjustments and are more likely to fit into standard shoes. The disadvantages are that they are relatively difficult to adjust, relatively firm and provide less cushion to the foot. (2)

Flatfoot (Pediatric and Adult)

Flat feet (pes planovalgus) can be present from birth (congenital) or develop with time (acquired). Congenital flat foot may be the result of a deformity of one or more bones in the foot, or a failure of the bones to separate during growth before birth (tarsal coalition). Sometimes it simply runs in families. Acquired flat foot is usually the result of injury, arthritis, or a torn tendon (posterior tibial tendon). (3) Initial treatment options include activity modification, proper shoes and orthosis, exercises, and medication. Furthermore, comorbidities such as obesity and ligamentous laxity should be identified and managed, if applicable. (3)

If not treated, flatfoot is believed to lead to gait disorders later in life. Pediatric flatfoot is divided into two categories: flexible and rigid. Flexible flatfoot is characterized by a normal arch during non-weight bearing and a flattening of the arch on stance and may be asymptomatic or symptomatic. Rigid flatfoot is characterized by a stiff, flattened arch in both weight bearing and non-weight bearing positions. Most rigid flatfeet are associated with underlying pathology. Flatfoot (either flexible or rigid) may exist as an isolated pathology or as part of a larger clinical entity. These entities may include generalized ligamentous laxity, neurologic and muscular abnormalities, genetic conditions and syndromes, and collagen disorders (noted in Table 2). (4)

Table 2: Etiology of Pediatric Flatfoot (4)

Flexible	Rigid
• Accessory navicular bone, • Calcaneovalgus, • Collagen disorders (e.g., Ehlers–Danlos),	• Congenital vertical talus, • Iatrogenic, • Tarsal coalition,

• Deformities, • Generalized ligamentous laxity, • Genetic syndromes (e.g., Osteogenesis imperfecta, Marfan syndrome, Down syndrome), • Limb rotation, • Muscular abnormalities (e.g., Muscular dystrophy), • Neurologic disorders (e.g., Cerebral palsy, hypotonia), • Obesity, • Other biomechanical causes (e.g., Ankle equinus varus and valgus), • Physiologic variant of normal.	• Traumatic, • Peroneal spastic flatfoot.

Adult acquired flatfoot deformity (AAFD) is a group of disorders associated with abnormal pronation of the foot. The etiologies for adult flatfoot are varied including congenital, biomechanical, systemic disease, traumatic and iatrogenic. Consequently, the reported diagnosis may include, but are not limited to, the following (5):

<u>Congenital</u>

- Ligamentous laxity,
- Calcaneal valgus,
- Congenital convex pes valgus (vertical talus),
- Tarsal coalition,
- Neuromuscular conditions,
- Gastroc-soleal equinus,
- Abnormal talar ontogeny,
- Limb length discrepancy,
- Torsional and/or angulational leg deformities;

<u>Biomechanical</u>

- Torsional and/or angulational leg deformities,
- Compensated ankle equinus,
- Subtalar joint varus or valgus,
- Compensated metatarsus adductus,
- Medial column hypermobility,
- Compensated limb length discrepancy;

<u>Systemic Disease</u>

- Neuromuscular disorders (e.g., poliomyelitis, cerebral palsy, multiple sclerosis, Charcot Marie Tooth),
- Metabolic diseases producing peripheral neuropathy (e.g., Charcot joint),
- Inflammatory arthritis;

<u>Traumatic</u>

- Fracture of tarsal coalition,
- Malaligned foot, ankle or leg fracture,
- Posterior tendon laceration, rupture or avulsion,
- Lisfranc's joint dislocation or fracture;

Iatrogenic

- Overcorrection of metatarsus adductus or clubfoot,
- Overcorrection or under correction of equinus,
- Overcorrection or under correction of ankle or tarsal osteotomy,
- Malposition of fusion,
- Disruption of the posterior tibial tendon secondary to navicular or perinavicular surgery,
- First metatarsal elevatus secondary to osteotomy or fusion of the first ray.

Posterior Tibial Tendon Dysfunction (PTTD) is one of the most common problems of the foot and ankle. (6) It occurs when the posterior tibial tendon becomes inflamed or torn, resulting in pain and edema along the posterior tibial tendon, frequently between the medial malleolus and navicular. As a result, the tendon may not be able to provide stability and support for the arch of the foot, resulting in flatfoot.

Peroneal Spastic Flatfoot is usually associated with a subtalar joint coalition. This condition presents with pain and gait disturbance as coalition ossifies. Shortened peroneal and extensor tendons can be noted on the lateral foot and may be associated with diffuse tenderness around the tarsus. Ankle movement is normal, but subtalar movements are restricted or absent. Typically, tarsal pain is aggravated by activity. (7)

Inversion/Eversion Correction Devices (e.g., Agilium Freestep)

Agilium Freestep is an inversion/eversion correction device that offers dynamic off-loading of the knee joint for individuals with mild to moderate medial or lateral unicompartmental knee osteoarthritis. The device is applied to the foot, inside the shoe, instead of around the knee to shift the weight bearing line to a healthy area of the cartilage which relieves pain and stiffness and increases individual function. (8)

Stance-Control Knee-Ankle-Foot-Orthotic

The SensorWalk™ stance-control knee-ankle-foot-orthosis (KAFO) is designed to enhance stability during stance phase and provide stumble recovery by anticipating the need for stance stability even before the foot is in contact with the ground during the swing phase of gait. Stance control releases as the foot unloads, allowing a more natural gait because knee extension is not required to unlock the joint. Stance control is initiated in mid-swing, before contact with the ground, to make walking more secure and to provide stumble recovery. (9, 10)

The E-MAG Control is an electronically controlled orthosis system with a locking knee, which gives patients greater stability and security. The E-MAG is indicated for patients with post-traumatic conditions such as poliomyelitis, post-polio syndrome, failure or weakness of knee extensors. (11)

The FreeWalk is for patients who are unable to stabilize their knee without compensatory measures. Stance control technology locks during stance and unlocks during swing for a more efficient gait. The knee joint automatically locks prior to initial contact when joint is fully extended for added security. (12)

The C-Brace Orthotronic System uses a microprocessor-controlled gait to provide dynamic gait analysis and a more natural walking pattern. The internal microprocessor provides real-time control and adjusts the level of resistance with the goal of improving the patient's ability to recover safely in the event of a trip or stumble. (13)

Energy-Storing Exoskeletal Orthoses

The Intrepid Dynamic Exoskeletal Orthosis™ (IDEO) (first reported in 2009) is a high-performance, dynamic orthosis that was developed by the military to be used for individuals with severe lower limb trauma to return them to high levels of activity. The IDEO was introduced with a specialized return to run (RTR) therapy program with the goal of increasing the return to duty rates. The IDEO is a plantar flexion-powered brace that includes a rigid foot plate and ankle section that prevent motion at both of these levels; energy-storing carbon fiber struts that function to translate energy generated at the forefoot; and a clam-shell proximal cuff where the energy is delivered. The IDEO brace provides sufficient stability, energy return, and pain relief by bypassing a stiff or painful foot or ankle enough to allow participation in more aggressive rehabilitative therapies. (14)

Dynamic Movement Orthoses/Suit Therapy

Sensory Dynamic® Orthosis is a dynamic movement orthotic that may result in improved sensory and proprioceptive feedback, musculoskeletal support and alignment, postural control and proximal stability, improved function and quality of movement. This is thought to be due to the stimulation of the somatosensory and musculoskeletal systems which give changes in tone and postural alignment. According to the manufacturer, Jobskin, Sensory Dynamic Orthoses are designed to provide constant and consistent compression for sensory and proprioceptive feedback. They provide musculoskeletal alignment and resistance while allowing movement, which allows for motor learning and neural integration. Sensory Dynamic® Orthosis are actively used for patients with cerebral palsy, acquired spinal injury, cerebellar ataxia, spina bifida, post stroke, multiple sclerosis and dystonia. They can also be used for the management of conditions with joint instability and sensory deficit to include persistent low tone, inherited conditions (e.g., Ehlers Danlos Syndrome), hyper-mobility and joint laxity or in any condition with sensory modulation challenges. (15)

Dynamic Lycra® Orthoses are a relatively new approach to managing abnormal tone and neurological dysfunction in pediatric patients. The aim is to improve functional abilities through the application of an orthosis designed to meet individual needs and objectives. It is believed that the garment works by increased pressure on certain muscle groups and improved proprioception, which are supposed to lead to better awareness of the affected part of the body. Advantages are reported to be improved function from better posture, improved

proximal and distal stability and reduced involuntary movements, pain relief, decreased associated reactions, easier transfers and improved therapy sessions. Over time, improvement in function and control of movement should continue after the garment is removed. Dynamic Lycra® Orthoses are typically used for individuals who have conditions which affect muscle tone and sensory processing due to congenital reasons, illness and injury. Patients with neurological dysfunction as a result of cerebral palsy, stroke (CVA), head injury, multiple sclerosis and other neurological conditions may benefit from wearing an orthosis. (16)

TheraSuit® is a dynamic movement garment that is reported to improve and change proprioception (pressure from the joints, ligaments, muscles), reduce patient's pathological reflexes, restore physiological muscle synergies (proper patterns of movement) and load the entire body with weight, with the goal to influence muscle tone, balance and the position of the body in space. The TheraSuit®, worn over a prolonged time, is intended to facilitate rehabilitation of children with neurological disorders which result in decreased range of motion, muscle weakness, difficulties with movement against gravity, maintaining posture and other motor activities impairments. (17)

Spinal Pelvic Stabilizers

Spinal pelvic stabilizers are custom-made orthotics designed to stabilize the foundation of the pelvis and spine by addressing structural problems in the feet. Various chiropractic web sites define Foot Levelers Spinal Pelvic Stabilizers; they state that the pain felt in the neck could be caused by misalignment, abnormal forces, or stress on the spine, which contribute to unbalanced position in the feet. They propose that imbalances may occur even if you're not experiencing foot pain, and that these imbalances contribute to postural misalignments, pain in areas throughout your body and fatigue. (18, 19) Elite™ Energy XL Spinal Pelvic Stabilizers are custom-made orthotics that support all three arches of the foot and help align the feet, ankles, knees, hips and back to provide a balanced foundation for the body. (20)

AposTherapy (Biomechanical Shoe-Like Device)

The AposTherapy System consists of a pair of shoe-like uppers with two convex units (Pertupods) on the sole of each device, a screw fixation mechanism for securely attaching the Pertupod to the track and, adjustable spacers (i.e., pods) placed on the sole of the custom shoe aimed to correct gait patterns. Separately marketed and commercially available off-the-shelf (OTS) gait analysis software is used by physical therapists to analyze the walking pattern and inform their calibration of the pods. The pods help relieve pressure and pain from symptomatic joint and improve control of the muscular system and function. This is achieved by challenging the patient in a barely perceptible manner through the creation of micro-instability. (21)

Glossary (22)

- Bunion: A abnormal enlargement of the joint (the first metatarsophalangeal joint, or MTPJ) at the base of the great or big toe (hallux). It is caused by inflammation and usually results from chronic irritation and pressure from poorly fitting footwear.
- Callus: Localized hyperplasia of the horny layer of the epidermis due to pressure or friction.

- Corn: A circumscribed, conical, horny induration and thickening of the stratum corneum that causes severe pain by pressure on nerve endings in the corium. Corns are always caused by friction or pressure from poorly fitting shoes or hose. There are two kinds: the hard corn, usually located on the outside of the little toe or on the upper surfaces of the other toes; and the soft corn, found between the toes, usually the fourth and fifth toes, kept softened by moisture. syn: heloma.
- Hallux: Great toe.
- Hallux dolorosus: A condition, usually associated with flatfoot, in which walking causes severe pain in the metatarsophalangeal joint (MPJ) of the great toe. syn: painful toe.
- Hallux extensus: A deformity in which the great toe is held rigidly in the extended position.
- Hallux flexus: Hammertoe. syn: Hallux maleous.
- Hallux rigidus: A condition in which stiffness appears in the first MPJ; usually associated with the development of bone spurs on the dorsal surface. syn: stiff toe.
- Hallux valgus: A deviation of the distal portion of the great toe, at the MPJ, toward the outer or lateral side of the foot.
- Hallux varus: Deviation of the distal portion of the great toe, at the MPJ, to the inner side of the foot away from the second toe.
- Metatarsus latus: Broadened foot, due to spreading of the anterior part of the foot resulting from separation of the heads of the metatarsal bones from each other; also called broad foot or spread foot; syn: talipes transversoplanus.
- MPJ: Metatarsophalangeal joint.
- Pes planus: A condition in which the longitudinal arch is broken down, the entire sole touching the ground. syn: talipes planus; flatfoot.
- Stock orthotics: Off-the-shelf. (syn: over the counter [OTC]).
- Talipes—Deformity of the foot, which is twisted out of shape or position. syn: clubfoot.
- Talipes calcaneovalgus: Talipes calcaneus and talipes valgus combined; the foot is dorsiflexed, everted, and abducted.
- Talipes calcaneovarus: Talipes calcaneus and talipes varus combined; the foot is dorsiflexed, inverted, and adducted.
- Talipes calcaneus: A deformity due to weakness or absence of the calf muscles, in which the axis of the calcaneus becomes vertically oriented; commonly seen in poliomyelitis.
- Talipes cavus: An exaggeration of the normal arch of the foot; syn: contracted foot, pes cavus, talipes plantaris, clawfoot.
- Talipes equinovalgus: Talipes equinus and talipes valgus combined; the foot is plantarflexed, everted, and abducted; syn: equinovalgus, pes equinovalgus.
- Talipes equinovarus: Talipes equinus and talipes varus combined; the foot is plantarflexed, inverted, and adducted; syn: clubfoot, equinovarus, pes equinovarus.
- Talipes equinus: Permanent plantar flexion of the foot so that only the ball rests on the ground; it is commonly combined with talipes varus.
- Talipes Percavus: Talipes in which there is excessive plantar curvature.
- Talipes valgus: Permanent eversion of the foot, the inner side alone of the sole resting on the ground; it is usually combined with a breaking down of the plantar arch. syn: pes abductus, pes pronatus, pes valgus.

- Talipes varus: Inversion of the foot, the outer side of the sole only touching the ground; usually some degree of talipes equinus is associated with it, and often talipes cavus. syn: pes adductus, pes varus.

Rationale

This medical policy was created in May 1990. The current coverage is based on contractual language, Centers for Medicare & Medicaid Services (CMS) guidance, professional guidelines, and key literature through June 13, 2023.

Orthotics
In 2004, Rome et al. (23) evaluated two distinct types of foot orthoses used to treat plantar heel pain. Forty-eight patients were randomly assigned to receive either a functional or an accommodative orthosis. General (EuroQol) and specific (Foot Health Status Questionnaire) health-status measures were used. Data were measured at baseline and at 4- and 8-week intervals. Thirty-five patients completed the study. The results demonstrated a significant decrease in foot pain and a significant increase in foot function with the functional foot orthoses over the 8-week trial. The accommodative foot orthoses demonstrated a significant reduction in foot pain only at 4 weeks. The cost-effectiveness analysis demonstrated that functional orthoses, although initially more expensive, result in a better quality of life.

In 2008, Hume et al. (24) examined the effectiveness of foot orthotics for the treatment and prevention of lower limb injuries. Qualifying studies were mainly controlled trials, but some uncontrolled clinical trials of patients with chronic injuries were analyzed separately. Injuries included plantar fasciitis, tibial stress fractures and patello-femoral pain syndrome. Outcomes were pain, comfort, function, and injury status. Continuous measures were expressed as standardized differences using baseline between-subject standard deviations, and magnitudes were inferred from the intersection of 90 % confidence intervals (CIs) with thresholds of a modified Cohen scale. Effects based on frequencies were expressed as hazard ratios and their magnitudes were inferred from intersection of CIs with a novel scale of thresholds. The effects of foot orthotics for treatment of pain or injury prevention were mostly trivial. Foot orthoses were not effective in treating or preventing patello-femoral pain syndrome. Some studies showed moderate effects for treatment of plantar fasciitis. Only a few studies showed moderate or large beneficial effects of foot orthotics in preventing injuries. Customized semi-rigid foot orthotics have moderate to large beneficial effects in treating and preventing plantar fasciitis and posterior tibial stress fractures, and small to moderate effects in treating patello-femoral pain syndrome. Given the limited randomized controlled trials (RCT) available, it may be that benefit can be derived from the use of foot orthotics, but many studies did not provide enough information for the standardized effect sizes to be calculated. The authors concluded that further research with RCTs is needed to establish the clinical utility of a variety of foot orthotics for the treatment and prevention of various lower limb injuries.

In 2015, Gabriner et al. (25) stated that it has been suggested that foot orthotics may increase a chronic ankle instability patient's postural control therefore, investigators reviewed the evidence to examine if an orthotic intervention will help improve postural control. Studies of level 2 evidence or higher that investigated the effects of foot orthotics on postural control in patients with chronic ankle instability was searched. There were 5 possible studies for inclusion; 2 studies met the inclusion criteria and were included, 1 RCT and 1 outcomes study were included. Foot orthotics appeared to be effective at improving postural control in patients with chronic ankle instability. The authors concluded that there is moderate evidence to support the use of foot orthotics in the treatment of chronic ankle instability to help improve postural control. They noted that the Centre of Evidence Based Medicine recommended a grade of B for level 2 evidence with consistent findings.

In 2016, Papuga and Cambron (26) evaluated literature on the use of foot orthotics for low back pain (LBP) and made specific recommendations for future research. PubMed, EBSCO, GALE, Google Scholar, and clinicaltrials.gov databases were searched. The literature was examined to determine the current state of knowledge on the benefits of foot orthotics for LBP related to biomechanical mechanisms and clinical outcomes. It may be argued that foot orthotics are experimental, investigational, or unproven for LBP due to lack of sufficient evidence for their clinical effectiveness. This conclusion is based upon lack of high quality RCTs. However, there is extensive research on biomechanical mechanisms underlying the benefits of orthotics that may be used to address this gap. Additionally, promising pilot studies are beginning to emerge in the literature and ongoing large-scale RCTs are addressing effects of foot orthotics on chronic LBP. The authors concluded that based upon the critical evaluation of the current research on foot orthotics related to biomechanical mechanisms and clinical outcomes, recommendations for future research to address the evidence-practice gaps on the use of foot orthotics for LBP were presented.

In 2018, Bishop et al., conducted a three-arm randomized controlled trial with blinding of participants and assessors. (27) This study investigated the effect of wearing custom foot orthoses and new athletic footwear on first-step pain, average 24-hour pain and plantar fascia thickness in people with unilateral plantar fasciopathy over 12 weeks. At the end of the 12 weeks those wearing custom foot orthoses in new shoes showed a decrease in first-step pain and reduction in plantar fascia thickness compared to new shoes alone or a sham intervention.

Inversion/Eversion Correction Devices

Several small studies were identified that evaluated the use of the Agilium Freestep for use in osteoarthritis (OA) of the knee. In 2019, a prospective randomized trial compared conventional knee unloader braces and the Agilium FreeStep (a foot ankle orthosis). (28) Unloader braces have been a non-surgical treatment option for patients with medial OA, but many patients do not adhere to brace treatment due to bad fit and skin irritation. Skin irritation can occur under the pads at the level of the joint space. The primary outcome measure was pain. Secondary outcome measures were knee function, side effects, additional interventions, and compliance. The results of this clinical trial show that the foot ankle brace is as effective as a conventional knee unloader brace for the treatment of medial knee OA with regard to clinical outcome. The

rate of side effects such as bruises was significantly lower in the Agilium FreeStep group. The Agilium FreeStep group also reported significantly less bruises (23.5% vs 66.7%).

American Academy of Orthopedic Surgeons (AAOS)

The 2021 AAOS Osteoarthritis Guidelines of the Knee (Non-Arthroplasty) (29) states: "Brace treatment could be used to improve function, pain and quality of life in patients with knee osteoarthritis. Strength of Recommendation: Moderate (downgrade). The Braces recommendation has been downgraded one level because of heterogeneity. Future high-quality studies in populations with similar mechanical axis with a similar degree of osteoarthritis."

Electronic Stance-Control Knee-Ankle-Foot-Orthotic (KAFO)

Stance control knee-ankle foot orthoses (SCKAFO) differ from their traditional locked knee counterparts by allowing free knee flexion during swing while providing stability during stance. It is widely accepted that free knee flexion during swing normalizes gait and therefore improves walking speed and reduces the energy requirements of walking. Limited research has been carried out to evaluate the benefits of SCKAFOs when compared to locked KAFOs.

In 2010, Davis et al. (30) conducted a study to evaluate the effectiveness of SCKAFOs used for patients with lower limb pathology. Energy expenditure and walking velocity were measured in 10 subjects using an orthosis incorporating a Horton Stance Control knee joint. A GAITRite walkway was used to measure temporospatial gait characteristics. A Cosmed K4b2 portable metabolic system was used to measure energy expenditure and heart rate during walking. Two conditions were tested: Walking with stance control active (stance control) and walking with the knee joint locked. Ten subjects completed the GAITRite testing; nine subjects completed the Cosmed testing. Walking velocity was significantly increased in the stance control condition ($p < 0.001$). There was no difference in the energy cost of walking ($p = 0.515$) or physiological cost index (PCI) ($p = 0.093$) between conditions. This study supports previous evidence that SCKAFOs increase walking velocity compared to locked knee devices. Contrary to expectation, the stance control condition did not decrease energy expenditure during walking.

In 2016, Rafiaei and colleagues (31) compared the evidence of SCKAFO with drop locked knee joints in improving kinematic variables and energy efficiency of walking by subjects with quadricep muscle weakness caused by different pathologies. A literature review was performed in Google Scholar, PubMed, ScienceDirect, and ISI Web of Knowledge databases. In total, 18 articles were finally chosen for review. The results of this study demonstrated that this type of orthosis can improve the walking parameters of subjects with quadriceps muscle weakness and spinal cord injury patients when compared to a locked knee-ankle-foot orthosis. The authors concluded that there is evidence to show that stance control orthosis improve the gait kinematics but not energetic of KAFO users. Development of new designs of stance control orthoses to provide a more normal pattern of walking is still needed.

In 2021, an Ontario Health Technology Assessment reviewed four studies in their clinical evidence review. (32) The results showed, "We are uncertain if stance-control knee-ankle-foot

orthoses (SCKAFOs) improve walking ability, energy consumption, or activities of daily living compared with locked knee-ankle-foot orthoses (LKAFOs) (GRADE: Very low). Our economic evidence review identified one costing analysis that suggested that the costs of orthotic devices such as LKAFOs and SCKAFOs are highly variable according to the cost of materials, professional time, and customization required by the individual patient."

Energy-Storing Exoskeletal Orthoses

In 2012, Patzkowski et al. (33) reported a small study to determine whether the Intrepid Dynamic Exoskeletal Orthosis™ (IDEO) would improve functional performance compared with a non-custom carbon fiber orthosis (BlueRocker), a posterior leaf spring orthosis, and no brace. Eighteen subjects with unilateral dorsiflexion and/or plantar flexion weakness were evaluated with 6 functional tests while they were wearing the IDEO, BlueRocker, posterior leaf spring, or no brace. The brace order was randomized, and 5 trials were completed for each of the functional measures, which included a four-square step test, a sit-to-stand five times test, tests of self-selected walking velocity over level and rocky terrain, and a timed stair ascent. They also completed 1 trial of a forty-yard (37-m) dash, filled out a satisfaction questionnaire, and indicated whether they had ever considered an amputation and, if so, whether they still intended to proceed with it. The study determined that performance was significantly better with the IDEO with respect to all functional measures compared with all other bracing conditions ($p < 0.004$), with the exception of the sit-to-stand five times test, in which there was a significant improvement only as compared with the BlueRocker ($p = 0.014$). The forty-yard dash improved by approximately 35% over the values for the posterior leaf spring and no-brace conditions, and by 28% over the BlueRocker. The BlueRocker demonstrated a significant improvement in the forty-yard dash compared with no brace ($p = 0.033$), and a significant improvement in self-selected walking velocity on level terrain compared with no brace and the posterior leaf spring orthosis ($p < 0.028$). However, no significant difference was found among the posterior leaf spring, BlueRocker, and no-brace conditions with respect to any other functional measure. Thirteen patients initially considered amputation, but after completion of the clinical pathway, 8 desired limb salvage, 2 were undecided, and 3 still desired amputation. The authors concluded that the use of the IDEO significantly improved performance on validated tests of agility, power, and speed. The majority of subjects that initially considered amputation favored limb salvage after this noninvasive intervention. Further studies need to be conducted to determine clinical utility and improved outcomes, as well as the appropriate patient population for treatment.

In 2014, Bedigrew et al. (34) prospectively evaluated 84 service members (n=53 <2 years; n=31 >2 years after injury) who enrolled in an integrated orthotic and rehabilitation program. Fifty-eight sustained fractures, 53 sustained nerve injuries with weakness, and 6 had arthritis (there was some overlap in the patients with fractures and nerve injuries, which resulted in a total of >84). The patients completed 4 weeks of physical therapy without the orthosis followed by 4 weeks with it. Testing was conducted at week 0, 4, and 8. Validated physical performance tests, patient-reported outcome surveys and questions pertaining to whether patients were considering amputation were evaluated. By week 8, patients improved in all physical performance measures and patient-reported outcomes. It was noted that patients less than

and >2 years post injury improved similarly. Forty-one of 50 patients initially considering amputation favored limb salvage at 8 weeks. The authors concluded that the integrated orthotic and rehabilitation initiative improved physical performance, pain, and patient-reported outcomes in patients with severe, traumatic lower extremity deficits and that these improvements were sustained for >2 years after injury. Efforts are underway to determine whether the Return to Run clinical pathway with the IDEO can be successfully implemented at additional military centers in patients >2 years from injury while sustaining similar improvements in patient outcomes. The ability to translate this integrated orthotic and rehabilitation program into the civilian setting is unknown and warrants further investigation.

Quacinella et al. (35) (2018) prospectively evaluated all active-duty military Intrepid Dynamic Exoskeletal Orthosis (IDEO) users at a single institution who had previously sustained a pilon fracture. Three-dimensional gait analysis was performed two times: first wearing shoes at a self-selected speed and second after a custom-made IDEO was fabricated for the patient and completion of the Return-to-Run pathway. Patients reported their average pain while ambulating using a numeric rating scale. Gait variables of interest were velocity, cadence, stride length, and single stance time. Median gait velocity improved from 1.1 (interquartile range [IQR], 0.9-1.2) to 1.3 m/s (IQR, 1.2-1.5; p = 0.01). All other variables did not change: cadence 98.4 (IQR, 93.0-107.2) to 104.5 steps/min (IQR, 103.0-109.0; p = 0.13), affected stride length 1.3 (IQR, 1.0-1.4 m) to 1.4 m (IQR, 1.3-1.6 m; p = 0.07), and affected single stance 0.42 (IQR, 0.41-0.47) to 0.43 (IQR, 0.42-0.44; p = 0.80). Pain did not change between time points: 3 (IQR, 2-3) to 2.5 (IQR, 1-3.5; p = 0.90). Three of seven patients returned to duty. At self-selected walking speeds, no improvements were observed in gait parameters or pain after application of the IDEO that would likely be considered clinically important. It is possible that for higher demand users such as elite athletes, the IDEO could have a role after severe lower extremity trauma; however, this must be considered speculative until or unless proven in future studies.

Dynamic Movement Orthoses/Suit Therapy

In 2011, Bailes et al. (36) randomized 20 children to either an experimental (TheraSuit) or a control (control suit) group who participated in an intensive therapy program. The Pediatric Evaluation of Disability Inventory (PEDI) and Gross Motor Function Measure (GMFM)-66 were administered before and after (4 and 9 weeks). Parent satisfaction was also assessed. No significant differences were found between groups. Significant within-group differences were found for the control group on the GMFM-66 and for the experimental group on the GMFM-66, PEDI Functional Skills Self-care, PEDI Caregiver Assistance Self-care, and PEDI Functional Skills Mobility. No adverse events were reported. The study concluded that children wearing the TheraSuit during an intensive therapy program did not demonstrate improved motor function compared with those wearing a control suit during the same program.

In 2017, Almeida et al. (37) evaluated the evidence on the effects of interventions based on the use of therapeutic suits in the treatment of impairments and functional limitations of children with cerebral palsy. The following databases were searched by 3 independent reviewers: MEDLINE, SciELO, BIREME, LILACS, PEDro and CENTRAL databases. The reviewers evaluated the methodological quality of selected studies using the Checklist for Measuring Quality. The

Grading of Recommendations Assessment, Development and Evaluation was used to synthesize the quality of evidence and strength of recommendation. From the 13 studies, 2 evaluated the Full Body Suit, 2 tested the Dynamic Elastomeric Fabric Orthose, 3 evaluated TheraTogs and 6 tested the TheraSuit/AdeliSuit protocols. The quality of evidence for the Full Body Suit, the Dynamic Elastomeric Fabric Orthose and the TheraSuit/AdeliSuit protocols was very low for body structure and function outcomes, while the evidence for TheraTogs was low quality. Regarding the activity outcomes, the Full Body Suit and TheraSuit showed very low-quality evidence while the evidence for TheraSuit/AdeliSuit protocols were of low quality. This systematic review determined that new therapeutic approaches in children with cerebral palsy need to be guided by scientific evaluation. The low-quality of evidence suggests caution in recommending the use of these therapeutic suits.

Giray et al. (38) (2020) performed a single-blinded, randomized controlled study to evaluate the effects of vest type dynamic elastomeric fabric orthosis on posture and balance during sitting and gross manual dexterity and to compare the efficacy of daily wearing time of two hours versus six hours. The study included 24 children with cerebral palsy (CP) that were randomized to either of three groups: a control group who received only conventional exercise therapy; dynamic elastomeric fabric orthosis 2 hour group who wore the orthosis for two hours during therapy and dynamic elastomeric fabric orthosis six group who wore the orthosis for four hours in addition to the two hours of wear along with therapy during hospital inpatient stay for two weeks. Children continued to use dynamic elastomeric fabric orthosis during the post-discharge period. The primary outcome measure was the Sitting Assessment Scale. The secondary outcome measurements were the sitting dimension of Gross Motor Function Measure, Box and Block Test and Parent Satisfaction Survey. Assessments were made before treatment, at post-treatment, at one-month post-treatment, and at three-months post-treatment. Sitting Assessment Scale and Box and Block Test were also assessed when immediately after wearing the orthosis. All groups showed similar improvements except the control group which showed less improvement in Sitting Assessment Scale scores compared to the dynamic elastomeric fabric orthosis groups. Dynamic elastomeric fabric orthosis groups showed greater improvements compared to the control group in the Sitting Assessment Scale but not in the sitting dimension of Gross Motor Function Measure and Box and Block Test at posttreatment, at 1-month post-treatment and at 3-months post-treatment. When the dynamic elastomeric fabric orthosis groups (two versus six hours) were compared, there were no significant differences in any of the assessments. The Sitting Assessment Scale and Box and Block Test scores also improved immediately after the patients put on the orthosis. The study was limited by the small number of subjects. Larger studies are needed in order to establish impact of this orthosis type in children with CP at different functional levels and ages.

No large randomized controlled trials were found that support the long-term safety and efficacy and clinical utility of dynamic movement orthoses, including the Therasuit and the Sensory Dynamic Orthosis.

Spinal Pelvis Stabilizers

In 2010, Sahar et al. (39) reported a Cochrane review of insoles for prevention and treatment of back pain. They included six trials that studied populations who did extensive standing and walking in the course of their daily jobs. Three prevention studies (2061 participants) examined the effects of both customized and non-customized insoles for the prevention of back pain. Three studies with mixed populations (256 participants) examined the effects of customized insoles for back pain without being clear whether they were aimed at primary or secondary prevention or treatment. None of the studies showed that insoles prevented back pain. No included trials assessed insoles exclusively for treatment for back pain. Although half of the trials were of high methodological quality and therefore had a low potential for bias, the results should still be read with caution. Most of the trials examined specific young, highly active male populations. Finally, no long-term treatment and prevention data are available. The authors concluded there is strong evidence that insoles do not prevent back pain, while the current evidence on insoles as treatment for low-back pain does not allow any conclusions. Better trials assessing the association between insoles and back pain are required before professional recommendation for the use of insoles become standard.

In 2011, Cambron et al. (40) reported a pilot study to investigate the feasibility of a randomized clinical trial of shoe orthotics for chronic low back pain. The study recruited 50 patients with chronic low back pain through media advertising in a midwestern suburban area. Medical history and a low back examination were completed at a chiropractic clinic. Subjects were randomized to either a treatment group receiving custom-made shoe orthotics or a wait-list control group. After 6 weeks, the wait-list control group also received custom-made orthotics. This study measured change in perceived pain levels (Visual Analog Scale) and functional health status (Oswestry Disability Index) in patients with chronic low back pain at the end of 6 weeks of orthotic treatment compared with no treatment and at the end of 12 weeks of orthotic treatment. This study showed changes in back pain and disability with the use of shoe orthotics for 6 weeks compared with a wait-list control group. It appears that improvement was maintained through the 12-week visit, but the subjects did not continue to improve during this time. This pilot study showed that the measurement of shoe orthotics to reduce low back pain and discomfort after 6 weeks of use is feasible. A larger clinical trial is needed to verify these results.

AposTherapy

In 2016, Barzilay et al. conducted a retrospective analysis of 60 chronic non-specific low back pain (CNSLBP) patients. (41) The purpose of the study was to assess the changes in gait pattern and clinical symptoms of patients with CNSLBP following a home-based biomechanical treatment (HBBT). All patients underwent a gait evaluation and completed self-assessment questionnaires at pre-treatment and after 3 and 6 months of a HBBT (AposTherapy). Twenty-four healthy, aged-matched individuals served as a reference group. Results showed significant differences were found in all gait parameters and clinical symptoms between patients with CNSLBP and healthy people before treatment. Significant improvements were found in all gait parameters and clinical measures following 6 months of therapy including an increase in gait velocity (10.6 %), step length (5.6 %), cadence (5 %), and quality of life and a decrease in pain (13.3 %). There were no significant differences between groups in the gait parameters following

6 months of treatment. In conclusion, significant differences exist between patients with CNSLBP and healthy controls in terms of gait pattern and self-assessed health status. The examined HBBT led to significant improvements in gait pattern, reduction in pain, improved function and increased quality of life. However, future studies should validate these results while comparing this treatment to other treatment modalities. Limitations include that this is a retrospective study with no placebo control group. This study included only spatiotemporal gait data rather than a three-dimensional gait analysis that provide more information on the kinematics and kinetics. A three-dimensional gait test, however, is relatively cumbersome and costly.

In 2020, Miles and Greene conducted a retrospective analysis on a United Kingdom (UK) population to determine the treatment of a non-invasive foot worn biomechanical device of subjective and objective measures in patients with knee osteoarthritis (OA). (42) This study was performed on 455 patients with knee OA. All subjects were evaluated using a computerized gait test and 2 self-assessment questionnaires (Western Ontario and McMaster Osteoarthritis Index [WOMAC] and Short Form 36 [SF-36] Health Survey) at baseline and after 3 and 6 months of treatment. The biomedical device is a shoe-like device with convex pods under the sole that have the capability of changing foot center of pressure and training neuromuscular control. After 6 months of treatment significant improvements were seen in all gait parameters ($p < 0.01$). Specifically, gait velocity, step length and single limb support of the more symptomatic knee improved by 13, 7.8 and 3%, respectively. These were supported by significant improvements in pain, function and quality of life (48.6, 45.7 and 22% respectively; $p < 0.001$). A sub-group analysis revealed no baseline differences between those who were recommended joint replacement and those who were not. Both groups improved significantly over time ($p < 0.05$ for all). Study limitations identified included retrospective analysis of patients from the centres database and therefore had no control group. In addition, patients were allowed to continue with traditional care, and we cannot determine that other treatment did not affect the results of this study. Lastly, this study did not monitor the overall activity level of the patients in general and this compliance to the treatment plan in specifics. We cannot confirm the usage time of the device at home other than when the patients returned to the clinic for a follow-up appointment and reported that they have been using the device daily. Future studies should enforce methods to monitor compliance to the treatment plan at home.

In 2020, Reichenbach et al., conducted a RCT at a Swiss university hospital to access the effect of a biomechanical footwear therapy vs control footwear over 24 weeks of follow-up. (43) Participants (N=220) with symptomatic, radiologically confirmed knee osteoarthritis were recruited between April 2015 and January 2017. Participants were randomized to biomechanical footwear involving shoes with individually adjustable external convex pods attached to the outsole (n = 111) or to control footwear (n = 109) that had visible outsole pods that were not adjustable and did not create a convex walking surface. The primary outcome was knee pain at 24 weeks of follow-up assessed with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscore standardized to range from 0 (no symptoms) to 10 (extreme symptoms). The secondary outcomes included WOMAC physical

function and stiffness subscores and the WOMAC global score, all ranging from 0 (no symptoms) to 10 (extreme symptoms) at 24 weeks of follow-up, and serious adverse events. Among the 220 randomized participants (mean age, 65.2 years [SD, 9.3 years]; 104 women [47.3%]), 219 received the allocated treatment and 213 (96.8%) completed follow-up. At 24 weeks of follow-up, the mean standardized WOMAC pain subscore improved from 4.3 to 1.3 in the biomechanical footwear group and from 4.0 to 2.6 in the control footwear group (between-group difference in scores at 24 weeks of follow-up, -1.3 [95% CI, -1.8 to -0.9]; P < .001). The results were consistent for WOMAC physical function subscore (between-group difference, -1.1 [95% CI, -1.5 to -0.7]), WOMAC stiffness subscore (between-group difference, -1.4 [95% CI, -1.9 to -0.9]), and WOMAC global score (between-group difference, -1.2 [95% CI, -1.6 to -0.8]) at 24 weeks of follow-up. Three serious adverse events occurred in the biomechanical footwear group compared with 9 in the control footwear group (2.7% vs 8.3%, respectively); none were related to treatment. Twenty-six participants (23.4%) in the biomechanical footwear group and 38 participants (34.9%) in the control footwear group experienced an adverse event and 3 (2.7%) and 9 (8.3%), respectively, experienced serious adverse events. In conclusion, it was noted that among participants with knee pain from osteoarthritis, use of biomechanical footwear compared with control footwear resulted in an improvement in pain at 24 weeks of follow-up that was statistically significant but of uncertain clinical importance. Further research would be needed to assess long-term efficacy and safety, as well as replication, before reaching conclusions about the clinical value of this device.

In 2023, Greene and Miles published a short report of long-term outcomes on the rates of total knee replacement amongst patients with end-stage knee osteoarthritis who meet surgical criteria and received a non-invasive biomechanical intervention. (44) In this retrospective analysis, 455 patients with knee OA were evaluated using a computerized gait test and 2 self-assessment questionnaires (Western Ontario and McMaster Osteoarthritis Index [WOMAC] and Short Form 36 [SF-36] Health Survey) at baseline and after 3 and 6 months of treatment. The biomedical device (Apos system) is a shoe-like device with convex pods under the sole that have the capability of changing foot center of pressure and training neuromuscular control. The device was individually calibrated for each patient to minimize symptoms while walking and train neuromuscular control. Subjects used the device for short periods during activities of daily living (ADL). Repeated measures statistical analyses were carried out to compare differences over time. After 6 months of treatment significant improvements were observed in all gait parameters ($p < 0.01$). Specifically, gait velocity, step length and single limb support of the more symptomatic knee improved by 13 %, 7.8 % and 3 %, respectively. These were supported by significant improvements in pain, function and quality of life (48.6 %, 45.7 %and 22%, respectively; $p < 0.001$). The authors stated that this study had several drawbacks. This was a retrospective study and therefore had no control group. Additionally, patients were allowed to continue with traditional care, and these investigators could not determine that other treatment did not affect the results of this study. The treatment was often undertaken as a final attempt to address the condition non-invasively before the need for a surgical intervention. As a result, these investigators believed most of the clinical effect observed in this study could be attributed to the AposTherapy and treatment plan as opposed to any adjunctive or continued

treatment modalities. Longer term results, past six months, would give more insight into the lasting effects of treatment.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	97760, 97762
HCPCS Codes	A4566, A5500, A5501, A5503, A5504, A5505, A5506, A5507, A5508, A5510, A5512, A5513, A9285, K0672, K0903, K1015, L0112, L0113, L0120, L0130, L0140, L0150, L0160, L0170, L0172, L0174, L0180, L0190, L0200, L0220, L0450, L0452, L0454, L0455, L0456, L0457, L0458, L0460, L0462, L0464, L0466, L0467, L0468, L0469, L0470, L0472, L0480, L0482, L0484, L0486, L0488, L0490, L0491, L0492, L0621, L0622, L0623, L0624, L0625, L0626, L0627, L0628, L0629, L0630, L0631, L0632, L0633, L0634, L0635, L0636, L0637, L0638, L0639, L0640, L0641, L0642, L0643, L0648, L0649, L0650, L0651, L0700, L0710, L0810, L0820, L0830, L0859, L0861, L0970, L0972, L0974, L0976, L0978, L0980, L0982, L0984, L0999, L1000, L1001, L1005, L1010, L1020, L1025, L1030, L1040, L1050, L1060, L1070, L1080, L1085, L1090, L1100, L1110, L1120, L1200, L1210, L1220, L1230, L1240, L1250, L1260, L1270, L1280, L1290, L1300, L1310, L1499, L1600, L1610, L1620, L1630, L1640, L1650, L1652, L1660, L1680, L1681, L1685, L1686, L1690, L1700, L1710, L1720, L1730, L1755, L1900, L1902, L1904, L1906, L1907, L1910, L1920, L1930, L1932, L1940, L1945, L1950, L1951, L1960, L1970, L1971, L1980, L1990, L2000, L2005, L2010, L2020, L2030, L2034, L2035, L2036, L2037, L2038, L2040, L2050, L2060, L2070, L2080, L2090, L2106, L2108, L2112, L2114, L2116, L2126, L2128, L2132, L2134, L2136, L2180, L2182, L2184, L2186, L2188, L2190, L2192, L2200, L2210, L2220, L2230, L2232, L2240, L2250, L2260, L2265, L2270, L2275, L2280, L2300, L2310, L2320, L2330, L2335, L2340, L2350, L2360, L2370, L2375, L2380, L2385, L2387, L2390, L2395, L2397, L2405, L2415, L2425, L2430, L2492, L2500, L2510, L2520, L2525, L2526, L2530, L2540, L2550, L2570, L2580, L2600, L2610, L2620, L2622, L2624, L2627, L2628, L2630, L2640, L2650, L2660, L2670, L2680, L2750, L2755, L2760, L2768, L2780, L2785, L2795, L2800, L2810, L2820, L2830, L2840, L2850, L2861, L2999, L3000, L3001, L3002, L3003, L3010, L3020, L3030, L3031, L3040, L3050, L3060, L3070, L3080, L3090, L3100, L3140, L3150, L3160, L3170, L3201, L3202, L3203, L3204, L3206, L3207, L3208, L3209, L3211, L3212, L3213, L3214,

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2023	Document updated with literature review. The following change in coverage was made: Added not medically necessary statement for AposTherapy. References 21, 41-44 added; others removed.
03/15/2023	Reviewed. No changes.
10/15/2022	Document updated with literature review. Coverage unchanged. References 14, 18, 19, 26,27 and 30 added; others removed.
09/01/2021	Reviewed. No changes.
01/01/2021	Document updated with literature review. Coverage unchanged. References 38-41 added.
12/15/2019	Reviewed. No changes.
04/01/2019	Document updated with literature review. Coverage for spring-loaded dynamic splints and bi-directional static progressive stretch splits moved to medical policy DME103.009 Mechanical Stretching Devices. Added references 1, 3, 4, 6, 7, 10, 19-24, 27, 29, 34, 35.
01/01/2017	Document updated with literature review. The following was added to Coverage: Inversion/eversion correction devices (e.g., Agilium Freestep) are considered experimental, investigational and/or unproven.
11/01/2015	Document updated with literature review. The following was added to Coverage: 1) Energy-storing exoskeletal orthoses are considered experimental, investigational and/or unproven, including but not limited to Intrepid Exoskeletal Orthosis (IDEO) brace. 2) Dynamic movement orthoses

	and/or suit therapy are considered experimental, investigational and/or unproven, including but not limited to: a) Sensory dynamic orthosis; b) Dynamic movement brace; c) Therasuit.
09/01/2014	Document updated with literature review. The following changes were made: 1) Spring-loaded dynamic splints and bi-directional static progressive stretch (SPS) splints may be considered medically necessary to restore range of motion for the shoulder; 2) A stance-control-knee-ankle-foot-orthotic (SCKAFO) with electronic or microprocessor stance control is considered experimental, investigational and/or unproven, including but not limited to SensorWalk™, E Mag™, and FreeWalk™; 3) Foot Levelers Spinal Pelvis Stabilizers are considered experimental, investigational and/or unproven.
08/15/2011	Codes Revised/Added/Deleted
12/15/2009	Routine scheduled update with literature review; no changes to coverage.
04/01/2008	Revised/Updated Entire Document
05/15/2007	Revised/Updated Entire Document
10/01/2003	Revised/Updated Entire Document
02/01/2002	Revised/Updated Entire Document
03/01/2000	Codes Revised/Added/Deleted
11/01/1999	Codes Revised/Added/Deleted
07/01/1999	Codes Revised/Added/Deleted
09/01/1998	Codes Revised/Added/Deleted
05/01/1996	Revised/Updated Entire Document
07/01/1994	Codes Revised/Added/Deleted
04/01/1994	Codes Revised/Added/Deleted
05/01/1990	New medical document