Medical Coverage Policy

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Orthotic Devices and Shoes

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where

coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses orthotic devices. Orthotic devices are defined as orthopedic appliances used to support, align, prevent or correct deformities. Static orthoses are rigid and are used to support weakened or paralyzed body parts in a particular position. Dynamic orthoses are used to facilitate body motion to allow optimal function. Myoelectric orthotic devices use neurologic sensors, microprocessor units, and electric motors to provide self-initiated movement.

The policy statements below provide medical necessity criteria or coverage information for the following:

Coverage Policy

Coverage for orthotic devices varies across benefit plans. Please refer to the customer's benefit plan document to determine benefit availability and the terms and conditions of coverage.

In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

For the intent of this policy, microprocessor-controlled/computer-controlled devices are considered a type of power enhanced/controlled device.

GENERAL CRITERIA FOR AN ORTHOTIC DEVICE

An orthotic device is considered medically necessary when BOTH of the following criteria are met:

- The orthosis is prescribed to support, align, prevent or correct a deformity
- Evidence of a physical examination within the prior twelve months, for a condition that supports the use of the item prescribed, is documented in the individual's medical record.

An orthotic device is not covered or reimbursable when the above criteria is not met.

When coverage is available for the specific orthotic device, the following orthoses are considered eligible for coverage:

- Non Foot Orthosis
  - Cranial Orthotic Devices for Positional or Deformational Plagiocephaly
  - Upper Limb
  - Lower Limb
  - Knee Braces
  - Shoes
  - Spinal Orthotic Devices
- Custom Foot Orthosis

An addition or component to an orthotic device is considered medically necessary when it is required for the effective use of the orthosis.

A custom-foot orthosis for the treatment of plantar fasciitis is considered clinically equivalent but not superior to a conventional orthosis, is significantly more expensive than a conventional device, and is therefore considered not medically necessary under many benefit plans.

NON FOOT ORTHOSIS

I. Cranial Orthosis — Coding for Cranial Orthoses

- **A custom molded/fitted cranial orthotic device (HCPCS code S1040) is considered medically necessary for the treatment of synostotic plagiocephaly (i.e., craniosynostosis) following surgical correction when the benefit plan includes coverage for this indication.**

- **A custom molded/fitted cranial orthotic device (HCPCS code S1040) is considered medically necessary for the treatment of moderate to severe nonsynostotic positional plagiocephaly when the benefit plan includes coverage for this indication and ALL of the following conditions are met:**

  - Child is **EITHER ONE** of the following:
    - between three and five months of age and has failed to respond to a two-month trial of repositioning therapy
    - age six months to 18 months
  - Cranial asymmetry as evidenced by **EITHER** of the following:
    - cephalic index ± at least two standard deviations from the mean for the appropriate gender/age (see Table 1)
    - asymmetry of 12 mm or more in **ONE** of the following measures:
      - cranial vault

- skull base
- orbitotragial depth (see Table 2)

➢ **A subsequent custom molded/fitted cranial orthotic device to accommodate growth changes is considered medically necessary when significant cranial asymmetry persists and further meaningful improvement in the asymmetry is expected with continued use of a cranial orthotic device.**

Please note: A protective helmet (HCPCS codes A8000–A8004) is not a cranial remolding device. A protective helmet (HCPCS codes A8000-A8004) is considered a safety device worn to prevent injury to the head rather than a device needed for active treatment. See "Not Covered or Reimbursable" section below.

II. Upper Limb Orthosis **Coding for Upper Limb Orthoses**

➢ **An upper extremity orthotic device (HCPCS codes L3650-L3984) (i.e., non-myoelectric, non-power enhanced, non-custom fitted or custom fabricated hand) is considered medically necessary for an individual requiring stabilization or support to the upper limb and who is expected to have improved function with the use of the device:**

- ➢ to substitute for weak muscles (e.g., following cervical spine injury, brachial plexus injury, peripheral nerve injury [e.g., median, ulnar or radial nerves], sprain, strain)
- ➢ to support or immobilize a structure (e.g., rheumatoid arthritis, osteoarthritis, overuse syndromes [e.g., lateral epicondylitis, cubital tunnel syndrome, carpal tunnel syndrome, de Quervain tenosynovitis, trigger finger], trauma, following surgical repairs, fractures [e.g., acromioclavicular dislocation, clavicle fracture])
- ➢ prevent contracture or deformity from neurological injury (e.g., brain injury, stroke [i.e., spasticity], spinal cord injury, brachial plexus injury, peripheral nerve injury)
- ➢ correct joint contractures resulting from disease or immobilization (e.g., post fracture, burns)
- ➢ when necessary to carry out activities of daily living (ADLs) (e.g., spinal cord injured individuals)

• **A custom fitted (HCPCS codes L3807, L3915, L3917, L3923, L3929, L3931) or custom fabricated (HCPCS codes L3763-L3766, L3806, L3808, L3891, L3900, L3901, L3905, L3906, L3913, L3919, L3921, L3933, L3935, L3956, L4205) hand orthotic is medically necessary when the patient's clinical findings are severe and dysfunctional such that an off-the-shelf orthotic is insufficient for the patient's needs when the above medical necessity criteria has been met for an upper limb orthotic and BOTH of the following criteria are met:**

- ➢ One or more of the following additional criteria are met:
  - post-surgical intervention
  - orthotic requires unique components (e.g., pulleys, rubber bands)
  - neurologic co-morbidities (e.g., sensory deficit, spasticity)
  - swelling/lymphedema comorbidity
  - multiple-joint involvement
  - plan of care for serial splinting
  - orthotic will need frequent modification
  - skin impairment co-morbidity

- The clinical documentation supports the medical necessity of a custom fitted or custom fabricated orthotic beyond what is necessary for an off-the-shelf orthotic.

III. **Lower Limb Orthosis** **Coding for Lower Limb Orthoses**

- **An ankle orthosis is considered medically necessary for treatment of ankle fracture, sprain, or injury requiring immobilization and/or stabilization.**

- **A nonambulatory ankle-foot orthosis (AFO)/night splint (HCPCS codes L4396, L4397, L4398) is considered medically necessary for the following indications:**

  - Achilles tendonitis
  - plantar fasciitis
  - plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a non-fixed contracture) when ALL of the following criteria are met:
    - reasonable expectation of the ability to correct the contracture
    - contracture interferes or is expected to interfere significantly with the person's functional abilities
    - ankle contracture splint is used as a component of a therapy program that includes active stretching of the involved muscles and/or tendons

- **A nonambulatory AFO/night splint (HCPCS codes L4396, L4397, L4398) for ANY other indication, including the following, is not covered or reimbursable:**

  - the plantar flexion contracture is fixed
  - foot drop in the absence of ankle flexion contracture
  - for the prevention or treatment of heel pressure ulcer

- **Each of the following is not covered or reimbursable:**

  - foot drop splints used as recumbent positioning devices (HCPCS codes L4394, L4398)
  - any orthosis used to treat pressure ulcers (HCPCS code A9283)

- **The following prefabricated ankle-foot (AFO) or knee-ankle-foot orthoses (KAFO) are each considered medically necessary:**

  - an AFO for an AMBULATORY individual with a weakness or deformity of the foot and ankle requiring stabilization who is expected to have improved function with the use of the device; HCPCS codes used to represent an ankle-foot device include: L1902, L1906, L1910, L1930, L1932, L1933, L1951, L1952, L1971, L2112-L2116, L2132, L2134, L2136, L4350, L4360, L4361, L4386, and L4387.
  -
  - a KAFO for an AMBULATORY individual who meets criteria for an ankle-foot orthosis and who requires additional knee stability; HCPCS codes used to represent a knee-ankle-foot device include: L2035, L2132-L2136, and L4370.

- **A custom-fabricated AFO or KAFO (HCPCS codes L1900, L1904, L1907, L1920, L1940-L1950, L1960-L1970, L1980-L2108, L2000-L2034, L2036-L2128, L4631) in an AMBULATORY individual who meets the above medical necessity**

criteria for an AFO or KAFO is considered medically necessary when ANY of the following criteria applies:

- The individual cannot be fitted with a prefabricated (off-the-shelf) AFO or has a documented neurological, circulatory or orthopedic status that necessitates custom fabrication to prevent tissue injury.
- The condition necessitating the orthosis is expected to be permanent or of long-standing duration (> 6 months).
- There is a need to control movement about the knee, ankle or foot in more than one plane.
- The individual has a healing fracture that lacks normal anatomical integrity or anthropometric proportions.

IV. **Knee Brace** **Coding for Knee Braces**

- **A fracture knee brace or a rehabilitative knee brace is considered medically necessary when applied at the time of initial stabilization (e.g., post-surgery, post-injury, post- fracture).**

- **A patellofemoral knee brace is considered medically necessary for the treatment of patellofemoral dislocations or chronic patellar symptomatic subluxation for EITHER of the following indications:**

  - following reduction for an acute (initial) patellar dislocation
  - recurrent dislocation/subluxation of the patella following failure of a three-month trial of exercise and strengthening

- **A prefabricated (i.e., off-the-shelf, custom-fitted) functional knee brace is considered medically necessary when there is documented knee instability and the individual is not considered a surgical candidate for ligament reconstruction.**

- **A custom-fabricated functional knee brace is considered medically necessary when the criteria for a prefabricated functional knee brace have been met and the individual is unable to be fitted with a prefabricated device as a result of ANY of the following (this list may not be all-inclusive):**

  - abnormal limb contour (e.g., disproportionate size/shape)
  - knee deformity (e.g., valgus, varus deformity)
  - minimal muscle mass upon which to suspend the orthosis

- **A prefabricated unloading/offloading knee brace is considered medically necessary for the treatment of moderate to severe osteoarthritis of the knee when ALL of the following criteria are met:**

  - unicompartmental disease that requires load reduction to an affected compartment
  - documented failure of prior medical treatment modalities (e.g., nonsteroidal anti-inflammatory medications, steroid injections, viscoelastic supplementation)
  - radiographic documentation of single-compartment osteoarthritis with or without varus/valgus deformity
  - persistent knee pain limiting activities of daily living

- **A custom-fabricated unloading/offloading knee brace is considered medically necessary when criteria for a prefabricated unloading/offloading brace have been met and the individual is unable to be fitted with a prefabricated device as a result of ANY of the following (this list may not be all-inclusive):**

  - abnormal limb contour (e.g., disproportionate size/shape)
  - knee deformity (e.g., valgus, varus deformity)
  - minimal muscle mass upon which to suspend the orthosis

- **Accessories to a Knee Brace: a heavy duty knee joint (HCPCS codes L2385, L2395) is considered medically necessary when medical necessity criteria for the knee brace has been met and the individual weighs greater than 300 pounds.**

- **Accessories to a Knee Brace: high-strength, lightweight material (HCPCS code L2755) is considered medically necessary for an individual who meets medical necessity criteria for a custom-fabricated knee brace with EITHER of the following indications:**

  - daily activity level (e.g., employment) requires a brace designed for high-impact/high-stress activities
  - weight greater than 250 lbs

V. **Shoes** **Coding for Shoes**

- **Depth shoes (including inlays provided with the shoe) are considered medically necessary (HCPCS code A5500) for an individual with ANY of the following systemic conditions, that are significant enough to result in severe circulatory insufficiency and/or areas of decreased peripheral sensation in the lower extremity:**

  - diabetes mellitus
  - peripheral vascular disease
  - peripheral neuropathy

- **Custom molded shoes (including inlays provided with the shoe) are considered medically necessary (HCPCS code A5501) when criteria have been met for a depth shoe, and the type and/or severity of foot deformity results in failure, contraindication or intolerance to a depth shoe.**

- **The following modifications to depth or custom-molded shoes may be considered medically necessary:**

  - rigid rocker bottoms (HCPCS code A5503)
  - roller bottoms (HCPCS code A5503)
  - wedges (HCPCS code A5504)
  - metatarsal bars (HCPCS code A5505)
  - offset heels (HCPCS code A5506)

- **A depth shoe, custom molded shoe or shoe modification, (including the above and deluxe features, compression molded inlays/inserts) for any other indication is not covered or reimbursable.**

VI. **Spinal Orthosis** **Coding for Spinal Orthoses**

- **A spinal orthosis (e.g., cervical orthosis, cervical-thoracic orthosis, thoracic orthosis, thoracic-lumbar-sacral orthosis, lumbar-sacral orthosis, lumbar orthosis) is considered medically necessary for ANY of the following indications:**

  - when mobility restriction is necessary to alleviate pain of spinal origin (e.g., joint instability, hypermobility)
  - postoperatively or post-injury to facilitate healing of the spine or related soft tissues
  - as support for weak spinal musculature or a spinal deformity that significantly impacts the ability to perform activities of daily living
  - scoliosis bracing for children or adolescents (e.g., Milwaukee, Charleston, Boston or Wilmington Brace)

CUSTOM FOOT ORTHOSIS **Coding for Custom Foot Orthoses**

- **A custom-fabricated foot orthosis (HCPCS codes L3000-L3031) is considered medically necessary when there is failure, contraindication, or intolerance to a prefabricated foot orthosis for ANY of the following conditions:**

  - impaired peripheral sensation and/or altered peripheral circulation (e.g., diabetic neuropathy and peripheral vascular disease)
  - the foot orthosis is an integral part of a leg brace and is necessary for the proper functioning of the brace
  - the foot orthosis is used to compensate for a missing portion of the foot (e.g., amputation) and is necessary for the alleviation or correction of illness, injury or congenital defect
  - neurologic or neuromuscular condition (e.g., cerebral palsy, hemiplegia, spina bifida) producing spasticity, malalignment or pathological positioning of the foot where there is reasonable expectation of improvement
  - acquired or congenital foot deformity when ALL of the following criteria are met:
    - The deformity is the result of ONE of the following:
      - symptomatic rigid flatfoot
      - posterior tibial tendon dysfunction
      - mid- or hind-foot arthritis
    - The deformity is associated with significant pain that interferes with activities of daily living and there is impaired gait, balance or mobility as a result of the condition.
    - Conservative medical management has failed.
    - There is a reasonable expectation that the condition will improve through the use of the orthotic device.

- **A custom-fabricated foot orthosis (HCPCS codes L3000-L3031) for any other indication is not covered or reimbursable.**

NOT COVERED OR REIMBURSABLE

The following orthoses are each not covered or reimbursable:

- custom molded/fitted cranial orthotic device for indications other than those specifically listed above
- protective helmet (HCPCS codes A8000-A8004)
- upper limb orthosis (non-powered) for indications other than those specifically listed above
- any orthosis used to treat edema
- any orthosis used primarily for improved athletic performance or sports participation
- any orthosis used on uninjured body parts or to prevent injury
- prophylactic knee braces
- patellofemoral knee braces/sleeves for the treatment of postoperative knee effusion or patellofemoral syndrome without subluxation or dislocation
- prefabricated knee brace with inflatable air bladder (HCPCS codes L1847, L1848)
- a spinal orthosis for indications other than listed above, including as a preoperative diagnostic tool prior to lumbar fusion surgery
- prefabricated foot orthoses
- separate orthotic devices for an additional pair of shoes
- socks and brace sleeves used in conjunction with an orthotic device
- an additional removable or nonremovable interface (HCPCS codes L2820, L2830, K0672) dispensed with the initial device
- any of the following items that are considered convenience items and do not treat an underlying physical condition:
    - prophylactic elastic lumbar supports (e.g., tool belts, lumbar belt)
    - inflatable lumbar support pillows/cushions
    - back rest supports

EXPERIMENTAL, INVESTIGATIONAL OR UNPROVEN (EIU)

The following orthoses are each considered experimental, investigational or unproven:

- myoelectric and/or power enhanced upper extremity orthotic device (e.g., MyoPro® 2)
- foot adductus positioning device (e.g., UNFO foot brace) for the treatment of metatarsus adductus
- Apos® biomechanical device (AposHealth®)
- magnetic insole (i.e., orthosis with magnetic foil)
- electronic/electromagnetic activated stance control KAFO devices (e.g., E-MAG Active, Sensor Walk™, C-Brace®)
- Copes spinal scoliosis brace
- SpineCor® spinal orthosis

REPAIR/REPLACEMENT

Repair and/or replacement of an orthotic device is considered medically necessary under the following circumstances:

- when anatomical change or reasonable wear and tear renders the item nonfunctional and the repair will make the equipment usable

- when anatomical change or reasonable wear and tear renders the item nonfunctional and nonrepairable

Repair or replacement is considered not medically necessary when an orthosis becomes unusable or non-functioning because of misuse, abuse or neglect.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

Orthotic Device
An orthotic device is a rigid or semi-rigid device used to support, align, prevent or correct a deformity. Orthotics may also redirect, eliminate or restrict motion of an impaired body part.

Medical necessity for any orthotic device must be documented in the individual's medical record. Supportive documentation includes a prescription for the specific device, recent physical examination for the condition being treated, an assessment of functional capabilities/limitations and any other comorbidities.

Orthoses may be prefabricated or custom fabricated. A prefabricated orthosis is any orthosis that is manufactured in quantity without a specific patient in mind. A prefabricated orthosis can be modified (e.g., trimmed, bent, or molded) for use by a specific patient and is then considered a custom-fitted orthosis. An orthosis that is made from prefabricated components is considered a prefabricated orthosis. Any orthosis that does not meet the standard definition of custom-fabricated is considered to be a prefabricated device.

A custom-fabricated orthosis is one that is specifically made for an individual patient starting with the most basic materials that may include plastic, metals, leather or various textiles. The construction of these devices requires substantial labor such as cutting, bending, molding and sewing, and may even involve the use of some prefabricated components. A molded-to-patient model orthosis is a type of custom-fabricated device for which an impression of the specific body part is made (e.g., by means of a plaster cast, or computer-aided design/computer-aided manufacturing [CAD-CAM] technology). The impression is then used to make a specific patient model. The actual orthosis is molded from the patient-specific model. CAD-CAM and other technologies, such as those that determine alignment of the device, are considered integral to the fitting and manufacturing of the base device.

An unmodified, prefabricated orthosis is generally used in treating a condition prior to a custom-fitted orthosis (prefabricated orthosis that is modified by bending or molding for a specific patient). A custom-fitted orthosis is generally attempted prior to the use of a custom-fabricated orthosis (individually constructed from materials). Custom fabricated devices are considered medically necessary only when the established medical necessity criteria is met for the device and

the individual cannot be fitted with a prefabricated (off-the-shelf) device or one is not available. Examples of conditions precluding the use of a prefabricated device typically include abnormal limb contour (e.g., disproportionate size/shape) or deformity (e.g., valgus, varus deformity) or when there is minimal muscle mass upon which to suspend the orthosis.

Orthoses and accessories that are used for participation in sports, to improve athletic performance, that are used to prevent injury in an otherwise uninjured body part, and that are used in conjunction with the device (e.g., socks) are considered not medically necessary.

Identical, spare orthoses used only for the patient's convenience are considered not medically necessary. Additionally, one orthotic per foot is considered appropriate; separate orthotic devices for additional pairs of shoes are not considered medically necessary.

U.S. Food and Drug Administration (FDA)
A majority of orthotic devices are regulated by the FDA as Class I devices. Class I devices are subject to the least regulatory control. Cranial orthoses are regulated by the FDA as Class II medical devices and require 510(k) clearance. According to the FDA, cranial orthoses are intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly.

Cranial Orthotic Devices for Positional or Deformational Plagiocephaly
Cranial orthotic devices, also referred to as cranial remolding helmets, are used for treating cranial asymmetry, a condition caused by mechanical factors in-utero or after birth that lead to misshaping of the skull. These cranial deformities may present in several ways:

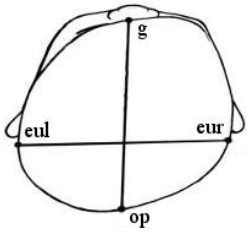
- Craniosynostosis: A premature closure of the cranial sutures, or growth plates; a pathological condition which often requires surgery
- Nonsynostotic plagiocephaly: Also known as positional or deformational plagiocephaly, or "flat head syndrome," the head asymmetry develops from external forces (e.g., laying on a flat surface).

The most common abnormal head shapes include:

- Plagiocephaly: often appears as flattening on one side of the head, with displacement of the forehead and ear
- Brachycephaly: the occiput (back of the head) is flattened, with bilateral widening on the sides of the head
- Scaphocephaly: flattening of the sides of the head, with elongation front to back (i.e., a long, narrow skull); seen most frequently in premature infants

Cranial orthotic devices are indicated to promote corrective shaping as a treatment of synostotic or nonsynostotic plagiocephaly, as well as to prevent recurrence of the deformity.

Evaluation of Plagiocephaly
Cephalic Index: Evaluation of cranial asymmetry may be based on the cephalic index, a ratio between the width (side to side) and length (front to back) of the head. Head width is calculated by subtracting the distance from the euryon on the right side of the head (eur) to the euryon on the left side of head (eul) and multiplying by 100. Head length is generally calculated by measuring the distance from the glabella midpoint (g) (midpoint of the flat area of bone just above the nose between the eyebrows) to the opisthocranion point (op), the most projecting point at the back of the head (posterior most point in the midsagittal plane of the occiput) (Figure A).



(Cranial Technologies, 2014)

Figure A

The cephalic index is then calculated as:

$$\frac{\text{Head width (eu – eu)} \times 100}{\text{Head length (g – op)}}$$

The cephalic index is considered abnormal if it is two standard deviations (SD) above or below the mean measurements (American Academy of Orthotists and Prosthetists [AAOP], 2004; Farkas and Munro, 1987). The indices for infants up to 12 months may be found on the following table:

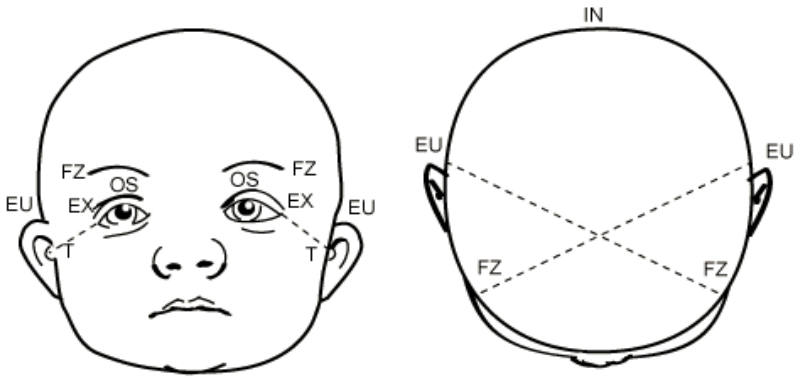
Table 1
Cephalic Index

Gender	Age	- 2 SD	- 1SD	Mean	+ 1SD	+ 2SD
Male	16 days–6 months	63.7	68.7	73.7	78.7	83.7
	6–12 months	64.8	71.4	78.0	84.6	91.2
Female	16 days–6 months	63.9	68.6	73.3	78.0	82.7
	6–12 months	69.5	74.0	78.5	83.0	87.5

Anthropometric Measurements: The evaluation of cranial asymmetry may also be made based on one or more of three anthropometric measures: cranial vault, skull base or orbitotragial depth measurements (AAOP, 2004; Littlefield, et al., 1998). A physician or technician skilled in anthropometry should perform all anthropometric measurements. Cranial orthoses have been indicated for moderate to severe plagiocephaly defined as asymmetry of 12 mm or more (Moss, 1997). Table 2 below defines how these measurements are taken and Figure 1 below illustrates some of the anthropometric landmarks.

Table 2
Specifications for Taking Anthropometric Measurements

Anthropometric Measure	Measurement
Cranial Vault	[left frontozygomatic point (fz) to right euryon (eu)] **minus** [right frontozygomatic point (fz) to left euryon (eu)]
Skull Base	[subnasal point (sn) to left tragus (t)] **minus** [subnasal point (sn) to right tragus (t)]
Orbitotragial Depth	[left exocanthion point (ex) to left tragus (t)] **minus** [right exocanthion point (ex) to right tragus (t)]



Key: EU, euryon; EX, exocanthion; IN, inion; OS, orbitale superius; FZ, frontozygomatic; T, tragus.

Figure 1. Anthropomorphic Landmarks

(Hayes, 2017)

Upper Limb Orthotic Devices

Upper Limb (Non Powered): Non powered upper limb orthotic devices are most commonly used to treat injuries and disorders of the finger, hand, wrist, elbow and infrequently, the shoulder. The devices may be classified according to the anatomic region (e.g., wrist, hand), by purpose (e.g., correction, restricting motion) or by function (e.g., compensating for deformity, weakness). Various types of upper limb orthotic devices are available including but not limited to shoulder orthoses, elbow orthoses, finger orthoses, and elbow-wrist-hand orthoses, to name a few. These devices can also be classified as either static (e.g., used to prevent deformity, reduce tone, provide stretch), dynamic (e.g., allow restricted motion) or adaptive/functional (e.g., used to compensate for absent function). Static devices do not allow motion, provide rigid support and are typically used to treat fractures, inflammatory conditions, or nerve injuries. Dynamic devices do allow motion and are most often used to treat weakened muscles and joint contractures. Adaptive/functional devices are used to assist with restoring function, such as for performance of activities of daily living (ADL).

Published evidence indicates a number of devices are available for a variety of uses and generally supports that upper extremity orthoses are clinically effective for the following indications:

- to substitute for weak or absent muscles (e.g., following cervical spine injury, brachial plexus injury, peripheral nerve injury [e.g., median, ulnar or radial nerves], sprain, strain,
- protect damaged or diseased muscles/joints by limiting motion (e.g., rheumatoid arthritis, osteoarthritis, overuse syndromes [e.g., lateral epicondylitis, cubital tunnel syndrome, carpal tunnel syndrome, de Quervain tenosynovitis, trigger finger], trauma, following surgical repairs, fractures [e.g., acromioclavicular dislocation, clavicle fracture])
- prevent risk of contracture or deformity from neurological injury (e.g., brain injury, stroke [i.e., spasticity], spinal cord injury, brachial plexus injury, peripheral nerve injury)
- correct joint contractures resulting from disease or immobilization (e.g., post fracture, burns)
- when necessary to carry out ADLs (e.g., spinal cord injured individuals)

Upper Limb Myoelectric: Myoelectric powered upper-extremity orthotic devices use neurologic sensors, microprocessor units, and electric motors to provide self-initiated movement of the affected upper extremity. One device, the MyoPro® (Myomo, Inc., Boston, MA), is a myoelectric arm orthosis designed to support a weak or deformed arm. It is purported the MyoPro can enable

individuals to self-initiate and control movements of a partially paralyzed or weakened arm using their own muscle signals. The device may be used as exercise equipment during rehabilitation or as a personal assistive device. Individuals with traumatic brain injury, spinal cord injury, brachial plexus injury, amyotrophic lateral sclerosis, stroke, multiple sclerosis and other upper limb neuromuscular deficits may be considered candidates for use of the device. According to the manufacturer there are several MyoPro models available; all models are myoelectrically controlled by the wearer's own muscle signal. The Motion E features a powered elbow with static rigid wrist support; Motion W has a powered elbow and a multi-articulating wrist, with flexion/extension and supination/pronation; and Motion G offers a powered elbow, a multi-articulating wrist and a powered elbow.

According to the United States Food and Drug Administration (FDA), Myomo Inc. received 510(k) clearance for the Myomo e100 in 2007 as a Class 2 device, described further as "exercise equipment, powered, EMG-triggered". The FDA order stated the device is indicated for use by stroke patients undergoing rehabilitation to facilitate stroke rehabilitation by muscle re-education, and/or maintaining or increasing range of motion.

Evidence in the peer-reviewed published scientific literature evaluating an upper limb myoelectric orthotic device consists primarily of review articles, retrospective studies, and few randomized controlled trials with small patient populations reporting short term outcomes. Much of the evidence evaluates use of robotic movement training in a rehabilitation setting as an adjunct to conventional therapies or for exercise training, with limited evidence evaluating use of the myoelectric device in the home setting (Chang, et al., 2024; Chang, et al., 2023; Pundik, et al., 2022; McCabe, et al., 2019; Page, et al., 2013; Willigenburg, et al., 2013; Stein, et al., 2007).

One randomized controlled trial published by Page and colleagues (2020) involved 34 subjects with chronic, moderate post-stroke upper extremity hemiparesis. Subjects were divided into one of three groups: use of Myomo with repetitive task specific practice, task specific practice only, or Myomo only. The Fugl–Meyer score was the primary outcome used to determine success with a secondary outcome measure being the Arm Motor Activity Test. A total of 31 subjects completed the analysis, for the primary outcome measure, all three groups demonstrated near-identical score increases of approximately +2 points, with no difference in the amount of change. For secondary scores both Myomo groups demonstrated near-identical score increases of +1 point; the repetitive task group had a 2.6 point increase. The authors noted they rejected their initial study hypothesis that Myomo would result in significantly greater reductions in upper extremity impairment and concluded that changes using the Myomo device were comparable to those of manual-based therapies. Limitations of the trial include small sample population, use of devices that worked improperly, and limited activities and tasks that could be performed.

Although myoelectric powered upper extremity orthotic devices are an evolving technology, more recently including those manufactured using 3D technology, additional well-designed, large-scale clinical studies evaluating benefits and harms of this technology after stroke and other neurological injuries are needed to firmly establish safety and clinical efficacy.

Lower Limb Orthotic Devices

Lower limb orthoses are classified by anatomic location (e.g., ankle orthoses, ankle-foot orthoses [AFO], knee-ankle-foot orthoses [KAFO]). Ankle orthoses are supportive devices used to provide immobilization to the ankle. AFOs have a shoe insert component as well as an ankle component. KAFOs contain a knee component, ankle component and shoe insert.

Ankle Orthoses: An ankle orthosis is a type of orthotic device used to treat acute ankle injuries such as a sprain, for rehabilitation after the initial injury and to prevent re-injury of the ankle.

They are also used to treat chronically unstable ankles. Ankle orthotic device options include lightweight sports plastics/Velcro models, hinged devices, lace-up devices, neoprene sleeves, ankle wraps and taping, braces, various types of casts, stabilizing shoes and air stirrups.

Ankle-Foot Orthoses (AFO): An AFO extends well above the ankle to the top of the calf. It requires fastening at the lower leg, just above the ankle. This device may be considered medically necessary for ambulatory patients with weakness or deformity of the foot and ankle, which also require stabilization for medical reasons and when the patient has the potential to benefit functionally from use of the device. Commonly, AFOs are used to treat disorders including but not limited to ankle dorsiflexion (upward motion), plantar flexion (downward motion), inversion and eversion (turning inward or outward), spastic diplegia due to cerebral palsy, lower motor neuron weakness due to poliomyelitis and spastic hemiplegia associated with cerebral infarction.

Knee-Ankle-Foot Orthoses (KAFO): A KAFO is an AFO with metal uprights, a mechanical knee joint and two thigh bands. KAFOs may be medically necessary for ambulatory patients who meet criteria for an ankle-foot orthosis, and who also require additional support to the knee for stability. HCPCS codes representing KAFOs include L2000–L2038, L2126–L2136, and L4370.

AFOs and KAFOs may be used by individuals for the treatment of edema and/or for the prevention or treatment of pressure ulcers. When the individual is ambulatory these devices are considered not medically necessary because when used for prevention/treatment of edema or pressure ulcers as the devices are not being used to treat a weakness or deformity that requires stabilization and do not meet the definition of a brace. Similarly, walking boots (L4360 and L4386) are AFOs that may be used to relieve pressure on the sole of the foot or that may be used for patients with foot ulcers, when used for these indications these devices are also considered not medically necessary. A walking boot may be considered medically necessary when it is used to provide stabilization for treatment of orthopedic conditions or when used postoperatively for orthopedic surgery.

Additions to AFO/KAFO Devices: Additions to AFOs or KAFOs (L2180–L2550, L2750–L2830) are considered not medically necessary if either the base orthosis is not medically necessary or the specific addition is not medically necessary.

Nonambulatory AFO/Splints: A splint is defined as an appliance for preventing movement of joints or for the fixation of a displaced or movable body part. Nonambulatory AFO devices, often referred to as splints, include the ankle contracture splint, a night splint and/or a foot drop splint/recumbent positioning device.

A static or dynamic positioning AFO (HCPCS L4396, L4397), also referred to as an ankle contracture splint, is a prefabricated AFO that has all of the following characteristics:

- designed to accommodate an ankle with a plantar flexion contracture of up to 45°
- applies dorsiflexion force to the ankle
- for use by a patient who is minimally ambulatory or nonambulatory
- has a soft interface

These devices may be used to treat plantar flexion contracture of the ankle, Achilles tendonitis, and plantar fasciitis. Ankle flexion contracture is a condition where the muscles and/or tendons that plantarflex the ankle are shortened, resulting in an inability to bring the ankle to 0° by passive range of motion. At 0° flexion, the ankle is perpendicular to the lower leg. Plantar fasciitis is an inflammation of the heel of the foot. Achilles tendonitis is a condition where there is painful inflammation of the Achilles tendon, most often the result of overuse. Conservative treatment for these conditions includes physical therapy, NSAIDS, non-weight-bearing, and strengthening and

stretching of the tendons. Nonambulatory AFO/splint devices maintain elongation/stretching of the tendons and reduce tension when worn, typically at bedtime.

When used to treat a fixed contracture and/or in patients who demonstrate foot drop without an ankle-flexion contracture these devices are considered not medically necessary. Furthermore when used to correct positioning of the knee or hip, the effectiveness of these splints is not well-established in the peer-reviewed literature.

A foot drop splint/recumbent positioning device (HCPCS L4398) is a prefabricated AFO and has all of the following characteristics:

- designed to maintain the foot at a fixed position of 0° (i.e., perpendicular to the lower leg)
- not designed to accommodate an ankle with a plantar flexion contracture
- for use by a patient who is nonambulatory
- has a soft interface

Foot drop is a condition where there is a weakness and/or lack of use of the muscles that dorsiflex the ankle, but the ability to bring the ankle to 0° by passive range of motion remains. A foot drop splint/recumbent positioning device is not considered medically necessary for the treatment of foot drop when the individual is non-ambulatory because there are other more appropriate treatment modalities.

Stance Control Orthoses: A stance control orthosis is an orthotic knee joint or custom-fabricated KAFO that allows swing-phase knee flexion. The knee joint locks when weight-bearing to provide stance phase stability and, when not weighted, it unlocks to allow a swinging motion of the knee. It is proposed that the stance control components allow the patient to swing their impaired limb with sufficient ground clearance to provide a more normal gait. While there are no specific patient criteria, it is intended for use in patients with lower extremity weakness and who demonstrate some control of hip muscles. Candidates who may benefit from this type of device typically have conditions such as polio, post-polio syndrome, spinal cord injuries, multiple sclerosis, stroke or trauma. Examples of such devices include the Agilik™ (Bionic Power, Inc., Vancouver, BC), the E-MAG Active, the Sensor Walk, and the C-Brace® (the next generation of the Sensor Walk device) (Ottobock, Vienna, AT).

These devices can be activated by a mechanical mechanism controlled by activated movement (e.g., ankle range of motion, limb inclination), or mechanical and controlled electronically (e.g., microprocessor-controlled, electromagnetic). Classifications of the devices include the ankle driven device that requires ankle motion to lock and unlock the knee joint; a gait driven device which requires the individual have the ability to reach full hip extension in stance and full knee extension in swing phase in order to unlock and lock the knee joint; or weight driven which locks the knee joint when weight is transferred onto foot plates. Electronic activated devices generally add resistance to knee flexion when the limb is loaded in less than a fully extended position, potentially improving function when the individual is ascending stairs or walking on uneven surfaces.

Evidence in the published, peer-reviewed scientific literature evaluating stance control orthotic devices is limited. Most of the evidence that support some improvement of gait pattern are in the form of literature reviews (Rafiaei, et, al. 2015), small case reports (Kim, et al., 2016; Yakamovich et al., 2006; Herbert and Liggins, 2005) and small case series (Probsting, et al., 2017; Bernhardt, et al., 2011; Irby, et al., 2007; Irby, et al., 2005) and lack high statistical power. The types of devices in these trials vary making comparisons across studies difficult. Furthermore, much of the information available for these devices is from the manufacturers. As a result, drawing strong conclusions that support improved clinical outcomes with the use of these

devices is difficult. Stance control devices have not been clearly established as superior to conventional devices and there is limited evidence to suggest it is considered equivalent (Ontario Health [Quality], 2021). Published scientific evidence evaluating enhanced features such as electronic controls (i.e., microprocessor, electromagnetic activation) is inadequate to support clinical utility.

Ruetz et al. (2023) conducted a multicenter randomized controlled cross-over trial (n=102) to assess the potential benefits of a microprocessor stance and swing control orthosis (C-Brace) in existing KAFO users with lower limb paralysis. Subjects were randomized to start the study with either their own traditional KAFO or the C-Brace. Subjects in the C-Brace-first group used the device at home for three months, after which they returned to their traditional KAFO for a one-month wash-out period, followed by another three-month home-use period with their KAFO. Subjects in the traditional KAFO-first group continued to use their existing orthosis for three months and crossed over to a three-month home-use period of the C-Brace. Subjects were required to use the C-Brace at least one hour per day for five days per week during the home-use period. The study inclusion criteria included active use of a KAFO in the prior three months; a Berg Balance Scale (BBS) score <45; demonstrated minimum physical requirements to be fit with a C-Brace; and the potential to use the C-Brace successfully. The exclusion criteria were: individuals who had never been fit with an orthosis before; already had a C-Brace; were not able to use the C-Brace trial tool; used existing orthosis less than two hours per day five days per week; weight > 125 kg; lower limb amputation requiring combination prosthesis and orthosis; uncontrolled moderate to severe spasticity; vertigo or known history of falls unrelated to orthosis use; and pregnancy. The study outcome measures included the Berg Balance Scale (BBS) score; Dynamic Gait Index (DGI); the 6-minute walk test (6MWT), and other patient-reported outcomes, including falls. Follow-up assessments were conducted at the end of each three-month home-use period with the traditional KAFO or C-Brace. Twenty six subjects (25%) were lost to follow-up; 69 subjects completed the protocol. All subjects were included in the intention-to-treat (ITT) analysis. After three months of use, both groups (KAFO and C-Brace) showed statistically significant improvements compared to baseline in BBS score and the DGI, with significant between-group differences favoring the C-Brace. The number of subjects with the highest fall risk (BBS scores <40) was significantly lower compared to baseline with both KAFO and C-Brace use ($p=0.008$ and $p<0.0001$, respectively), with a significant between-group difference (C-Brace, $p=0.018$). In the 6MWT, the distance walked with the KAFO was significantly longer than at baseline ($p=0.03$), while there was no significant improvement with the C-Brace ($p=0.14$); there was no significant between-group difference. The reported mean falls was significantly lower with the C-Brace versus the KAFO (1.1 ± 3.3 vs 4.0 ± 16.8; $p=0.002$). Author-noted limitations of the study included the cross-over study design and lack of separate control group; the potential deconditioning effect of the COVID 19 pandemic; high attrition rate; extensive medical heterogeneity of the study sample; and the inclusion of only participants with BBS scores <45. The study was funded by the manufacturer of the C-Brace (Otto Bock Healthcare Products).

University of California Berkeley Laboratory (UCBL) Orthosis (HCPCS code L3000): This orthosis is a variant of the traditional prefabricated arch support and was originally designed to maintain a flexible, paralytic valgus foot deformity in the corrected position. This orthosis is cast in a semi-weight-bearing position. Some authors recommend the device to treat flatfoot, plantar fasciitis, calcaneal spurs, posterior tibial tendon dysfunction and rheumatoid arthritis (American Academy of Orthopaedic Surgeons [AAOS], 2023).

Knee Braces

A brace is defined as an orthosis or orthopedic appliance that supports or holds in correct position any movable part of the body and that allows for motion of that part. It must be a rigid or semirigid device used for the purpose of supporting a weak or deformed body member or

restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce on the limb on which it is being used. For individuals who weigh more than 300 pounds, heavy duty knee joints may be medically necessary.

Types of Knee Braces
There are four basic kinds of knee braces referenced in the published literature:

- prophylactic braces, which are designed to prevent or reduce the severity of knee injury
- functional braces, which are designed to (a) provide stability for the anterior-cruciate ligament (ACL) or other ligament deficiency of the knee and (b) provide protection for the ACL or other ligaments after repairs or reconstructions
- rehabilitative braces, which are designed to allow protected motion of injured knees or knees that have been treated operatively
- unloader/offloader braces, which are designed to provide pain relief in arthritic knees

Prophylactic Knee Braces: The objective of using a prophylactic knee brace is to prevent or reduce the severity of injury to a healthy knee. The prophylactic knee brace is generally indicated for protection of the medial-collateral ligament (MCL) against valgus knee stresses and ACL protection from rotational stress in similar situations and are available off-the-shelf. There is insufficient evidence to provide strong conclusions that use of prophylactic knee braces significantly reduces knee injuries (American Academy of Orthopaedic Surgeons [AAOS], 2022; American Academy of Pediatrics [AAP], 2001).

Functional Knee Braces: Functional knee braces, also referred to as derotational braces (e.g., HCPCS code L1840), provide stability to an unstable knee when rotational and anterior-posterior forces are applied to the ligaments. Their main function is to reduce risk of injuries without significantly impairing function (AAP, 2001) and can either be purchased off-the-shelf or are custom fabricated. The brace is designed to be worn during activities and to allow protected motion, as well as to prevent excessive loading. The published, peer-reviewed scientific literature reveals few clinical studies to support improvement in subjective responses with use of the functional brace, such as increased stability, decreased pain, improved performance or increased patient confidence. However, there is some evidence to indicate that functional braces are beneficial when the patient has demonstrated knee instability and is not a candidate for ACL reconstruction.

Rehabilitative Knee Braces: Rehabilitative knee braces (e.g., HCPCS codes L1832, L1844) are intended to control the knee flexion-extension angle during the initial healing period after cruciate ligament or meniscal fracture management or reconstructive surgery. Rehabilitative braces are typically used short term for the early postoperative period to protect the fracture site or surgical repair while range-of-motion, weight-bearing and muscle activity are initiated. There is little published evidence and data supporting the use of rehabilitative braces, although they appear to be well accepted clinically and avoid the risks to the knee associated with cast immobilization.

Unloading/Offloading Knee Braces: Unloading braces are recommended for the treatment of pain and disability that may result from moderate to severe osteoarthritis of the knee. Osteoarthritis of the knee is associated with an overload of a focal area of cartilage. This focal overload leads to failure of the load-bearing capacity of the affected cartilage and subchondral bone. Grading of osteoarthritis is often determined by the Kellgren-Lawrence scale which describes the severity of articular cartilage changes associated with osteoarthritis; grade 3 or 4 on the grading scale is considered moderate to severe osteoarthritis. In most cases, unicompartmental osteoarthritis and varus and valgus deformities can be treated by unloading braces, although joint disease that is present in both medial and lateral compartments and patellofemoral joint disease has not been successfully treated with braces (Pruitt, 2005). Varus

deformities cause overload to the medial compartment, while valgus deformities cause overload to the lateral compartment. Knee braces with varus or valgus adjustments (e.g., HCPCS code L1843, L1844, L1845) may be medically necessary for patients who are ambulatory and require bracing to alleviate pressure on the medial or lateral compartment of the knee. Evidence in the published, peer-reviewed scientific literature evaluating the use of knee bracing for osteoarthritis (Matsuno, et al., 1997; Kirkley, et al., 1999; Richards, et al., 2005; Rannou, et al., 2010; Duivenvoorden, et al., 2015; AAOS, 2021) tends to support some effectiveness and demonstrate reduction in pain, improved functionality, and reduced loading to the damaged compartment.

Fracture Brace: Another less commonly utilized knee brace is a fracture brace (e.g., HCPCS code L1832). This type of brace has been employed for the treatment of tibial-femoral fractures and may be custom-made or prefabricated. It is a functional brace that is applied after initial stabilization. It allows protected weightbearing and motion of the joints above and below the fracture. Published literature suggests this brace promotes early joint movement, prevention of contractures, and early weightbearing, which results in earlier healing.

Patellofemoral Knee Brace: Knee sleeves, also known as patellofemoral knee braces (e.g., HCPCS code L1810), are elastic sleeves used to provide a feeling of support to the knee. These devices are intended to resist lateral displacement of the patella and thereby decrease knee pain. Generally, these devices function as a counterforce brace and have little efficacy for improving pain and function in the treatment of patellar subluxation, dislocation, or patellar hypermobility. The sleeve may be modified to include an opening for the patella, movable straps or a buttress (e.g., felt, inflatable air pocket) and is used to stabilize the patella. Plain knee sleeves may be used to treat postoperative knee effusions and patellofemoral pain syndrome in the absence of subluxation, although clinical efficacy has not been firmly established when used for these conditions (France and Paulos, 1994; Paluska and McKeag, 2000; LaBella, 2004; Lun, et al., 2005; Chew, et al., 2007).

Shoes (Therapeutic)

In contrast to standard shoes, therapeutic shoes have additional depth and may be used to accommodate foot deformities. In general, therapeutic shoes may be considered medically necessary for the treatment of some foot conditions, are accommodative or functional, and are fitted and furnished by a specially trained health professional (e.g., podiatrist, orthotist, prosthetist) or certified pedorthotist. Shoe selection is based primarily on the foot condition or related disease, the shape of the foot, and the individual's daily activities (Janisse and Janisse, 2008). Standard shoes (basic shoes) purchased over-the-counter are not considered therapeutic shoes.

According to the American Diabetes Association (ADA), diabetic individuals with neuropathy or evidence of plantar pressure may be adequately managed with a well-fitted walking shoe or athletic shoe; those with bony deformities (e.g., hammertoes, prominent metatarsal heads, bunions) may require extra-depth shoes; those with extreme bony deformities (e.g., Charcot foot) who cannot be accommodated with commercial therapeutic footwear may require custom-molded shoes (ADA, 2024). Early management is important for prevention or delay of ulceration and/or amputation.

Shoe Types and Accessories: Therapeutic shoes that may be considered medically necessary for a person with systemic conditions that involve impaired circulation and/or loss of protective sensation, including diabetes mellitus, include a depth shoe (HCPCS code A5500) or a custom-molded shoe (HCPCS code A5501), and may or may not have an internally seamless toe. A depth shoe is defined as follows:

- has a full length, heel-to toe filler that when removed provides a minimum of 3/16" of additional depth used to accommodate custom-molded or customized inserts
- is made from leather or other suitable material of equal quality
- has some form of closure (e.g., Velcro, lace or zipper)
- is available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoe according to the American standard last sizing schedule or its equivalent. (The American last sizing schedule is the numerical shoe sizing system used for shoes in the United States.)

A custom-molded shoe is defined as follows:

- is constructed over a positive model or mold of an individual's foot
- is made of leather or other suitable material of equal quality
- has removable inserts which can be altered or replaced as the individual's condition warrants
- has some form of shoe closure (lace, Velcro, zipper).

Therapeutic shoe inserts (HCPCS codes A5512, A5513, A5514) and/or modifications (HCPCS codes A5503, A5504, A5505, A5506, and A5507) may be considered medically necessary and are often required for correct fitting of the shoe. Inserts are total contact (continuous physical contact with weight-bearing portion of the foot) multiple density removable inlays that are directly molded to the plantar surface of the individual's foot or a model of the foot. Modifications of depth or custom-molded shoes include but are not limited to:

- rigid rocker bottoms
- roller bottoms
- wedges
- metatarsal bars
- offset heels
- flared heels

Deluxe features (HCPCS codes A5508) such as special colors, special leathers, and styles do not contribute to the accommodative or therapeutic function of the shoe and are not considered medically necessary.

Inlays (i.e., inserts) that reflect compression molding to the individual's foot over time through heat and pressure generated by wearing a shoe with the insert present (HCPCS code A5510), without external heat sources, do not offer total contact and are not considered medically necessary.

Soft, open toe post-operative shoes (i.e., Sroufe "toe shoe") do not meet the definition of durable medical equipment, are not considered orthotics, and are considered convenience items.

A foot adductus positioning device (e.g., UNFO foot brace, UNOS Medical ltd., Holon Israel) is a device intended for the treatment of metatarsus adductus in newborns. Metatarsus adductus is a condition resulting in medial deviation of the forefoot on the hindfoot, also referred to as "in-toeing." Management of metatarsus adductus depends on degree of flexibility, treatment often involves only observation with spontaneous resolution in a majority of cases. In some cases, passive stretching or serial casting may be recommended (i.e., if no improvement by six months of age). Long term functional problems are rare even if in-toing does not completely resolve (Rosenfeld, et al., 2024).

According to the manufacturer, components of the UNFO foot brace include a rigid plastic insert to support the foot. The insert is covered by a soft thermoplastic material to prevent pressure sores. The medial wall is curved as "anti-adductus shape" to allow more space at the mid-foot for adequate correction. The cushion is molded over the first metatarsus and the big toe for better consistent fixation of the foot in the brace. A circular adjustable strap immobilizes the foot in the brace. Fixed over the medial wall of the brace, the Velcro strap (which features a wide and soft pillow for comfort) can be adjusted by the treating physician as the treatment progresses. The strap has two major functions: to stabilize the heel in the heel cage and the whole foot in the brace, which ensures that the foot remains securely fixed in the brace and to apply corrective pressures on the mid foot for adequate realignment of the foot. According to the FDA approval for this device, it is a Class I device, classified as a corrective orthotic shoe. Evidence in the peer-reviewed scientific literature evaluating the foot adductus positioning device is lacking therefore conclusions regarding safety, efficacy, and improved net health outcomes cannot be made.

Apos® is a customized shoe-like device claimed by the manufacturer to be a noninvasive biomechanical treatment for osteoarthritis (OA) of the knee and lower back pain (AposHealth® and Apos US Management Inc., New York, NY). It is purported adjustable external spacers (i.e., pods) placed in the sole of the custom shoe aim to correct gait patterns. Apos (formerly AposTherapy) is initiated by a physical therapist using computerized gait analysis software to analyze the walking pattern. The physical therapist then calibrates the pods which provide perturbation on the bottom of the Apos shoes based on the analysis. It is claimed the biomechanical device works to retrain muscles around the knee by adjusting the center of pressure, thereby changing the way one's foot interacts with the ground. In theory, the pod causes an imbalance requiring one to realign the weight placed on joints and correct abnormal walking patterns, thereby correcting back, hip and knee alignment during ambulation. The device is proposed as an addition to or alternative to non-surgical standard care. Other nonsurgical comparators for treatment of OA include but are not limited to physical therapy, splints, supports, braces, and intra-articular joint injections.

The evidence base to date consists mainly of retrospective case series, prospective trials, and non-randomized trials (Elbaz, et al., 2010; Drexler, et al., 2012; Segal, et al., 2013; Bar-Ziv, et al., 2013; Yaari, et al., 2015; Barzilay, et al., 2016; Yaari, et al., 2015; Tenenbaum, et al., 2017; Solomonow-Avnon, et al., 2017, Debbi, et al., 2019; Reichenbach et al., 2020; Drew, et al., 2022; Shema-Shiratzky, et al., 2023; Greene, et al., 2023; Benn, et al., 2023). There is a growing body of evidence evaluating the incidence rate of total knee replacement (TKR) following initiation of treatment, which is mainly retrospective and lacks comparators, (Shema-Shiratzky, et al., 2023; Greene, et al., 2023; Drew, et al., 2022). Results of these trials extend two to five years, Drew and associates (2022) reported that 86% of participants who utilized AposTherapy (204/237 subjects) avoided TKR at two years, Greene, et. al., (2023) reported that 84% of subjects (305/365) who met criteria for TKR did not progress to having a TKR upon use of AposTherapy at two years follow-up, and Shema-Shiratzky et al. (2023) reported a low incidence of TKR in their study at five year follow up (18%, n=414). Shema-Shiratzky and colleagues compared their results to prior reports that 50% of patients who sustain knee pain caused by OA will ultimately have a total knee replacement (TKR) after exhausting non-surgical treatment solutions. The trial was a retrospective study, with self-reported outcomes and lacked a control group. Limitations of this study include retrospective design, lack of confirmational imaging of OA (clinical diagnosis determined by physiotherapist), and lack of data surrounding treatment plans, adjustments, and use of the device, therefore strong conclusions cannot be made at this time. Furthermore, these outcomes suggest that surgery was delayed, whether AposTherapy results in complete avoidance of surgery has yet to be proven, long-term data is insufficient.

In 2020 Reichenbach and colleagues published the results of a randomized controlled trial evaluating the effect of biomechanical footwear therapy (n=111) versus control footwear (n=109) for treatment of pain related to knee osteoarthritis at 24 weeks follow up. The experimental group

wore two shoes with two convex adjustable rubber pods screwed to the outsole at the heel while the control group wore footwear which had a device that had visible outsole pods that were not adjustable and did not create a convex walking surface. Follow-up occurred at 24 weeks with outcomes measured using WOMAC pain subscores standardized to range from 0 (no symptoms) to 10 (extreme symptoms) and secondary outcomes which included WOMAC physical function and stiffness subscores and the WOMAC global score, all ranging from 0 (no symptoms) to 10 (extreme symptoms). A total of 213 subjects completed follow-up. All scores improved in all groups at 24 weeks, the authors reported the experimental group scores demonstrated a larger decrease in scores compared to the control group and that results were statistically significant, but of uncertain clinical importance. In addition to lack of long term outcomes, some limitations of the trial noted by the authors include differences in appearance of the shoes, lack of blinding, longer daily shoe wear in the experimental group, and allowance of supplemental analgesic use (Reichenbach, et al., 2020).

The device has been investigated as a treatment for a number of conditions including OA of the knee and hip, pre- and post- total arthroplasty, as well as chronic back pain and other miscellaneous musculoskeletal conditions (e.g., osteonecrosis, ankle instability). However studies have primarily been in the form of case series and cohort studies with small patient populations, short-term follow-up and lack controls and there is a lack of comparative evidence with other commonly accepted non-surgical treatments. There is some evidence supporting significant improvement in short and mid-term outcomes using WOMAC scores and SF-36 questionnaires as well as improvement in gait velocity, cadence and stride length. Additionally, some evidence supports use of Apos Therapy results in reduction of pain medication, physical therapy, and other non-pharmacological interventions, while improving pain and function in some subjects. Although the available data suggest that the device may improve pain and function short-term for some individuals, larger, well designed studies with long-term follow-up are needed to establish the role of Apos in the management of musculoskeletal conditions. Clinical trials in the form of RCTs evaluating the effectiveness of Apos for knee pain due to OA are in progress. At present, there is insufficient evidence in the published peer-reviewed medical literature to support clinical efficacy of Apos as a treatment for musculoskeletal conditions, including but not limited to knee osteoarthritis and/or chronic low back pain.

Spinal Orthotic Devices

Spinal orthoses include cervical orthoses (CO), cervical-thoracic orthoses, (CTO), thoracic orthoses (TO), thoracic-lumbar-sacral orthoses, (TLSO), lumbar-sacral orthoses (LSO), and lumbar orthoses (LO). These devices are used to relieve pain, reduce progression of disease/injury, and to improve function related to various spine conditions such as spinal stenosis, vertebral fractures, scoliosis, spondylosis, spondylolisthesis, Scheuermann's disease (kyphotic deformity), and sprains. A spinal orthosis can be designed to control gross movement of the trunk and intersegmental motion of the vertebrae in one or more planes of motion. If the device does not provide control of motion in one or more planes, or if it does not provide intracavitary pressure, then the item is not considered a spinal orthosis.

Studies addressing the use of spinal orthotic devices such as lumbar supports and belts for the prevention of injury report that despite their use, efficacy is debatable (van Poppel, et al., 1998), and individual workers presenting with no prior history of low-back pain are unlikely to benefit from back belt use (Ammendolia, et al., 2005). In general, research has not demonstrated these devices are effective when used for the prevention of injury (Erdil, 2023; Bataller Cervero, et al., 2019; Bigos, et al., 2009; van Duijvenbode, et al., 2009; van Poppel, 2004; Lahad, et al., 1994). Evidence evaluating use of these devices for treatment of various clinical conditions, including non-specific back pain, is mixed, although some evidence supports improved clinical outcomes with use of these devices a majority of the evidence suggests there is little to no difference in

outcomes (Gignoux, et al , 2022; Urquhart, et al., 2017; Takasaki, et al., 2017; Skoch, et al., 2016; Newman, et al., 2016; Negrini, et al., 2016; Agabegi, et al., 2010; van Duijvenbode, et al., 2008; Yee, et al., 2008).

The results of one prospective RCT (Annaswamy, et al., 2021) designed to evaluate the effect of semi-rigid back bracing for treatment of low back pain was halted early due to worse Pain Disability Questionnaire, Patient Reported Outcome Measurement Information System and EQ-5D scores in the treatment group when compared to the control group. All subjects underwent back school instruction, the treatment group also underwent use of a semi-rigid lumbar orthosis, worn as needed, for symptom relief. Outcomes were measured at baseline, six weeks, 12 weeks and six months. An interim analysis at the halfway point were 61 of the planned 120 subjects were enrolled, demonstrated there was no relief of pain when compared with exercise and instruction alone.

Evidence evaluating spinal orthoses for treatment of adolescent idiopathic scoliosis (AIS) has been published. The goal of treatment for AIS is a curve with a Cobb angle of <40° at skeletal maturity. Natural history studies indicate that curves <40° do not progress after skeletal maturity. In skeletally immature patients with AIS, bracing reduces the risk of curve progression to ≥50° (the usual threshold for surgery) at skeletal maturity. The efficacy of bracing is directly related to the number of hours per day that the brace is worn. Most curves can be managed with an underarm brace (a TLSO, also known as the Boston brace). The TLSO is relatively easy to hide under clothing and fairly well accepted by most patients. Other types of underarm braces include the Charleston brace and the Providence brace, which are designed to be worn only at night. A small percentage of curves require a brace with an under-chin extension (a CTLSO, also known as the Milwaukee brace). The CTLSO is more difficult to hide under clothes and less well-tolerated by patients.

Rigid braces (i.e., Boston, Charleston, Rigo Cheneau) have been used for decades in the treatment of adolescent idiopathic scoliosis, with studies indicating varying levels of effectiveness in preventing curve progression and/or avoiding surgery. However, data supporting the safety and efficacy of other brace types such as flexible/dynamic braces (e.g., SpineCor® spinal brace; Copes Scoliosis Brace) is limited. Studies suggest the SpineCor brace may be less effective in preventing curve progression versus standard rigid bracing, and that use of the SpineCor brace may be associated with an increased risk of requiring surgery (Scherl, 2024; Gutman, et al., 2016; Guo, et al., 2014). There is a lack of published evidence evaluating the Copes scoliosis bracing system.

Custom Foot Orthosis

A foot orthosis is a type of shoe insert that does not extend beyond the ankle and may include items such as heel wedges and/or arch supports. The goal of treating conditions with foot orthoses is to decrease pain and increase function. They may also be indicated to correct foot deformities and provide shock absorption to the foot. Evidence in the published, scientific, peer-reviewed literature and clinical practice guidelines tend to suggest custom-fitted and custom-fabricated foot orthoses are at least as effective as prefabricated orthoses for the treatment of heel-pain syndromes and other conditions; the evidence does not indicate custom fabricated devices are clinically more effective when compared to prefabricated devices.

Conditions for which shoe orthoses may be indicated include the following when there is failure, contraindication, or intolerance to a prefabricated device:

- treatment of impaired peripheral circulation and sensation (i.e., diabetic peripheral neuropathy, altered biomechanics, peripheral vascular disease, skin pathology, ulcers)

- when the orthosis is an integral part of a leg brace and is necessary for the proper functioning of the brace
- treatment of neurologic or neuromuscular conditions (i.e., stroke, neoplasms, hemiplegia, cerebral palsy, myelomeningocele, lower extremity spasticity, hypotonicity of certain muscles, neuromuscular imbalances) and there is reasonable expectation of improvement
- for congenital or acquired foot deformities (i.e., symptomatic rigid flatfoot, posterior tibial tendon dysfunction, mid- or hind-foot arthritis) when there is associated significant pain, impaired gait and prior conservative management has failed.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found.	
LCD	CGS Administrators, LLC; Noridian Healthcare Solutions, LLC	Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686)	1/23/2024
LCD	CGS Administrators, LLC; Noridian Healthcare Solutions, LLC	Knee Orthoses (L33318)	1/1/2020
LCD	CGS Administrators, LLC; Noridian Healthcare Solutions, LLC	Orthopedic Footwear (L33641)	1/1/2020
LCD	CGS Administrators, LLC; Noridian Administrators, LLC	Spinal Orthoses: TLSO and LSO (L33790)	1/1/2020
LCD	CGS Administrators, LLC; Noridian Administrators, LLC	Therapeutic Shoes for Persons with Diabetes (L33369)	1/1/2020

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

I. CRANIAL ORTHOSIS

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
S1040	Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

Protective Helmet: Considered a safety device and not covered or reimbursable:

HCPCS Codes	Description
A8000	Helmet, protective, soft, prefabricated, includes all components and accessories
A8001	Helmet, protective, hard, prefabricated, includes all components and accessories
A8002	Helmet, protective, soft, custom fabricated, includes all components and accessories
A8003	Helmet, protective, hard, custom fabricated, includes all components and accessories
A8004	Soft interface for helmet, replacement only

II. UPPER LIMB ORTHOSIS

Considered Medically Necessary when criteria in the applicable policy statements listed above are met for non-powered upper limb orthosis:

HCPCS Codes	Description
L3650*	Shoulder orthosis, figure of eight design abduction restrainer, prefabricated, off-the-shelf
L3660*	Shoulder orthosis, figure of eight design abduction restrainer, canvas and webbing, prefabricated, off-the-shelf
L3670*	Shoulder orthosis, acromio/clavicular (canvas and webbing type), prefabricated, off-the-shelf
L3671*	Shoulder orthosis, shoulder joint design, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3674*	Shoulder orthosis, abduction positioning (airplane design), thoracic component and support bar, with or without nontorsion joint/turnbuckle, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3675*	Shoulder orthosis, vest type abduction restrainer, canvas webbing type or equal, prefabricated, off-the-shelf
L3677*	Shoulder orthosis, shoulder joint design, without joints, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3678*	Shoulder orthosis, shoulder joint design, without joints, may include soft interface, straps, prefabricated, off-the-shelf
L3702*	Elbow orthosis, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3710*	Elbow orthosis, elastic with metal joints, prefabricated, off-the-shelf
L3720*	Elbow orthosis, double upright with forearm/arm cuffs, free motion, custom fabricated

HCPCS Codes	Description
L3730*	Elbow orthosis, double upright with forearm/arm cuffs, extension/ flexion assist, custom fabricated
L3740*	Elbow orthosis, double upright with forearm/arm cuffs, adjustable position lock with active control, custom fabricated
L3760*	Elbow orthosis (EO), with adjustable position locking joint(s), prefabricated, item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3761*	Elbow orthosis (EO), with adjustable position locking joint(s), prefabricated, off-the-shelf
L3762*	Elbow orthosis, rigid, without joints, includes soft interface material, prefabricated, off-the-shelf
L3763*	Elbow wrist hand orthosis, rigid, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3764*	Elbow wrist hand orthosis, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3765*	Elbow wrist hand finger orthosis, rigid, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3766*	Elbow wrist hand finger orthosis, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3806*	Wrist hand finger orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, custom fabricated, includes fitting and adjustment
L3807*	Wrist hand finger orthosis, without joint(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3808*	Wrist hand finger orthosis, rigid without joints, may include soft interface material; straps, custom fabricated, includes fitting and adjustment
L3809*	Wrist hand finger orthosis, without joint(s), prefabricated, off-the-shelf, any type
L3891*	Addition to upper extremity joint, wrist or elbow, concentric adjustable torsion style mechanism for custom fabricated orthotics only, each
L3900*	Wrist hand finger orthosis, dynamic flexor hinge, reciprocal wrist extension/ flexion, finger flexion/extension, wrist or finger driven, custom fabricated
L3901*	Wrist hand finger orthosis, dynamic flexor hinge, reciprocal wrist extension/ flexion, finger flexion/extension, cable driven, custom fabricated
L3905*	Wrist hand orthosis, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3906*	Wrist hand orthosis, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3908*	Wrist hand orthosis, wrist extension control cock-up, non-molded, prefabricated, off-the-shelf
L3912*	Hand finger orthosis (HFO), flexion glove with elastic finger control, prefabricated, off-the-shelf
L3913*	Hand finger orthosis, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3915*	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated item that has been

HCPCS Codes	Description
	trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3916*	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated, off-the-shelf
L3917*	Hand orthosis, metacarpal fracture orthosis, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3918*	Hand orthosis, metacarpal fracture orthosis, prefabricated, off-the-shelf
L3919*	Hand orthosis, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3921*	Hand finger orthosis, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3923*	Hand finger orthosis, without joints, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3924*	Hand finger orthosis, without joints, may include soft interface, straps, prefabricated, off-the-shelf
L3925*	Finger orthosis, proximal interphalangeal (PIP)/distal interphalangeal (DIP), non-torsion joint/spring, extension/flexion, may include soft interface material, prefabricated, off-the-shelf
L3927*	Finger orthosis, proximal interphalangeal (PIP)/distal interphalangeal (DIP), without joint/spring, extension/flexion (e.g., static or ring type), may include soft interface material, prefabricated, off-the-shelf
L3929*	Hand finger orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3930*	Hand finger orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated, off-the-shelf
L3931*	Wrist hand finger orthotic, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated, includes fitting and adjustment
L3933*	Finger orthosis, without joints, may include soft interface, custom fabricated, includes fitting and adjustment
L3935*	Finger orthosis, nontorsion joint, may include soft interface, custom fabricated, includes fitting and adjustment
L3956*	Addition of joint to upper extremity orthotic, any material; per joint
L3960*	Shoulder elbow wrist hand orthosis, abduction positioning, airplane design, prefabricated, includes fitting and adjustment
L3961*	Shoulder elbow wrist hand orthosis, shoulder cap design, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3962*	Shoulder elbow wrist hand orthosis, abduction positioning, Erb's palsy design, prefabricated, includes fitting and adjustment
L3967*	Shoulder elbow wrist hand orthosis, abduction positioning (airplane design), thoracic component and support bar, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment

HCPCS Codes	Description
L3971*	Shoulder elbow wrist hand orthosis, shoulder cap design, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3973*	Shoulder elbow wrist hand orthosis, abduction positioning (airplane design), thoracic component and support bar, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3975*	Shoulder elbow wrist hand finger orthosis, shoulder cap design, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3976*	Shoulder elbow wrist hand finger orthosis, abduction positioning (airplane design), thoracic component and support bar, without joints, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3977*	Shoulder elbow wrist hand finger orthosis, shoulder cap design, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3978*	Shoulder elbow wrist hand finger orthosis, abduction positioning (airplane design), thoracic component and support bar, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment
L3980*	Upper extremity fracture orthosis, humeral, prefabricated, includes fitting and adjustment
L3981*	Upper extremity fracture orthosis, humeral, prefabricated, includes shoulder cap design, with or without joints, forearm section, may include soft interface, straps, includes fitting and adjustments
L3982*	Upper extremity fracture orthosis, radius/ulnar, prefabricated, includes fitting and adjustment
L3984*	Upper extremity fracture orthosis, wrist, prefabricated, includes fitting and adjustment

Not Covered or Reimbursable:

HCPCS Codes	Description
L3995*	Addition to upper extremity orthosis, sock, fracture or equal, each

Considered Experimental/Investigational/Unproven when used to report an upper limb electric orthotic or a MyoPro 2 device:

HCPCS Codes	Description
L3904*	Wrist hand finger orthosis, external powered, electric, custom fabricated
L3999*	Upper limb orthosis, not otherwise specified
L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated

III. LOWER LIMB ORTHOSIS

Non Ambulatory Ankle-Foot Orthosis/Night Splint

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
L4394†*	Replace soft interface material, foot drop splint
L4396*	Static or dynamic ankle-foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4397*	Static or dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated, off-the-shelf
L4398†*	Foot drop splint, recumbent positioning device, prefabricated, off-the-shelf

†Note: Not covered or reimbursable when foot drop splints are used as recumbent positioning devices.

ICD-10-CM Diagnosis Codes	Description
M24.571	Contracture, right ankle
M24.572	Contracture, left ankle
M24.573	Contracture, unspecified ankle
M24.574	Contracture, right foot
M24.575	Contracture, left foot
M72.2	Plantar facial fibromatosis
M76.61-M76.62	Achilles tendinitis

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
	All other codes

Orthosis for Prevention/Treatment of Ulcer/Pressure Reduction

Not Covered or Reimbursable:

HCPCS Codes	Description
A9283*	Foot pressure off-loading/supportive device, any type, each
L2840*	Addition to lower extremity orthosis, tibial length sock, fracture or equal, each

L2850*	Addition to lower extremity orthosis, femoral length sock, fracture or equal, each

ICD-10-CM Diagnosis Codes	Description
	All codes

Basic Ankle, Ankle-Foot Orthosis (AFO): Ambulatory Use

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
L1900*	Ankle-foot orthosis (AFO), spring wire, dorsiflexion assist calf band, custom fabricated
L1902*	Ankle orthosis, ankle gauntlet or similar, with or without joints, prefabricated, off-the-shelf
L1904*	Ankle orthosis, ankle gauntlet or similar, with or without joints, custom fabricated
L1906*	Ankle foot orthosis, multiligamentous ankle support, prefabricated, off-the-shelf
L1907*	Ankle orthosis, supramalleolar with straps, with or without interface/pads, custom fabricated
L1910*	Ankle orthosis, posterior, single bar, clasp attachment to shoe counter, prefabricated, includes fitting and adjustment
L1920*	Ankle orthosis, single upright with static or adjustable stop (Phelps or Perlstein type), custom fabricated
L1930*	Ankle foot orthosis, plastic or other material, prefabricated, includes fitting and adjustment
L1932*	Ankle-foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment
L1933*	Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf (Code effective 04/01/2025)
L1940*	Ankle foot orthosis, plastic or other material, custom fabricated
L1945*	Ankle foot orthosis, plastic, rigid anterior tibial section (floor reaction), custom fabricated
L1950*	Ankle foot orthosis, spiral, (Institute of Rehabilitative Medicine type), plastic, custom fabricated
L1951*	Ankle foot orthosis, spiral, (Institute of Rehabilitative Medicine type), plastic or other material, prefabricated, includes fitting and adjustment
L1952*	Ankle foot orthosis, spiral, (Institute of Rehabilitative Medicine type), plastic or other material, prefabricated, off-the-shelf (Code effective 04/01/2025)
L1960*	Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
L1970*	Ankle foot orthosis, plastic, with ankle joint, custom fabricated
L1971*	Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment
L1980*	Ankle foot orthosis, single upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar "BK" orthosis), custom fabricated
L1990*	Ankle foot orthosis, double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (double bar "BK" orthosis), custom fabricated
L2106*	Ankle foot orthosis, fracture orthosis, tibial fracture cast orthosis, thermoplastic type casting material, custom fabricated

HCPCS Codes	Description
L2108*	Ankle foot orthosis, fracture orthosis, tibial fracture cast orthosis, custom fabricated
L2112*	Ankle foot orthosis, fracture orthosis, tibial fracture orthosis, soft, prefabricated, includes fitting and adjustment
L2114*	Ankle foot orthosis, fracture orthosis, tibial fracture orthosis, semi-rigid, prefabricated, includes fitting and adjustment
L2116*	Ankle foot orthosis, fracture orthosis, tibial fracture orthosis, rigid, prefabricated, includes fitting and adjustment
L4350*	Ankle control orthosis, stirrup style, rigid, includes any type interface (e.g., pneumatic, gel), prefabricated, off-the-shelf
L4360*	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4361*	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated, off-the-shelf
L4386*	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4387*	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated, off-the-shelf
L4631*	Ankle foot orthosis, walking boot type, varus/valgus correction, rocker bottom, anterior tibial shell, soft interface, custom arch support, plastic or other material, includes straps and closures, custom fabricated

Basic Knee-Ankle-Foot Orthosis (KAFO): Ambulatory

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
L2000*	Knee-ankle-foot-orthosis, single upright, free knee, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar "AK" orthosis), custom fabricated
L2010*	Knee ankle foot orthosis, single upright, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar "AK" orthosis), without knee joint, custom fabricated
L2020*	Knee ankle foot orthosis, double upright, free ankle, solid stirrup, thigh and calf bands/cuffs (double bar "AK" orthosis), custom fabricated
L2030*	Knee ankle foot orthosis, double upright, free ankle, solid stirrup, thigh and calf bands/cuffs, (double bar "AK" orthosis), without knee joint, custom fabricated
L2034*	Knee ankle foot orthosis, full plastic, single upright, with or without free motion knee, medial lateral rotation control, with or without free motion ankle, custom fabricated
L2035*	Knee ankle foot orthosis, full plastic, static (pediatric size), without free motion ankle, prefabricated, includes fitting and adjustment
L2036*	Knee ankle foot orthosis, full plastic, double upright, with or without free motion knee, with or without free motion ankle, custom fabricated
L2037*	Knee ankle foot orthosis, full plastic, single upright, with or without free motion knee, with or without free motion ankle, custom fabricated

L2038*	Knee ankle foot orthosis, full plastic, with or without free motion knee, multiaxis ankle, custom fabricated
L2126*	Knee ankle foot orthosis, fracture orthosis, femoral fracture cast orthosis, thermoplastic type casting material, custom fabricated
L2128*	Knee ankle foot orthosis, fracture orthosis, femoral fracture cast orthosis, custom fabricated
L2132*	Knee ankle foot orthosis, femoral fracture cast orthosis, soft, prefabricated, includes fitting and adjustment
L2134*	Knee ankle foot orthosis, femoral fracture cast orthosis, semi-rigid, prefabricated, includes fitting and adjustment
L2136*	Knee ankle foot orthosis, fracture orthosis, femoral fracture cast orthosis, rigid, prefabricated, includes fitting and adjustment
L4370*	Pneumatic full leg splint, prefabricated, off-the-shelf

Additions to Basic Lower Limb Orthosis

Considered Medically Necessary only when medical necessity for a basic lower limb orthotic device has been met:

HCPCS Codes	Description
L2180*	Addition to lower extremity fracture orthosis, plastic shoe insert with ankle joints
L2182*	Addition to lower extremity fracture orthosis, drop lock knee joint
L2184*	Addition to lower extremity fracture orthosis, limited motion knee joint
L2186*	Addition to lower extremity fracture orthosis, adjustable motion knee joint, Lerman type
L2188*	Addition to lower extremity fracture orthosis, quadrilateral brim
L2190*	Addition to lower extremity fracture orthosis, waist belt
L2192*	Addition to lower extremity fracture orthosis, hip joint, pelvic band, thigh flange, and pelvic belt
L2200*	Addition to lower extremity, limited ankle motion, each joint
L2210*	Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint
L2220*	Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint
L2230*	Addition to lower extremity, split flat caliper stirrups and plate attachment
L2232*	Addition to lower extremity orthosis, rocker bottom for total contact ankle foot orthosis, for custom fabricated orthosis only
L2240*	Addition to lower extremity, round caliper and plate attachment
L2250*	Addition to lower extremity, foot plate, molded to patient model, stirrup attachment
L2260*	Addition to lower extremity, reinforced solid stirrup (Scott-Craig type)
L2265*	Addition to lower extremity, long tongue stirrup
L2270*	Addition to lower extremity, varus/valgus correction ("T") strap, padded/lined or malleolus pad
L2275*	Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined
L2280*	Addition to lower extremity, molded inner boot
L2300*	Addition to lower extremity, abduction bar (bilateral hip involvement), jointed, adjustable
L2310*	Addition to lower extremity, abduction bar-straight

HCPCS Codes	Description
L2320*	Addition to lower extremity, non-molded lacer, for custom fabricated orthosis only
L2330*	Addition to lower extremity, lacer molded to patient model, for custom fabricated orthosis only
L2335*	Addition to lower extremity, anterior swing band
L2340*	Addition to lower extremity, pre-tibial shell, molded to patient model
L2350*	Addition to lower extremity, prosthetic type, (BK) socket, molded to patient model, (used for "PTB," "AFO" orthoses)
L2360*	Addition to lower extremity, extended steel shank
L2370*	Addition to lower extremity, Patten bottom
L2375*	Addition to lower extremity, torsion control, ankle joint and half solid stirrup
L2380*	Addition to lower extremity, torsion control, straight knee joint, each joint
L2387*	Addition to lower extremity, polycentric knee joint, for custom fabricated knee ankle foot orthosis, each joint
L2390*	Addition to lower extremity, offset knee joint, each joint
L2397*	Addition to lower extremity orthosis, suspension sleeve
L2405*	Addition to knee joint, drop lock, each
L2415*	Addition to knee lock with integrated release mechanism (bail, cable, or equal), any material, each joint
L2425*	Addition to knee joint, disc or dial lock for adjustable knee flexion, each joint
L2430*	Addition to knee joint, ratchet lock for active and progressive knee extension, each joint
L2492*	Addition to knee joint, lift loop for drop lock ring
L2500*	Addition to lower extremity, thigh/weight bearing, gluteal/ischial weight bearing, ring
L2510*	Addition to lower extremity, thigh/weight bearing, quadri-lateral brim, molded to patient model
L2520*	Addition to lower extremity, thigh/weight bearing, quadri-lateral brim, custom fitted
L2525*	Addition to lower extremity, thigh/weight bearing, ischial containment/narrow M-L brim molded to patient model
L2526*	Addition to lower extremity, thigh/weight bearing, ischial containment/narrow M-L brim, custom fitting
L2530*	Addition to lower extremity, thigh/weight bearing, lacer, non-molded
L2540*	Addition to lower extremity, thigh/weight bearing, lacer, molded to patient model
L2550*	Addition to lower extremity, thigh/weight bearing, high roll cuff
L2750*	Addition to lower extremity orthosis, plating chrome or nickel, per bar
L2760*	Addition to lower extremity orthosis, extension, per extension, per bar (for lineal adjustment for growth)
L2768*	Orthotic side bar disconnect device, per bar
L2780*	Addition to lower extremity orthosis, non-corrosive finish, per bar
L2785*	Addition to lower extremity orthosis, drop lock retainer, each
L2795*	Addition to lower extremity orthosis, knee control, full kneecap
L2800*	Addition to lower extremity orthosis, knee control, kneecap, medial or lateral pull, for use with custom fabricated orthosis only
L2810*	Addition to lower extremity orthosis, knee control, condylar pad
L2820*	Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
L2830*	Addition to lower extremity orthosis, soft interface for molded plastic, above knee section

Stance Control KAFO

Considered Experimental/Investigational/Unproven when used to represent an electronic/electromagnetic activated stance control KAFO device (e.g., E-Mag Active, Sensor Walk, C-brace®):

HCPCS Codes	Description
L2006	Knee ankle foot device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated

ICD-10-CM Diagnosis Codes	Description
	All codes

Casting

Considered Medically Necessary and when used to report bilateral casting for a medically necessary custom-fabricated lower limb orthosis:

HCPCS Codes	Description
S0395*	Impression casting of a foot performed by a practitioner other than the manufacturer of the orthotic

Repair/Replacement

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
L4002*	Replacement strap, any orthosis, includes all components, any length, any type
L4010*	Replace trilateral socket brim
L4050*	Replace molded calf lacer, for custom fabricated orthotic only
L4055*	Replace non-molded calf lacer, for custom fabricated orthosis only
L4060*	Replace high roll cuff
L4070*	Replace proximal and distal upright for KAFO
L4080*	Replace metal bands KAFO, proximal thigh
L4090*	Replace metal bands KAFO-AFO, calf or distal thigh
L4100*	Replace leather cuff KAFO, proximal thigh
L4110*	Replace leather cuff KAFO-AFO, calf or distal thigh
L4130*	Replace pretibial shell
L4205*	Repair of orthotic device, labor component, per 15 minutes
L4210*	Repair of orthotic device, repair or replace minor parts

L4392*	Replacement, soft interface material; static AFO

IV. KNEE BRACES

Prefabricated Knee Brace

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
L1810*	Knee orthosis, elastic with joints, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1812*	Knee orthosis, elastic with joints, prefabricated, off-the-shelf
L1820*	Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment
L1830*	Knee orthosis, immobilizer, canvas longitudinal, prefabricated, off-the-shelf
L1831*	Knee orthosis, locking knee joint(s), positional orthosis, prefabricated, includes fitting and adjustment
L1832*	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1833*	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf
L1836*	Knee orthosis, rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf
L1843*	Knee orthosis, single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1845*	Knee orthosis, double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1850*	Knee orthosis, Swedish type, prefabricated, off-the-shelf
L1851*	Knee orthosis (KO), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf
L1852*	Knee orthosis (KO), double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf

Not Covered or Reimbursable:

HCPCS Codes	Description

L1847*	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1848*	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf

Custom-Fabricated Knee Brace

Considered Medically Necessary:

HCPCS Codes	Description
L1834*	Knee orthosis, without knee joint, rigid, custom fabricated
L1844	Knee orthosis, single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, custom fabricated
L1846	Knee orthosis, double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, custom fabricated
L1860*	Knee orthosis, modification of supracondylar prosthetic socket, custom fabricated (SK)

Additions to Knee Brace

Considered Medically Necessary when criteria for a knee brace is met and the individual weighs more than 300 pounds:

HCPCS Codes	Description
L2385*	Addition to lower extremity, straight knee joint, heavy-duty, each joint
L2395*	Addition to lower extremity, offset knee joint, heavy-duty, each joint

Considered Medically Necessary for an individual who meets criteria for a custom-fabricated knee brace and either daily activity level requires a brace designed for high-impact/high stress activities or the individual weighs greater than 250 pounds:

HCPCS Codes	Description
L2755*	Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only

Considered Not Medically Necessary:

HCPCS Codes	Description
K0672†*	Addition to lower extremity orthosis, removable soft interface, all components, replacement only, each
L2397*	Addition to lower extremity orthosis, suspension sleeve
L2820†*	Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
L2830†*	Addition to lower extremity orthosis, soft interface for molded plastic, above knee section

L2840*	Addition to lower extremity orthosis, tibial length sock, fracture or equal, each
L2850*	Addition to lower extremity orthosis, femoral length sock, fracture or equal, each

†Note: Not Covered or Reimbursable when billed in addition to the initial dispensing of the device.

V. SHOES

Basic Shoe/Modifications to Shoe

Considered Medically Necessary only when coverage is available for shoes. Benefit exclusions and limitations may apply. Shoes and shoe modifications are specifically excluded under many plans and therefore are generally not covered:

HCPCS Codes	Description
A5500*	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multi-density insert(s), per shoe
A5501*	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe
A5503*	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with roller or rigid rocker bottom, per shoe
A5504*	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with wedge(s), per shoe
A5505*	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with metatarsal bar, per shoe
A5506*	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with off-set heel(s), per shoe
A5507*	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe, per shoe
A5512*	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of shore a 35 durometer or 3/16 inch material of shore a 40 durometer (or higher), prefabricated, each
A5513*	For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each
A5514*	For diabetics only, multiple density insert, made by direct carving with CAM technology from a rectified CAD model created from a digitized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each

ICD-10 Diagnosis Codes	Description
E08.00-E08.9	Diabetes mellitus due to underlying condition

E09.00-E09.9	Drug or chemical induced diabetes mellitus
E10.10-E10.9	Type 1 diabetes mellitus
E11.00-E11.9	Type 2 diabetes mellitus
E13.00-E13.9	Other specified diabetes mellitus
G57.81-G57.83	Other specified mononeuropathies of lower limb
G60.0	Hereditary motor and sensory neuropathy
G60.1	Refsum's disease
G60.3	Idiopathic progressive neuropathy
G60.8	Other hereditary and idiopathic neuropathies
G60.9	Hereditary and idiopathic neuropathy, unspecified
G99.0	Autonomic neuropathy in diseases classified elsewhere
I67.0	Dissection of cerebral arteries, nonruptured
I73.00-I73.9	Other peripheral vascular diseases
I77.70-I77.79	Other arterial dissection
I79.1	Aortitis in diseases classified elsewhere
I79.8	Other disorders of arteries, arterioles and capillaries in diseases classified elsewhere

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	**Description**
	All other codes

Other Shoe Modifications

Not Covered or Reimbursable:

HCPCS Codes	**Description**
A5508*	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe
A5510*	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe

ICD-10-CM Diagnosis Codes	**Description**
	All codes

IV. SPINAL ORTHOSIS

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
L0120*	Cervical, flexible, nonadjustable, prefabricated, off-the-shelf (foam collar)
L0130*	Cervical, flexible, thermoplastic collar, molded to patient
L0140*	Cervical, semi-rigid, adjustable (plastic collar)
L0150*	Cervical, semi-rigid, adjustable molded chin cup (plastic collar with mandibular/occipital piece)
L0160*	Cervical, semi-rigid, wire frame occipital/mandibular support, prefabricated, off-the-shelf
L0170*	Cervical collar, molded to patient model
L0172*	Cervical collar, semi-rigid thermoplastic foam, two piece, prefabricated, off-the-shelf
L0174*	Cervical collar, semi-rigid, thermoplastic foam, two piece with thoracic extension, prefabricated, off-the-shelf
L0180*	Cervical, multiple post collar, occipital/mandibular supports, adjustable
L0190*	Cervical, multiple post collar, occipital/mandibular supports, adjustable cervical bars (SOMI, Guilford, Taylor types)
L0200*	Cervical, multiple post collar, occipital/mandibular supports, adjustable cervical bars, and thoracic extension
L0220*	Thoracic, rib belt, custom fabricated
L0450*	TLSO, flexible, provides trunk support, upper thoracic region, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, prefabricated, off-the-shelf
L0452*	TLSO, flexible, provides trunk support, upper thoracic region, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, custom fabricated
L0454*	TLSO flexible, provides trunk support, extends from sacrococcygeal junction to above T-9 vertebra, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0455*	TLSO, flexible, provides trunk support, extends from sacrococcygeal junction to above T-9 vertebra, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks with rigid stays or panel(s), includes shoulder straps and closures, prefabricated, off-the-shelf
L0456*	TLSO, flexible, provides trunk support, thoracic region, rigid posterior panel and soft anterior apron, extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks, includes straps and closures, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0457*	TLSO, flexible, provides trunk support, thoracic region, rigid posterior panel and soft anterior apron, extends from sacrococcygeal junction and terminates just inferior to the scapular spine, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks, includes straps and closures, prefabricated, off-the-shelf

HCPCS Codes	Description
L0458*	TLSO, triplanar control, modular segmented spinal system, two rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the xiphoid, soft liner, restricts gross trunk motion in the sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0460*	TLSO, triplanar control, modular segmented spinal system, two rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in the sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0462*	TLSO, triplanar control, modular segmented spinal system, three rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in the sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0464*	TLSO, triplanar control, modular segmented spinal system, four rigid plastic shells, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0466*	TLSO, sagittal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, restricts gross trunk motion in sagittal plane, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0467*	TLSO, sagittal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, restricts gross trunk motion in sagittal plane, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated, off-the-shelf
L0468*	TLSO, sagittal-coronal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, extends from sacrococcygeal junction over scapulae, lateral strength provided by pelvic, thoracic, and lateral frame pieces, restricts gross trunk motion in sagittal, and coronal planes, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0469*	TLSO, sagittal-coronal control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, extends from sacrococcygeal junction over scapulae, lateral strength provided by pelvic, thoracic, and lateral frame pieces, restricts gross trunk motion in sagittal and coronal planes, produces intracavitary pressure to reduce load on intervertebral disks, prefabricated, off-the-shelf
L0470*	TLSO, triplanar control, rigid posterior frame and flexible soft anterior apron with straps, closures and padding, extends from sacrococcygeal junction to scapula,

HCPCS Codes	Description
	lateral strength provided by pelvic, thoracic, and lateral frame pieces, rotational strength provided by subclavicular extensions, restricts gross trunk motion in sagittal, coronal, and transverse planes, produces intracavitary pressure to reduce load on the intervertebral disks, includes fitting and shaping the frame, prefabricated, includes fitting and adjustment
L0472*	TLSO, triplanar control, hyperextension, rigid anterior and lateral frame extends from symphysis pubis to sternal notch with two anterior components (one pubic and one sternal), posterior and lateral pads with straps and closures, limits spinal flexion, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes fitting and shaping the frame, prefabricated, includes fitting and adjustment
L0480*	TLSO, triplanar control, one piece rigid plastic shell without interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0482*	TLSO, triplanar control, one piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0484*	TLSO, triplanar control, two piece rigid plastic shell without interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0486*	TLSO, triplanar control, two piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0488*	TLSO, triplanar control, one piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, prefabricated, includes fitting and adjustment
L0490*	TLSO, sagittal-coronal control, one piece rigid plastic shell, with overlapping reinforced anterior, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates at or before the T-9 vertebra, anterior extends from symphysis pubis to xiphoid, anterior opening, restricts gross trunk motion in sagittal and coronal planes, prefabricated, includes fitting and adjustment
L0491*	TLSO, sagittal-coronal control, modular segmented spinal system, two rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the xiphoid, soft liner, restricts gross trunk motion in the sagittal and coronal planes,

HCPCS Codes	Description
	lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0492*	TLSO, sagittal-coronal control, modular segmented spinal system, three rigid plastic shells, posterior extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, anterior extends from the symphysis pubis to the xiphoid, soft liner, restricts gross trunk motion in the sagittal and coronal planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment
L0621*	Sacroiliac orthosis, flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, prefabricated, off-the-shelf
L0622*	Sacroiliac orthosis, flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, custom fabricated
L0623*	Sacroiliac orthosis, provides pelvic-sacral support, with rigid or semi-rigid panels over the sacrum and abdomen, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, prefabricated, off-the-shelf
L0624*	Sacroiliac orthosis, provides pelvic-sacral support, with rigid or semi-rigid panels placed over the sacrum and abdomen, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, custom fabricated
L0625*	Lumbar orthosis, flexible, provides lumbar support, posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include pendulous abdomen design, shoulder straps, stays, prefabricated, off-the-shelf
L0626*	Lumbar orthosis, sagittal control, with rigid posterior panel(s), posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0627*	Lumbar orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0628*	Lumbar-sacral orthosis, flexible, provides lumbo-sacral support, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include stays, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0629*	Lumbar-sacral orthosis, flexible, provides lumbo-sacral support, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include stays, shoulder straps, pendulous abdomen design, custom fabricated
L0630*	Lumbar-sacral orthosis, sagittal control, with rigid posterior panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated

HCPCS Codes	Description
	item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0631*	Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0632*	Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, custom fabricated
L0633*	Lumbar-sacral orthosis, sagittal-coronal control, with rigid posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0634*	Lumbar-sacral orthosis, sagittal-coronal control, with rigid posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, custom fabricated
L0635*	Lumbar-sacral orthosis, sagittal-coronal control, lumbar flexion, rigid posterior frame/panel(s), lateral articulating design to flex the lumbar spine, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, anterior panel, pendulous abdomen design, prefabricated, includes fitting and adjustment
L0636*	Lumbar-sacral orthosis, sagittal-coronal control, lumbar flexion, rigid posterior frame/panels, lateral articulating design to flex the lumbar spine, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, anterior panel, pendulous abdomen design, custom fabricated
L0637*	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0638*	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, custom fabricated

HCPCS Codes	Description
L0639*	Lumbar-sacral orthosis, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0640*	Lumbar-sacral orthosis, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, custom fabricated
L0641*	Lumbar orthosis, sagittal control, with rigid posterior panel(s), posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0642*	Lumbar orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from L-1 to below L-5 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0643*	Lumbar-sacral orthosis, sagittal control, with rigid posterior panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0648*	Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0649*	Lumbar-sacral orthosis, sagittal-coronal control, with rigid posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, stays, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0650*	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0651*	Lumbar-sacral orthosis, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated, off-the-shelf

HCPCS Codes	Description
L0700*	Cervical-thoracic-lumbar-sacral orthoses (CTLSO), anterior-posterior-lateral control, molded to patient model, (Minerva type)
L0710*	CTLSO, anterior-posterior-lateral-control, molded to patient mode, with interface material, (Minerva type)
L0720*	Cervical-thoracic-lumbar-sacral-orthoses (CTLSO), anterior-posterior-lateral control, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise (Code effective 4/1/2025)
L0970*	TLSO, corset front
L0972*	LSO, corset front
L0974*	TLSO, full corset
L0976*	LSO, full corset
L0980*	Peroneal straps, prefabricated, off-the-shelf, pair
L0999†*	Addition to spinal orthosis, not otherwise specified
L1000*	Cervical-thoracic-lumbar-sacral orthosis (CTLSO) (Milwaukee), inclusive of furnishing initial orthosis, including model
L1001*	Cervical thoracic lumbar sacral orthosis, immobilizer, infant size, prefabricated, includes fitting and adjustment
L1005*	Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment
L1010*	Addition to cervical-thoracic-lumbar-sacral orthosis (CTLSO) or scoliosis Orthosis, axilla sling
L1020*	Addition to CTLSO or scoliosis orthosis, kyphosis pad
L1025*	Addition to CTLSO or scoliosis orthosis, kyphosis pad, floating
L1030*	Addition to CTLSO or scoliosis orthosis, lumbar bolster pad
L1040*	Addition to CTLSO or scoliosis orthosis, lumbar or lumbar rib pad
L1050*	Addition to CTLSO or scoliosis orthosis, sternal pad
L1060*	Addition to CTLSO or scoliosis orthosis, thoracic pad
L1070*	Addition to CTLSO or scoliosis orthosis, trapezius sling
L1080*	Addition to CTLSO or scoliosis orthosis, outrigger
L1085*	Addition to CTLSO or scoliosis orthosis, outrigger, bilateral with vertical extensions
L1090*	Addition to CTLSO or scoliosis orthosis, lumbar sling
L1100*	Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather
L1110*	Addition to CTLSO or scoliosis orthosis, ring flange, plastic or leather, molded to patient model
L1120*	Addition to CTLSO or scoliosis orthosis, cover for upright, each
L1200*	Thoracic-lumbar-sacral-orthosis (TLSO), inclusive of furnishing initial orthosis only
L1210*	Addition to TLSO, (low profile), lateral thoracic extension
L1220*	Addition to TLSO, (low profile), anterior thoracic extension
L1230*	Addition to TLSO, (low profile), Milwaukee type superstructure
L1240*	Addition to TLSO, (low profile), lumbar derotation pad
L1250*	Addition to TLSO, (low profile), anterior ASIS pad
L1260*	Addition to TLSO, (low profile), anterior thoracic derotation pad
L1270*	Addition to TLSO, (low profile), abdominal pad
L1280*	Addition to TLSO, (low profile), rib gusset (elastic), each
L1290*	Addition to TLSO, (low profile), lateral trochanteric pad
L1300*	Other scoliosis procedure, body jacket molded to patient model
L1310*	Other scoliosis procedure, post-operative body jacket

HCPCS Codes	Description
L1499††*	Spinal orthosis, not otherwise specified

†Note: Considered Medically Necessary when used to report an addition to a medically necessary spinal orthosis in the absence of a specific code and when criteria in the applicable policy statements listed above are met

††Note: Considered Medically Necessary when used to report a medically necessary spinal orthosis in the absence of a specific code and when criteria in the applicable policy statements listed above are met

Considered Experimental/Investigational/Unproven when used to report Copes scoliosis brace or SpineCor® brace:

HCPCS Codes	Description
L1005*	Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment
L1499*	Spinal orthosis, not otherwise specified

Considered Not Primarily Medical in Nature/Convenience Items/Not Covered:

HCPCS Codes	Description
L0982*	Stocking supporter grips, prefabricated, off-the-shelf, set of four (4)
L0984*	Protective body sock, prefabricated, off-the-shelf, each

CUSTOM FOOT ORTHOSIS

Custom Foot Orthosis When Benefit Plan Document Excludes Treatment for Plantar Fasciitis

When a custom foot orthosis for the treatment of plantar fasciitis is specifically excluded in a benefit plan document the following items are excluded, even if a benefit exists for a custom foot orthosis:

HCPCS Codes	Description
L3000*	Foot, insert, removable, molded to patient model, "UCB" type, Berkeley shell, each
L3001*	Foot, insert, removable, molded to patient model Spenco, each
L3002*	Foot, insert, removable, molded to patient model, Plastazote or equal, each
L3003*	Foot, insert, removable, molded to patient model, silicone gel, each
L3010*	Foot, insert, removable, molded to patient model, longitudinal arch support, each
L3020*	Foot, insert, removable, molded to patient model, longitudinal/metatarsal support, each
L3030*	Foot, insert, removable, formed to patient foot, each
L3031*	Foot, insert/plate, removable, addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, each

ICD-10-CM	Description

Diagnosis Codes	
M72.2	Plantar fascial fibromatosis

When a benefit exists for a custom foot orthosis, the following are considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
L3000*	Foot, insert, removable, molded to patient model, "UCB" type, Berkeley shell, each
L3001*	Foot, insert, removable, molded to patient model, Spenco, each
L3002*	Foot, insert, removable, molded to patient model, Plastazote or equal, each
L3003*	Foot, insert, removable, molded to patient model, silicone gel, each
L3010*	Foot, insert, removable, molded to patient model, longitudinal arch support, each
L3020*	Foot, insert, removable, molded to patient model, longitudinal/metatarsal support, each
L3030*	Foot, insert, removable, formed to patient foot, each
L3031*	Foot, insert/plate, removable, addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, each

ICD-10-CM Diagnosis Codes	Description
A52.15	Late syphilitic neuropathy
E08.40-E08.49	Diabetes mellitus due to underlying condition with neurological complications
E08.51-E08.59	Diabetes mellitus due to underlying condition with circulatory complications
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy
E09.40-E09.49	Drug or chemical induced diabetes mellitus with neurological complications
E09.51-E09.59	Drug or chemical induced diabetes mellitus with circulatory complications
E09.610	Drug or chemical induced diabetes mellitus with diabetic neuropathic arthropathy
E09.65	Drug or chemical induced diabetes mellitus due to underlying condition with hyperglycemia
E10.40-E10.49	Type 1 diabetes mellitus with neurological complications
E10.51-E10.59	Type 1 diabetes mellitus with circulatory complications
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E11.40-E11.49	Type 2 diabetes mellitus with neurological complications
E11.51-E11.59	Type 2 diabetes mellitus with circulatory complications
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E13.40-E13.49	Other specified diabetes mellitus with neurological complications
E13.51-E13.59	Other specified diabetes mellitus with circulatory complications
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy

ICD-10-CM Diagnosis Codes	Description
G11.4	Hereditary spastic paraplegia
G12.0-G12.9	Spinal muscular atrophy and related syndromes
G13.0	Paraneoplastic neuromyopathy and neuropathy
G13.1	Other systemic atrophy primarily affecting central nervous system in neoplastic disease
G24.09	Other drug induced dystonia
G24.2	Idiopathic nonfamilial dystonia
G24.8	Other dystonia
G57.01-G57.03	Lesion of sciatic nerve
G57.11-G57.13	Meralgia paresthetica
G57.21-G57.23	Lesion of femoral nerve
G57.31-G57.33	Lesion of lateral popliteal nerve
G57.40-G57.43	Lesion of medial popliteal nerve
G57.51-G57.53	Tarsal tunnel syndrome
G57.61-G57.63	Lesion of plantar nerve
G57.71-G57.73	Causalgia of lower limb
G57.81-G57.83	Other specified mononeuropathies of lower limb
G57.91-G57.93	Unspecified mononeuropathy of lower limb
G58.8	Other specified mononeuropathies
G58.9	Mononeuropathy, unspecified
G59	Mononeuropathy in diseases classified elsewhere
G60.0-G60.9	Hereditary and idiopathic neuropathy
G61.0-G61.9	Inflammatory polyneuropathy
G62.0-G62.9	Other and unspecified polyneuropathies
G63	Polyneuropathy in diseases classified elsewhere
G65.0	Sequelae of Guillain-Barre syndrome
G65.1	Sequelae of other inflammatory polyneuropathy
G65.2	Sequelae of toxic polyneuropathy
G71.00	Muscular dystrophy, unspecified
G71.01	Duchenne or Becker muscular dystrophy
G71.02	Facioscapulohumeral muscular dystrophy
G71.031	Autosomal dominant limb girdle muscular dystrophy
G71.032	Autosomal recessive limb girdle muscular dystrophy due to calpain-3 dysfunction

ICD-10-CM Diagnosis Codes	Description
G71.033	Limb girdle muscular dystrophy due to dysferlin dysfunction
G71.0340	Limb girdle muscular dystrophy due to sarcoglycan dysfunction, unspecified
G71.0341	Limb girdle muscular dystrophy due to alpha sarcoglycan dysfunction
G71.0342	Limb girdle muscular dystrophy due to beta sarcoglycan dysfunction
G71.0349	Limb girdle muscular dystrophy due to other sarcoglycan dysfunction
G71.035	Limb girdle muscular dystrophy due to anoctamin-5 dysfunction
G71.038	Other limb girdle muscular dystrophy
G71.039	Limb girdle muscular dystrophy, unspecified
G71.09	Other specified muscular dystrophies
G71.11-G71.19	Myotonic disorders
G71.20	Congenital myopathy, unspecified
G71.21	Nemaline myopathy
G71.220	X-linked myotubular myopathy
G71.228	Other centronuclear myopathy
G71.29	Other congenital myopathy
G80.0-G80.9	Cerebral palsy
G81.01-G81.04	Flaccid hemiplegia
G81.11-G81.14	Spastic hemiplegia
G81.91-G81.94	Hemiplegia, unspecified
G99.0	Autonomic neuropathy in diseases classified elsewhere
I67.0	Dissection of cerebral arteries, nonruptured
I69.041-I69.049	Monoplegia of lower limb following nontraumatic subarachnoid hemorrhage
I69.051-I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage
I69.141-I69.149	Monoplegia of lower limb following nontraumatic intracerebral hemorrhage
I69.151-I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage
I69.241-I69.249	Monoplegia of lower limb following other nontraumatic intracranial hemorrhage
I69.251-I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage
I69.341-I69.349	Monoplegia of lower limb following cerebral infarction
I69.351-I69.354	Hemiplegia and hemiparesis following cerebral infarction
I69.841-I69.849	Monoplegia of lower limb following other cerebrovascular disease
I69.851-I69.854	Hemiplegia and hemiparesis following other cerebrovascular disease

ICD-10-CM Diagnosis Codes	Description
I69.941-I69.949	Monoplegia of lower limb following unspecified cerebrovascular disease
I69.951-I69.954	Hemiplegia and hemiparesis following unspecified cerebrovascular disease
I73.00-I73.9	Other peripheral vascular diseases
I77.70-I77.79	Other arterial dissection
I79.1	Aortitis in diseases classified elsewhere
I79.8	Other disorders of arteries, arterioles and capillaries in diseases classified elsewhere
L40.50-L40.59	Arthropathic psoriasis
M05.071-M05.079	Felty's syndrome, ankle and foot
M05.171-M05.179	Rheumatoid lung disease with rheumatoid arthritis of ankle and foot
M05.271-M05.279	Rheumatoid vasculitis with rheumatoid arthritis of ankle and foot
M05.371-M05.379	Rheumatoid heart disease with rheumatoid arthritis of ankle and foot
M05.471-M05.472	Rheumatoid myopathy with rheumatoid arthritis of ankle and foot
M05.571-M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of ankle and foot
M05.771-M05.779	Rheumatoid arthritis with rheumatoid factor of ankle and foot without organ or systems involvement
M05.871-M05.879	Other rheumatoid arthritis with rheumatoid factor of ankle and foot
M06.071-M06.079	Rheumatoid arthritis without rheumatoid factor, ankle and foot
M06.271-M06.279	Rheumatoid bursitis, ankle and foot
M06.371-M06.379	Rheumatoid nodule, ankle and foot
M06.4	Inflammatory polyarthropathy
M06.871-M06.879	Other specified rheumatoid arthritis, ankle and foot
M07.671-M07.679	Enteropathic arthropathies, ankle and foot
M08.071-M08.079	Unspecified juvenile rheumatoid arthritis, ankle and foot
M08.271-M08.279	Juvenile rheumatoid arthritis with systemic onset, ankle and foot
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.471-M08.479	Pauciarticular juvenile rheumatoid arthritis, ankle and foot

ICD-10-CM Diagnosis Codes	Description
M08.871-M08.879	Other juvenile arthritis, ankle and foot
M12.071-M12.079	Chronic post rheumatic arthropathy [Jaccoud], ankle and foot
M12.171-M12.179	Kaschin-Beck disease, ankle and foot
M12.571-M12.579	Traumatic arthropathy, ankle and foot
M12.871-M12.879	Other specific arthropathies, not elsewhere classified, ankle and foot
M13.171-M13.179	Monoarthritis, not elsewhere classified, ankle and foot
M13.871-M13.872	Other specified arthritis, ankle and foot
M19.071-M19.072	Primary osteoarthritis, ankle and foot
M19.171-M19.172	Post-traumatic osteoarthritis, ankle and foot
M19.271-M19.279	Secondary osteoarthritis, ankle and foot
M21.071-M21.079	Valgus deformity, not elsewhere classified, ankle
M21.171-M21.172	Varus deformity, not elsewhere classified, ankle
M21.371-M21.372	Foot drop (acquired)
M21.531-M21.539	Acquired clawfoot
M21.541-M21.542	Acquired clubfoot
M21.6X1-M21.6X2	Other acquired deformities of foot
M21.961-M21.962	Unspecified acquired deformity of lower leg
M24.571-M24.575	Contracture, ankle and foot
M24.671-M24.676	Ankylosis, ankle and foot
M34.83	Systemic sclerosis with polyneuropathy
M76.811-M76.812	Anterior tibial syndrome
M76.821-M76.822	Posterior tibial tendinitis
Q05.0-Q05.9	Spina bifida
Q07.01	Arnold-Chiari syndrome with spina bifida
Q07.03	Arnold-Chiari syndrome with spina bifida and hydrocephalus

ICD-10-CM Diagnosis Codes	Description
Q66.00-Q66.02	Congenital deformities of feet
Q66.11-Q66.12	Congenital talipes calcaneovarus
Q66.211-Q66.219	Congenital metatarsus primus varus
Q66.221-Q66.229	Congenital metatarsus adductus
Q66.31-Q66.32	Other congenital varus deformities of feet
Q66.40-Q66.42	Congenital talipes calcaneovalgus
Q66.50-Q66.6	Congenital pes planus
Q66.71-Q66.72	Congenital pes cavus
Q66.80-Q66.89	Other congenital deformities of feet
Q66.90-Q66.92	Congenital deformity of feet, unspecified
Q72.10-Q72.13	Congenital absence of thigh and lower leg with foot present
Q72.20-Q72.23	Congenital absence of both lower leg and foot
Q72.30-Q72.33	Congenital absence of foot and toe(s)
Q72.40-Q72.43	Longitudinal reduction defect of femur
Q72.50-Q72.53	Longitudinal reduction defect of tibia
Q72.60-Q72.63	Longitudinal reduction defect of fibula
Q72.70-Q72.73	Split foot
Q72.811-Q72.819	Congenital shortening of lower limb
Q72.891-Q72.899	Other reduction defects of lower limb
Q72.90-Q72.93	Unspecified reduction defect of lower limb
Q90.9	Down syndrome, unspecified
S98.011D	Complete traumatic amputation of right foot at ankle level, subsequent encounter
S98.011S	Complete traumatic amputation of right foot at ankle level, sequela
S98.012D	Complete traumatic amputation of left foot at ankle level, subsequent encounter
S98.012S	Complete traumatic amputation of left foot at ankle level, sequela
S98.019D	Complete traumatic amputation of unspecified foot at ankle level, subsequent encounter
S98.019S	Complete traumatic amputation of unspecified foot at ankle level, sequela

ICD-10-CM Diagnosis Codes	Description
S98.021D	Partial traumatic amputation of right foot at ankle level, subsequent encounter
S98.021S	Partial traumatic amputation of right foot at ankle level, sequela
S98.022D	Partial traumatic amputation of left foot at ankle level, subsequent encounter
S98.022S	Partial traumatic amputation of left foot at ankle level, sequela
S98.029D	Partial traumatic amputation of unspecified foot at ankle level, subsequent encounter
S98.029S	Partial traumatic amputation of unspecified foot at ankle level, sequela
S98.111D	Complete traumatic amputation of right great toe, subsequent encounter
S98.111S	Complete traumatic amputation of right great toe, sequela
S98.112D	Complete traumatic amputation of left great toe, subsequent encounter
S98.112S	Complete traumatic amputation of left great toe, sequela
S98.119D	Complete traumatic amputation of unspecified great toe, subsequent encounter
S98.119S	Complete traumatic amputation of unspecified great toe, sequela
S98.121D	Partial traumatic amputation of right great toe, subsequent encounter
S98.121S	Partial traumatic amputation of right great toe, sequela
S98.122D	Partial traumatic amputation of left great toe, subsequent encounter
S98.122S	Partial traumatic amputation of left great toe, subsequent encounter
S98.129D	Partial traumatic amputation of unspecified great toe, subsequent encounter
S98.129S	Partial traumatic amputation of unspecified great toe, sequela
S98.131D	Complete traumatic amputation of one right lesser toe, subsequent encounter
S98.131S	Complete traumatic amputation of one right lesser toe, sequela
S98.132D	Complete traumatic amputation of one left lesser toe, subsequent encounter
S98.132S	Complete traumatic amputation of one left lesser toe, sequela
S98.139D	Complete traumatic amputation of one unspecified lesser toe, subsequent encounter
S98.139S	Complete traumatic amputation of one unspecified lesser toe, sequela
S98.141D	Partial traumatic amputation of one right lesser toe, subsequent encounter
S98.141S	Partial traumatic amputation of one right lesser toe, sequela
S98.142D	Partial traumatic amputation of one left lesser toe, subsequent encounter
S98.142S	Partial traumatic amputation of one left lesser toe, sequela
S98.149D	Partial traumatic amputation of one unspecified lesser toe, subsequent encounter
S98.149S	Partial traumatic amputation of one unspecified lesser toe, sequela
S98.211D	Complete traumatic amputation of two or more right lesser toes, subsequent encounter
S98.211S	Complete traumatic amputation of two or more right lesser toes, sequela
S98.212D	Complete traumatic amputation of two or more left lesser toes, subsequent encounter
S98.212S	Complete traumatic amputation of two or more left lesser toes, sequela
S98.219D	Complete traumatic amputation of two or more unspecified lesser toes, subsequent encounter
S98.219S	Complete traumatic amputation of two or more unspecified lesser toes, sequela
S98.221D	Partial traumatic amputation of two or more right lesser toes, subsequent encounter
S98.221S	Partial traumatic amputation of two or more right lesser toes, sequela
S98.222D	Partial traumatic amputation of two or more left lesser toes, subsequent encounter
S98.222S	Partial traumatic amputation of two or more left lesser toes, sequela

ICD-10-CM Diagnosis Codes	Description
S98.229D	Partial traumatic amputation of two or more unspecified lesser toes, subsequent encounter
S98.229S	Partial traumatic amputation of two or more unspecified lesser toes, sequela
S98.311D	Complete traumatic amputation of right midfoot, subsequent encounter
S98.311S	Complete traumatic amputation of right midfoot, sequela
S98.312D	Complete traumatic amputation of left midfoot, subsequent encounter
S98.312S	Complete traumatic amputation of left midfoot, sequela
S98.319D	Complete traumatic amputation of unspecified midfoot, subsequent encounter
S98.319S	Complete traumatic amputation of unspecified midfoot, sequela
S98.321D	Partial traumatic amputation of right midfoot, subsequent encounter
S98.321S	Partial traumatic amputation of right midfoot, sequela
S98.322D	Partial traumatic amputation of left midfoot, subsequent encounter
S98.322S	Partial traumatic amputation of left midfoot, sequela
S98.329D	Partial traumatic amputation of unspecified midfoot, subsequent encounter
S98.329S	Partial traumatic amputation of unspecified midfoot, sequela
S98.911D	Complete traumatic amputation of right foot, level unspecified, subsequent encounter
S98.911S	Complete traumatic amputation of right foot, level unspecified, sequela
S98.912D	Complete traumatic amputation of left foot, level unspecified, subsequent encounter
S98.912S	Complete traumatic amputation of left foot, level unspecified, sequela
S98.919D	Complete traumatic amputation of unspecified foot, level unspecified, subsequent encounter
S98.919S	Complete traumatic amputation of unspecified foot, level unspecified, sequela
S98.921D	Partial traumatic amputation of right foot, level unspecified, subsequent encounter
S98.921S	Partial traumatic amputation of right foot, level unspecified, sequela
S98.922D	Partial traumatic amputation of left foot, level unspecified, subsequent encounter
S98.922S	Partial traumatic amputation of left foot, level unspecified, sequela
S98.929D	Partial traumatic amputation of unspecified foot, level unspecified, subsequent encounter
S98.929S	Partial traumatic amputation of unspecified foot, level unspecified, sequela
Z89.411	Acquired absence of right great toe
Z89.412	Acquired absence of left great toe
Z89.421	Acquired absence of other right toe(s)
Z89.422	Acquired absence of other left toe(s)
Z89.431	Acquired absence of right foot
Z89.432	Acquired absence of left foot

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
	All other codes

Considered Experimental/Investigational/Unproven when used to report foot adductus positioning device (e.g., UNFO foot brace) or Apos® Biomechanical device:

HCPCS Codes	Description
L3161	Foot, adductus positioning device, adjustable
L3649*	Orthopedic shoe, modification, addition or transfer, not otherwise specified

***Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Focused review	No clinical policy statement changes.	4/15/2025
Annual review	No clinical policy statement changes.	9/15/2024
Focused review	Updated policy statement for general orthotic device	3/15/2024