BlueCross BlueShield of Illinois

Medical Policies

**Medical Policies - DME**

Print

# Orthotics

**Number:** DME103.001

**Effective Date:** 01-01-2017

**Coverage:**

***CAREFULLY CHECK STATE REGULATIONS AND/OR THE MEMBER CONTRACT***

**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,).

**NOTE 1:** Coverage of foot orthotics is defined separately (SEE BELOW).

**NOTE 2**: Coverage of knee braces is defined in the Medical Policy titled DME103.002 Knee Braces.

**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.

**Spring-loaded dynamic splints and bi-directional static progressive stretch (SPS) splints may be considered medically necessary** to restore range of motion for the knee, ankle, toe, shoulder, elbow, wrist, or finger in the following situations **only:**

- When the patient is not responding favorably (i.e., has a measurable lack of progress) using conventional management methods of restoring joint motion (e.g., physical therapy, standard splinting, non-steroidal anti-inflammatory medications [NSAIDS], etc.) following a sub-acute injury or postoperative period, i.e., at least three weeks, after injury or surgery; OR
- In the acute postoperative period for patients who have a prior documented history of joint motion stiffness/loss, and are having additional surgical procedures to improve motion in that joint; OR
- Management of chronic contractures and joint stiffness due to joint trauma, fractures, burns, head and spinal cord injury, rheumatoid arthritis, plantar fasciitis, multiple sclerosis, muscular dystrophy, or cerebral palsy.

**Spring-loaded dynamic splints and bi-directional SPS splints are considered experimental, investigational and/or unproven** for treatment

of carpal tunnel or TMJ (see SUR705.010 Temporomandibular Joint (TMJ) Disorders (TMJD))

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

**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™.

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

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

• Sensory dynamic orthosis;

• Dynamic movement brace/orthosis;

• Therasuit.

**FOOT ORTHOTICS (Functional and Accommodative Podiatric Appliances)**

**NOTE 3: 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.

**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 spastic peroneal 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 the following table when the listed prerequisites have been determined:

| **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<br>• Padding<br>• NSAIDS<br>• Cortisone injections | Yes |
| Hallux Limitus/Rigidus (Degenerative 1st MPJ) | >3 months | • Accommodating shoe wear<br>• Padding<br>• NSAIDS<br>• Cortisone injections | Yes |
| Hammertoes | >3 months | • Accommodating shoe wear<br>• Padding<br>• NSAIDS<br>• Cortisone injections | Yes |

| | | | |
|---|---|---|---|
| Tailor's Bunions (5th MPJ Area) | >3 months | • Accommodating shoe wear<br>• Padding<br>• NSAIDS<br>• Cortisone injections | Yes |
| Neuromas | >3 months | • Accommodating shoe wear<br>• Padding<br>• Over the counter (OTC) insoles<br>• NSAIDS<br>• Cortisone injections | Yes |
| Plantar Fasciitis/ Heel Spur Syndrome | >3 months | • Proper shoe wear<br>• OTC Arch supports worn > 6 weeks<br>• Stretching/Ice Therapy<br>• NSAIDS<br>• Cortisone injections | Yes |
| Metatarsalgia | >3 months | • Proper shoe wear<br>• Padding<br>• OTC insoles/Arch supports<br>• NSAIDS | Yes |

| | | | |
|---|---|---|---|
| Chronic Ankle Instability | >1 year | • Ankle support utilized for activities<br>• OTC arch support worn > 6 weeks<br>• NSAIDS | Yes |

**NOTE 4:** Some functional foot orthotics that are determined to be medically necessary may also have accommodative padding (e.g., for diabetic patients).

**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 OTC items (with or without a prescription).

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.**

## Description:

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. Examples of orthotics include braces, splints, immobilizers, and trusses.

Spring-loaded dynamic splints and bi-directional static progressive stretch (SPS) devices are intended to stretch joints that have reduced range of motion (ROM) secondary to immobilization, surgery, fracture, dislocation, or any of a number of non-traumatic disorders. The goal is to restore functioning ROM to a joint by causing permanent elongation of tissues, without compromising the stability and integrity of the connective tissue and joint. Dynamic splints are spring-loaded, adjustable-tension controlled devices that provide a low load, prolonged stretch to joints over 6-12 hours, usually while the patient is asleep. This process is called creep-based loading. SPS devices are also manually adjustable and apply a static force to the tissues. The joint is moved to an end range stretch position and is held there for a set period of time. The tissues relax or stretch in response to this end range stress. The device is then adjusted to a new position of stretch and held there. This process, called stress-relaxation loading, is repeated periodically throughout an SPS session, which usually requires 30-minute sessions three times per day for permanent stretch to occur. Examples of dynamic splints include, but are not limited to, Dynasplint™, ProGlide®, DeROM®, Ultraflex®, DeRoyal®, and Advance Dynamic®. JAS® is one example of an SPS device.

Orthotic devices for the foot may be used to change the conformity of

congenitally deformed bones and joints by applying continuous force over a period of months or years. Orthotics may also be used to relieve symptoms and produce more normal function in deformities caused by disease or congenital etiologies by providing support or altering weight bearing. Diagnosis, patient history and biomechanical evaluation determine the therapeutic benefit of functional orthotics.

Biomechanical problems are best treated with custom-made orthoses, while weight-bearing problems can usually be treated successfully with good quality, cushioned, over the counter shoe inserts. Biomechanical evaluation includes range of motion studies, measuring joint angles, tightness or laxity of muscle and gait analysis. This is usually done bilaterally on the lower extremities to evaluate biomechanical imbalances and deformities. The results of the biomechanical exam are used to assist in diagnosis and treatment.

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 for pain relief. (30)

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. (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. (15)

The Intrepid Dynamic Exoskeletal Orthosis™ (IDEO) 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 is a plantarflexion-powered brace that includes a rigid foot plate and ankle enlage 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. (24)

Dynamic Lycra® Orthoses are a relatively new approach to managing abnormal tone and neurological dysfunction. The aim is to improve functional abilities through the use of a snugly-fitted lycra garment. 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. 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. (25)

Sensory Dynamic® Orthosis is a dynamic movement orthotic that can result in improved motor output, improved reciprocal muscle activity, and can be used to maintain soft tissue length and 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, and will enhance function by improving motor control and fluency of movement. (26)

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 believed to correct proprioception and facilitate the development of new gross and fine motor skills like sitting, standing, and walking. (27)

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 Stabilisers; 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. (11, 12) 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. Stabilizers also help chiropractic adjustments hold longer, helping prolong patients’ wellness. (29)

Foot orthotics, or podiatric appliances, can be either functional or accommodative. An accommodative foot orthotic does not address functional abnormality. These are used to cushion, pad or relieve pressure from a painful or injured area on the bottom of the foot, e.g., calluses, sore bones, etc. They are generally more flexible and soft than functional foot orthoses. A functional orthotic is a device 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 pain 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.

Pediatric Ddsfunctional flatfoot is a complicated series of symptoms and joint changes of the midfoot, rearfoot and ankle that result in flattened appearance of the arch in a skeletally immature individual. Symptoms and deformities that may be present if flatfoot is allowed to progress include:

- Abnormal wear of shoes;
- Biomechanically induced dermatologic conditions such as corns, calluses, blisters, etc.;
- Flexible hammertoes and claw toe deformities;
- Genu recurvatum;
- Hallux abducto-valgus deformities;
- Leg, ankle and/or foot pain and fatigue;
- Limb length inequality;
- Night cramps/prolonged growing pains;
- Apophysitis;
- Splayfoot;
- Symptomatic of tibiale externum;
- Plantar fasciitis;
- Tailor’s bunion;
- Lower leg tendonitis;
- Avascular necrosis (Freiberg’s, Kohler’s);
- Equinus.

Adult dysfunctional flatfoot 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 be one of the following:

Congenital

- 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;

Biomechanical

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

Systemic disease

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

Traumatic

- 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 Tendon Dysfunction is pain and swelling along the course of the posterior tibial tendon frequently between the medial malleolus and navicular. The patient may have weakened ability or inability to single heel-rise, accompanied with arch flattening and increasing heel valgus.

Spastic Peroneal Flatfoot is usually associated with a subtalar joint coalition. Gait is antalgic with pain in the midfoot, rearfoot and ankle areas. Subtalar joint motion is virtually absent with a reactive tightness of peroneal musculature occurring to evert the foot to a comfortable position. The calcaneus is in valgus, and tarsal pain is aggravated by activity.

Glossary

- Bunion—inflammation and thickening of the bursa of the joint of the great toe, usually associated with marked enlargement of the joint and lateral displacement of the toe
- Callus—localized hyperplasia of the horny layer of the epidermis due to pressure or friction
- Corn—a horny induration or thickening of the stratum corneum of the skin of the toes, caused by friction and pressure from poorly fitting shoes or hose; it forms a conical mass pointing down into the corium, producing pain and inflammation; *hard corn (heloma durum)* usually located on the outside of the little toe or the upper surfaces of the other toes; *soft corn (heloma molle)* found between the toes, usually the $4^{th}$-$5^{th}$ toes
- 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 tip of the great toe, or main axis of the toe, toward the outer or lateral side of the foot
- Hallux varus—deviation of the main axis of the great toe 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
- OTC—over the counter; can be obtained with or without a prescription
- Pes planus—flatfoot; syn: talipes planus
- Stock Orthotics—syn: OTC, off-the-shelf
- Talipes—deformity of the foot, which is twisted out of shape or position;

also called 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

- 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 plantaris—talipes in which there is an exaggerated abnormal arch of the foot; syn: talipes cavus, talipes arcuatus

- 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:

Generally, conventional methods are effective in restoring range of motion (ROM); these include a variety of exercises and devices, depending on the joint or tissue involved. Exercises include passive ROM, assisted-active ROM, and active ROM, and involve the interaction of the patient with a physical therapist. Dynamic splinting devices and static progressive stretch devices are patient-controlled, non-motorized stretch devices that have been widely used in the orthopedic and physical therapy communities for selected patients who fail to improve with conventional treatment. A study of post-traumatic loss of motion at the wrist by Bonutti et al. (6) showed that the patients gained an average of 19 degrees extension and 18 degrees flexion, in an average treatment time of eight weeks. Bonutti et al. also studied static progressive stretch (SPS) for the elbow, showing an average of 69% increase in ROM, and no deterioration in ROM at one-year follow up. There are no published studies that support the use of dynamic or SPS stretching devices for management of chronic contractures and joint stiffness due to joint trauma, fractures, burns, head and spinal cord injury,

rheumatoid arthritis, plantar fasciitis, multiple sclerosis, muscular dystrophy, or cerebral palsy; when conventional methods of treating stiff or contracted joints have not been attempted; or for use on the shoulder.

**2009 Update**

A search of peer reviewed literature through November 2009 identified no new clinical trial publications or any additional information that would change the coverage position of this medical policy.

**2014 Update**

**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. Davis et al. (16) 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 stance control knee-ankle foot orthoses increase walking velocity compared to locked knee devices. Contrary to expectation, the stance control condition did not decrease energy expenditure during walking.

**Foot Levelers Spinal Pelvis Stabilizers**

In 2010, Sahar et al. (17) 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. (18) 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.

**Dynamic Splinting**

Berner et al. (20) conducted a retrospective study to examine the effect of using dynamic splinting on 156 patients (mean age 55.2 ± 15.6) diagnosed with carpal tunnel syndrome, (2007 to 2009 May). The Levine-Katz Function/Disability survey is commonly used in diagnosing CTS and this was the outcome measure of this study. This study tracked patients' results during the first two months using this new treatment modality. There was a significant change (reduction) in the scores of the Levine-Katz Function/Disability survey which showed decreased pain of 26%, ($P < 0.0001$, $T = 12.624$). Dynamic splinting was effective in reducing pain and associated symptoms for patients diagnosed with CTS in this study. Further randomized controlled long term studies are needed to evaluate dynamic splinting for carpal tunnel.

Search of the PubMed data base located several case reports, case series, and retrospective reviews of dynamic splinting for the jaw. (21, 22) Further randomized controlled long term studies are needed to evaluate dynamic splinting for the jaw to treat temporomandibular joint disorder.

**2015 Update**

In 2012, Patzkowski et al. (24) 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 six functional tests while they were wearing the IDEO,

BlueRocker, posterior leaf spring, or no brace. The brace order was randomized, and five 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 one 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.

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, eight desired limb salvage, two were undecided, and three still desired amputation. The authors concluded that use of the IDEO significantly improved performance on validated tests of agility, power, and speed. The majority of subjects initially considering amputation favored limb salvage after this noninvasive intervention. Further studies need to be conducted to determine clinical utility and improved outcomes, as well as to define the appropriate patient population.

Other than anecdotal reports, no studies were found that support the efficacy and clinical utility of other dynamic movement orthoses, including the Therasuit and the Sensory Dynamic Orthosis.

**2016 update**

Literature on inversion/eversion devices was searched through October 31, 2016. Several small studies were identified that evaluated the use of the Agilium Freestep for use in osteoarthritis of the knee. No randomized controlled trials were identified.

American Academy of Orthopedic Surgeons (AAOS)

The 2013 AAOS Osteoarthritis Guidelines of the Knee (31) does not recommend for or against the use of a valgus directing force brace (medial compartment unloader) for patients with symptomatic osteoarthritis of the knee. (Strength of Recommendation: Inconclusive).

**Section Summary**

Evidence for the use of inversion/eversion devices (e.g., Agilium Freestep) to treat knee osteoarthritis is limited to small nonrandomized studies. Long term randomized controlled trials with large sample sizes are needed to form conclusions about the impact on health outcomes.

## 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.**

## Coding:

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, or suit therapy.

**CODING:**

**Disclaimer for coding information on Medical Policies**

Procedure and diagnosis 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, device or diagnosis 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/HCPCS/ICD-9/ICD-10 Codes** |
|---|
| **The following codes may be applicable to this Medical policy and may not be all inclusive.** |
| **CPT Codes** |
| 97760, 97762 |
| **HCPCS Codes** |

A4566, A5500, A5501, A5503, A5504, A5505, A5506, A5507, A5508, A5510, A5512, A5513, A9285, E1800, E1801, E1802, E1805, E1806, E1810, E1811, E1812, E1815, E1816, E1818, E1820, E1821, E1825, E1830, E1831, E1840, E1841, K0672, K0903, 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, 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, L3215, L3216, L3217, L3219, L3221, L3222, L3224, L3225, L3230, L3250, L3251, L3252, L3253, L3254, L3255, L3257, L3260, L3265, L3300, L3310, L3320, L3330, L3332, L3334, L3340, L3350, L3360, L3370, L3380, L3390, L3400, L3410, L3420, L3430, L3440, L3450, L3455, L3460, L3465, L3470, L3480, L3485, L3500, L3510, L3520, L3530, L3540, L3550, L3560, L3570, L3580, L3590, L3595, L3600, L3610, L3620, L3630, L3640, L3649, L3650, L3660, L3670, L3671, L3674, L3675, L3677, L3678, L3702, L3710, L3720, L3730, L3740, L3760, L3762, L3763, L3764, L3765, L3766, L3806, L3807, L3808, L3809, L3891, L3900, L3901, L3904, L3905, L3906, L3908, L3912, L3913, L3915, L3916, L3917, L3918, L3919, L3921, L3923, L3924, L3925, L3927, L3929, L3930, L3931, L3933, L3935, L3956, L3960, L3961, L3962, L3967, L3971, L3973, L3975, L3976, L3977, L3978, L3980, L3981, L3982, L3984, L3995, L3999, L4000, L4002, L4010, L4020, L4030, L4040, L4045, L4050, L4055, L4060, L4070, L4080, L4090,

| |
|---|
| L4100, L4110, L4130, L4205, L4210, L4350, L4360, L4361, L4370, L4386, L4387, L4392, L4394, L4396, L4397, L4398, L4631, S0395, S8450, S8451, S8452 |
| **ICD-9 Diagnosis Codes** |
| Refer to the ICD-9-CM manual |
| **ICD-9 Procedure Codes** |
| Refer to the ICD-9-CM manual |
| **ICD-10 Diagnosis Codes** |
| Refer to the ICD-10-CM manual |
| **ICD-10 Procedure Codes** |
| Refer to the ICD-10-CM manual |

## Medicare Coverage:

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 not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

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

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## Policy History:

| Date | Reason |
|---|---|
| 1/1/2017 | 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. |
| 11/1/2015 | 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. |

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|---|---|
| 9/1/2014 | 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. |
| 8/15/2011 | Codes Revised/Added/Deleted |
| 12/15/2009 | Routine scheduled update with literature review; no changes to coverage. |
| 4/1/2008 | Codes Revised/Added/Deleted |
| 5/15/2007 | Revised/Updated Entire Document |
| 10/1/2003 | Codes Revised/Added/Deleted |
| 2/1/2002 | Revised/Updated Entire Document |
| 3/1/2000 | Codes Revised/Added/Deleted |
| 11/1/1999 | Codes Revised/Added/Deleted |
| 7/1/1999 | Codes Revised/Added/Deleted |
| 9/1/1998 | Codes Revised/Added/Deleted |
| 5/1/1996 | Revised/Updated Entire Document |
| 7/1/1994 | Codes Revised/Added/Deleted |
| 4/1/1994 | Codes Revised/Added/Deleted |
| 5/1/1990 | New medical document |

## Archived Document(s):

| Title: | Effective Date: | End Date: |
|---|---|---|
| Orthotics | 11-01-2015 | 12-31-2016 |
| Orthotics | 09-01-2014 | 10-31-2015 |
| Orthotics | 08-15-2011 | 08-31-2014 |
| Orthotics | 12-15-2009 | 08-14-2011 |
| Orthotics | 05-15-2007 | 12-14-2009 |
| Orthotics | 03-01-2000 | 05-14-2007 |