A RESOURCE FOR CANADA'S INSURANCE INDUSTRY

PEDORTHIC
ASSOCIATION OF CANADA

Revised May 2024

This content is subject to ongoing review and revision.

PEDORTHIC
ASSOCIATION OF CANADA

Contents

A note on language: The term "orthotic" is technically an adjective (e.g., "orthotic device"), but has come to be commonly used as a noun by patients, pedorthists, and other healthcare professionals. The correct noun is "orthosis" (plural, "orthoses").

Click here for quick access to our complete list of medical conditions potentially requiring pedorthic treatment

A resource for Canada's insurance industry

The Pedorthic Association of Canada and its members value the profession's relationship with Canada's insurance industry.

We encourage dialogue and are grateful for the opportunity to share our knowledge and positions about orthoses, footwear, and related products and services with insurers.

The purpose of this document is to describe the following:

- The role of Canadian Certified Pedorthists – C. Ped (C);
- The patient experience, something we like to call the "Pedorthic Journey";
- Our positions on key elements of pedorthic practice; and
- Common and accepted technical terminology in pedorthic practice.

PAC's Invitation to Insurers

Canadian Certified Pedorthists are happy to answer questions from Canada's insurance industry. Lab tours and presentations can also be arranged.

For more information, contact the Pedorthic Association of Canada office at 1-888-268-4404 or by email at info@pedorthic.ca.

PAC invites insurers to share information from www.pedorthic.ca with their customers and subscribers. Please contact the PAC office for details.

About Canadian Certified Pedorthists

Expertise

Canadian Certified Pedorthists – C. Ped (C) – are allied healthcare professionals trained in the assessment of lower limb anatomy and biomechanics. They specialize in the design, fit, and modification of custom-made orthotics, orthopaedic footwear, and braces. C. Ped (C)s determine a patient's treatment through a biomechanical exam and gait analysis.

Education

To become a Canadian Certified Pedorthist, one must first earn a university degree that includes courses in anatomy, biomechanics/gait analysis, medical conditions/diseases, physical assessment, and ethics.

Certification

After earning the degree, one must either: (a) complete the post-graduate program in Pedorthics at Western University; or (b) train as an apprentice for a minimum 3,500 hours in the areas of clinical practice, footwear (fit and modification), and the fabrication of custom orthoses. Upon completion, one must satisfy the rigours of an examination process, both written and practical. Examinations are administered by The College of Pedorthics of Canada (www.cpedcs.ca).

Regulation

Canadian Certified Pedorthists are governed by The College of Pedorthics of Canada. The College's role is to protect the interests of the public, regulate the profession, and hold its practitioners to the highest standards of professional practice and ethical behaviour.

Relationships

Pedorthists cooperate closely with physicians and allied health professionals in the provision of pedorthic solutions to lower limb and foot-related health problems. The College's Code of Ethics allows a pedorthist to enter into professional affiliations with others only if it is possible to maintain his/her professional integrity.

Community

As of May 2024, there were 600 Canadian Certified Pedorthists and interest in the profession continues to grow. Canadian Certified Pedorthists are committed to professional development and research reflecting a shared commitment to improve practice across Canada.

The Role of a Pedorthist

Canadian Certified Pedorthists – C. Ped (C) – are allied healthcare professionals trained in the assessment of lower limb anatomy and biomechanics. They specialize in the design, fit, and modification of custom-made orthotics, orthopaedic footwear, and braces. C. Ped (C)s determine a patient's treatment through a biomechanical exam and gait analysis

Canadian Certified Pedorthists consult with patients based on referrals from physicians, nurse practitioners, and other healthcare providers where insurance coverage is needed. The goal of every Canadian Certified Pedorthist is to help patients achieve and maintain proper foot care and lower limb health, and live healthy, active lives.

Through a sustained relationship between pedorthist and patient – and depending on the precise nature of a specific patient's condition – pedorthic care can help prevent further pain and debilitation, and the related inconvenience and expense for patients, insurers, and the healthcare system.

Pedorthic Designations

Certified Pedorthic Master Craftsman – C. Ped MC
A C. Ped MC has been certified as a C. Ped (C) and is also certified in custom shoe design and manufacturing.

Certified Pedorthist (Canada) – C. Ped (C) (also, "Canadian Certified Pedorthist")
A C. Ped (C) is highly educated in postural analysis, movement patterns, and musculoskeletal examination. More specifically, a C. Ped (C) focuses on the assessment of lower limb anatomy, muscle and joint function, as well as the interaction of the foot and lower limb with the rest of the body. In addition, a C. Ped (C) is trained in the design, manufacture, and modification of foot appliances, and the clinical fitting and modification of footwear for the purposes of: (a) alleviating painful or debilitating conditions; and (b) providing assistance for abnormalities or limited actions of the lower limb.

Certified Pedorthic Technician (Canada) – C. Ped Tech (C)
A C. Ped Tech (C) is trained in the practice of shoe fitting, footwear modification, and orthosis fabrication from files produced by healthcare professionals with the ability to assess, such as a C. Ped (C) or C. Ped MC. A C. Ped Tech(C) may perform the duties of a clinical pedorthist under the direct supervision of a C. Ped (C) or a C. Ped MC.

Certified Orthopaedic Footwear Specialist – COFS
This is a legacy status presented to founding members who joined together to create the Pedorthic Association of Canada. This is a closed membership category and no new designations are being awarded. COFS members laid the foundation of pedorthics and the College of Pedorthics of Canada has verified their competency. These practitioners provide assessments, casting, measuring, and manufacturing of orthoses, orthopaedic, and custom footwear.

Medical Conditions Potentially Requiring Pedorthic Treatment

The following is a non-exhaustive list of medical conditions potentially requiring pedorthic treatment by a Canadian Certified Pedorthist:

- Accessory navicular
- Achilles tendinitis (Achilles tendinopathy/Achilles tendinosis)
- Amputations: hallux, digital, transmetatarsal, Syme, Chopart
- Ankle fusion (ankle subtalar arthrodesis)
- Ankle impingement syndrome
- Ankle ligament sprains
- Ankle subtalar arthrodesis (ankle fusion)
- Balance impairment
- Bunion
- Bunionette (tailor's bunion)
- Calcaneal apophysitis (Sever's disease/syndrome)
- Calcaneal exostosis/pump bump
- Calcaneal fat pad contusion/rupture
- Calcaneal spurs
- Callus (intractable plantar keratosis [hard corn])
- Cerebral palsy
- Charcot foot
- Charcot-Marie-Tooth disease
- Chondromalacia patella
- Chronic ankle instability
- Clubfoot (congenital talipes equinovarus, CTEV)
- Compartment syndrome
- Complex regional pain syndrome (RSD)
- Congenital talipes equinovarus (clubfoot, CTEV)
- Congenital flat foot (calcaneovalgus) (rigid flat foot)
- Crossover toe deformity
- Cuboid syndrome
- Degenerative disc disease
- Diabetes mellitus
- Diabetic foot ulcer
- Duchenne muscular dystrophy
- Dupuytren's contracture
- Equinus
- Extensor tendinitis/tendinopathy
- Fat pad atrophy
- Fibromyalgia
- Fibularis muscle strain
- First metatarsal – medial cuneiform dorsal exostosis
- Flexor tenosynovitis
- Forefoot Varus deformities
- Forefoot Valgus deformities
- Fracture: calcaneus, fifth metatarsal avulsion, and Jones
- Freiberg's disease/infraction
- Functional hallux limitus
- Ganglion cyst
- Greater trochanteric bursitis
- Gluteus maximus tendinitis/ tendinopathy
- Gouty arthritis
- Haglund's deformity (pump bump, Bauer bump, calcaneal exostosis)
- Hallux abducto valgus
- Hallux adductus deformities
- Hallux limitus
- Hallux rigidus
- Hallux valgus
- Hammer toe, claw toe, mallet toe
- Iliotibial band friction syndrome (ITBFS)
- Infrapatellar bursitis
- Interdigital (soft) corns
- Interdigital neuritis
- Intermetatarsal neuroma
- Intractable plantar keratosis (hard corn) (callus)
- Kohler's disease
- Legg-Calve-Perthes disease
- Leg length discrepancy (LLD)
- Lisfranc injury
- Lower back pain
- Medial calcaneal nerve entrapment (tarsal tunnel syndrome)
- Medial tibial stress syndrome (MTSS, shin splints)
- Metatarsalgia
- Metatarsus adductus
- Meniscal tear
- Morton's (foot) syndrome
- Morton's neuroma
- MTP joint capsulitis
- MTP joint synovitis
- Multiple sclerosis
- Osgood–Schlatter disease
- Osteoarthritis – foot and ankle
- Osteoarthritis – hip
- Osteoarthritis – knee
- Osteochondrosis
- Parkinson's disease
- Patellar instability/subluxations
- Patellar tendinopathy/tendinitis
- Patellofemoral pain syndrome
- Peripheral neuropathy
- Peroneal muscle strain
- Peroneal tendinitis/tendinopathy
- Peroneal syndrome

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- Peroneal tendon subluxation
- Pes cavus
- Pes planus
- Piriformis syndrome
- Plantar fasciitis/fasciopathy/fasciosis
- Plantar fibromatosis
- Plantar plate tear/dysfunction/turf toe
- Plantar wart
- Posterior tibial tendon dysfunction/tibialis posterior tendinitis/tendinopathy/dysfunction
- Post-poliomyelitis syndrome
- RSD (complex regional pain syndrome)
- Psoriatic arthritis
- Retrocalcaneal bursitis (Achilles tendon disorders, heel pain, pump bump, bursitis, winter heel, cucumber heel, high-prow heel, knobby prow-beak deformity, tendo Achilles bursitis, hatchet heel, Albert's disease)
- Rheumatoid arthritis
- Rigid flat foot (congenital flat foot [calcaneovalgus])
- Sacroiliac joint dysfunction
- Scoliosis
- Sesamoiditis
- Sever's disease/syndrome (calcaneal apophysitis)
- Shin splints
- Sinus tarsi syndrome/sinus tarsi impingement
- Stress fractures (metatarsal, cuboid march fracture)
- Tailor's bunion (bunionette)
- Talar dome lesion
- Tarsal coalition
- Tarsal tunnel syndrome
- Tibialis anterior tendinopathy/tenosynovitis
- Turf toe
- Vascular impairment

The Pedorthic Journey: Referral, Clinical Assessment, Biomechanical Examination, and Gait Analysis

Canadian Certified Pedorthists enjoy an excellent relationship with Canada's doctors and other medical professionals.

A Canadian Certified Pedorthist will conduct a complete assessment which includes, but is not limited to, the following elements:

UNDERSTANDING THE DIAGNOSIS: The pedorthist will assist the patient in understanding their medical condition including the potential causes, contributing factors, and recommended treatments. Pedorthists focus on educating patients about their condition and outline how they can benefit from Pedorthic treatment plans that suit their needs and lifestyle.

CLINICAL ASSESSMENT: The main purpose of the assessment is to determine whether the medical condition with which the patient presents is related to abnormal foot structure or biomechanics. A thorough investigation includes:

History – It is imperative to gather a thorough history to identify patterns and expose factors contributing to the medical condition. This involves an in-depth inquiry of:

- Symptoms – description, duration, acute or chronic onset, injury patterns.
- Previous injuries – may affect or provide insight into the present state.
- Family history – to identify a potential pattern.
- Systemic diseases – many have a significant effect on the lower limb, i.e., diabetes, rheumatoid arthritis.
- Lifestyle and activities – help determine demand placed on feet throughout the day.
- Occupation – provides information on foot demand as well as footwear requirements.
- Footwear – footwear fit, style, wear patterns, and present condition (new or worn) can affect symptoms.

Biomechanical Examination – Foot structure and lower limb biomechanics are thoroughly examined during both static and dynamic non-weight-bearing and weight-bearing evaluation.

- Non-weight-bearing – determination of foot type; observation of pathologies, deformities, and abnormalities in appearance, structure, joint range of motion (hyper/hypomobility, restrictions/fixations, instability), muscle imbalances (hyper/hypoflexibility, weakness, tone), soft tissue anomalies (hyper/hypomobility, restrictions, adhesions), neurological (deficits/inhibitions/hyperactivity both sensory and motor), and vascularity (circulation deficits/swelling, edema).
- Weight-bearing – observation of foot position, lower limb alignment, symmetry and position of pelvis, overall posture, functional strength, range of motion, and balance testing during single and double stance.
- Functional testing – further examination and testing is tailored to the specific medical condition and presentation of symptoms to more accurately identify the nature of the problem.

Gait Analysis – observation of an individual while walking to identify unusual patterns or function resulting from abnormal lower limb or foot structure identified during examination. Each phase of the gait cycle is analyzed for irregularities and asymmetries of left to right:

- Heel Strike – referring to initial heel contact;
- Midstance – referring to full foot contact;
- Propulsion – referring to push-off; and
- Swing – referring to follow-through.

Evaluation – All of the information above must be considered to determine: (a) whether foot structure or alignment is playing a role in the presenting medical condition; and (b) whether a foot orthosis, footwear, and/or footwear modification is the appropriate method of treatment.

Our Position

Only after a complete and thorough assessment of the feet and lower limbs can the most effective treatment solutions be determined and orthotic devices be designed. Such assessment is best conducted by a practitioner who has extensive training and expertise, such as a Canadian Certified Pedorthist.

The Pedorthic Journey: Foot Capture/Casting/Scanning

Numbers in the text correspond to numbers on the flow charts on pages 9 and 11.

Creating a custom-made foot orthosis is an involved process that includes capturing a three-dimensional foot shape, an orthosis design process, and a manufacturing stage. The design and manufacture of an orthosis are performed to the specifications detailed by the foot care professional who performed the full clinical assessment, biomechanical examination, gait analysis, and who casted or scanned the foot. While technology and computer programs are used regularly throughout the fabrication process, it is imperative that the assessing clinician or fabrication technician provide the input to control the design and manufacture of the orthotic device and, as such, must be certified and trained in the relevant technologies.

The following procedures describe the steps in the manufacture of custom foot orthoses:

Foot Capture/Casting/Scanning:

The cast is the medium by which foot structure and position are captured. A cast is a physical or digital model that accurately captures the anatomy and contours of the plantar aspect of the foot while it is in a non-weight bearing, semi-weight-bearing, or full-weight-bearing position. This model must be three-dimensional in order to fabricate a custom-made orthosis for the patient.

Acceptable techniques that may be used to acquire a foot cast used in orthoses manufacturing are manual casting (1) (plaster or sock slipper casting, foam box casting, wax slipper casting, and raw material direct-to-foot moulding), contact digitizing, and optical/laser scanning.

3D Physical Cast: Slipper Casting (Plaster of Paris, Foot Impression Wax, Casting Sock (2))

- The clinician places the foot in its optimum position.
- A negative cast is taken with plaster, wax, or a polyurethane-embedded sock.
- The cast is used to yield a positive mould for further correction or modification before fabrication of the orthosis.
- This method captures the plantar contour of the foot, as well as the forefoot-to-rearfoot relationship.

Semi-Weight-Bearing Foam Box Casting (3):

- The clinician places the foot in the desired position to achieve optimum posture and carefully controls the posture of the foot during casting.
- A negative cast is taken with a low-density foam block.
- The cast is used to create a positive mould for fabrication of the orthosis. This method captures the contours of the plantar aspect of the foot in a functional posture.

Raw Material Direct-to-Foot Mould (4):

- The clinician chooses thermo-mouldable raw material to use as casting material that will ultimately form part of the finished orthosis.
- This material is heated to the desired temperature in order to make it malleable enough to contour to the structure of the foot.
- The material is then placed on the foot in a non-weight-bearing, semi-weight-bearing, or a full-weight-bearing position.
- The clinician positions the foot to achieve optimum posture and control during casting as the material cools.
- The material (now moulded to the foot) is removed and excess material is cut away.
- Reinforcing layers, padding layers, and other necessary components are then added (e.g., metatarsal pads and posting).
- The raw material is then ground into a shape to become an effective orthotic device.

(Note: Pre-made products (19) where an over-the-counter device is heated and moulded over the physical cast, or where the cast is "best matched" to a pre-made product, are not considered to be custom-made.)

3D Digital Scan (5): Laser/Optical Scanner/Contact Digitization

If digital technology is used in the provision of custom foot orthoses, the laser or scanning system must create a three-dimensional foot image from points read directly from the foot itself or from a direct model of the foot, such as a plaster slipper cast or foam impression. The scanning technology must not use computer algorithms,

extrapolations, or interpretations to calculate shapes and contours from two-dimensional pressure readings, ink impressions, single aspect photographs, or any other two-dimensional methods.

For the purpose of capturing the 3D model of the human foot, there are three main acceptable types of "digital" or "3D scanners" (at present):

1. Laser triangulation (red light) (6)
2. Structured light (white or infrared light) (7)
3. Contact digitization (8)

Laser triangulation uses a laser light to measure the distance between the laser source and the foot to create an accurate model of that foot.

Structured light scanners use the same trigonometric triangulation used in laser scanning, however instead of using a laser light, they project a light pattern onto an object and calculate the distance to the light source.

Contact digitization uses a three-dimensional pin matrix to capture the contours of the plantar aspect of the foot.

Unacceptable Methods

Unacceptable methods that use digital or manual computations to calculate a foot shape include pedographs (9), pressure-sensitive mats (10), and photogrammetry (11).[1] These methods do not directly capture the foot's shape and they require human or digital interpretations.

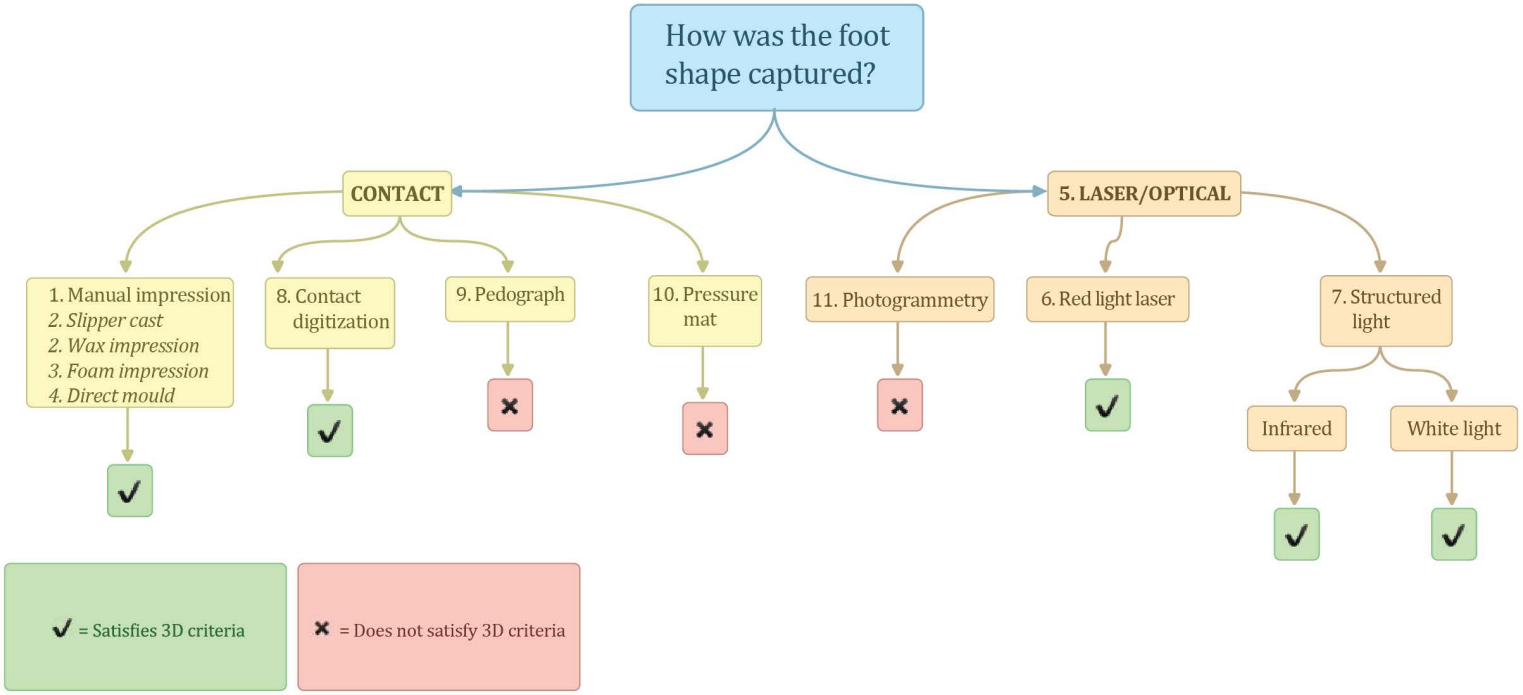
[1] *Photogrammetry is a method used to create three-dimensional images from a series of two-dimensional photographs. When used appropriately, it can be a highly accurate way to create a three-dimensional image of a foot. That said, this method has not proven to be clinically relevant when applied to casting for custom foot orthoses, as it is an inefficient process that requires significant computing power and clinical time. There are current systems that claim to use photogrammetry when, in reality, they require in-depth computer algorithms to create three-dimensional shapes from a single photograph of any one aspect of the foot. It is for these reasons that PAC recommends photogrammetry be excluded from the acceptable foot capture methods.*

Our Position

It is widely accepted that a three-dimensional model of the foot is necessary to produce the most effective custom-made orthosis or shoe possible. There are a variety of different casting techniques available to Canadian Certified Pedorthists, each with its own merits. It is a disservice to the patient to label any single technique as "standard" as it compromises the pedorthist's ability to choose the best method for a specific patient. Two-dimensional casting is not sufficient because it does not capture the height of the arch and is not a volumetric cast of the entire foot surface.

Chart 1
*Reference the Pedorthic Association of Canada Foot Capture/Casting/ Scanning document

Custom-made Foot Orthosis
Foot Capture/Casting/Scanning



The Pedorthic Journey: Orthoses Design and Manufacture

Numbers in the text correspond to numbers on the flow charts on pages 9 and 11.

Design

CAD/CAM (12) is an acronym for computer-aided design/computer-aided manufacturing – computer systems used to design and manufacture products. The term CAD/CAM implies that an individual can use the system both for designing a product and for controlling manufacturing processes.

In order to design a custom foot orthosis, it is imperative to have a detailed and accurate prescription and cast.

Based on the findings of the full clinical assessment, biomechanical examination, and gait analysis, the foot care professional will create the prescription for the custom foot orthosis, which is actually the detailed instruction on how the orthosis is to be made. The prescription specifically outlines the parameters of design, materials, composition, and fabrication of the orthosis intended to treat the patient's unique medical needs.

After choosing the best casting method to capture the patient's foot, the next phase involves the preparation of the cast or scan to ensure the actual orthosis is shaped to support, correct, or accommodate the foot structure and provide comfort during use. Cast dressing or modifying refers to this preparation in addition to excavations and additions to accommodate deformities and prominences, a process that can be performed manually (13) using hand-carved plaster from a physical cast (plaster or sock slipper casting, foam box casting, wax), or digitally (14) where a technician manipulates a scan using a computer program (contact digitization, laser/optical scanning).

To satisfy the custom-manufactured criteria using digital design, each scan must be processed individually and not be subject to batch processing, library,[2] or best-fit systems (15). The final scan file must be unique to the individual throughout the entire process of manufacturing the orthosis.

Once the design phase is completed, the orthosis's raw material is either vacuum-pressed (16) over a cast for manual design and manufacture, or the manipulated scan file is sent to a 3D milling machine (17) or a 3D printer (18).

Manufacture

To be considered custom-made, a foot orthosis must be fabricated from raw materials and made directly on a foot cast that captures the anatomy and contours of the plantar aspect of the foot as defined by the 3D casting criteria.

Currently, the acceptable manufacturing techniques that can be utilized to fabricate the orthosis shell and/or posting on or from the 3D cast using the raw materials include:

Vacuum forming (16): Sheets of thermoplastic material are heated to a forming temperature and stretched over the mould made from the cast to create the shell/footbed of the orthosis. Suction is applied to shape the material to the mould.

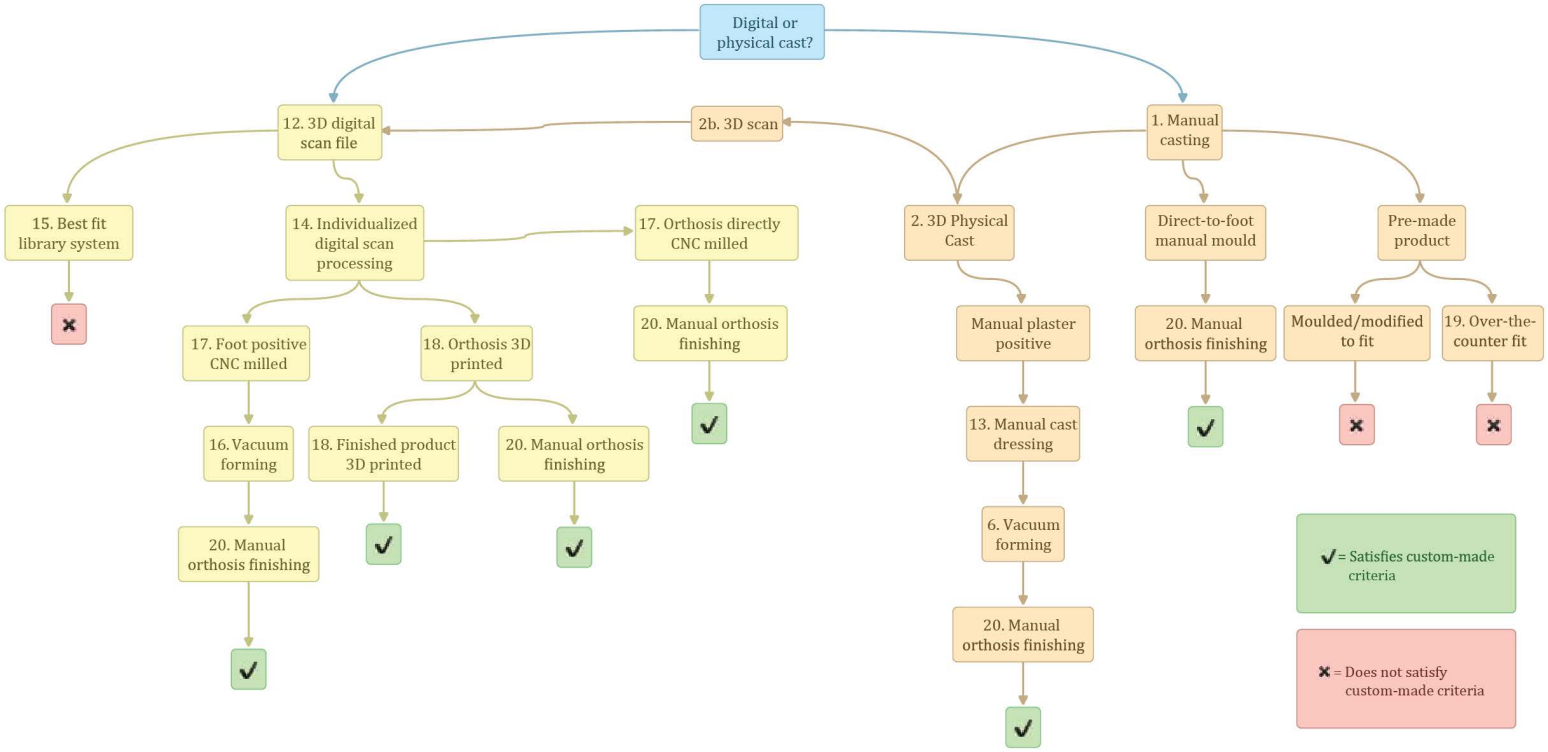
Milling/routing (subtractive manufacturing) (17): A CNC (computer numeric controlled) machine uses a router to carve a positive foot cast used for vacuum moulding or carve an orthosis directly from a variety of materials. Alternatively, a 3D physical cast may be scanned in order to create a digital copy of the cast (2b).

3D printing (additive manufacturing) (18): Most methods of 3D printing can be used in orthosis manufacturing. Fused deposition modelling (FDM) and Polyjet printers layer small jets of plastic through a nozzle to build an orthosis while selective laser sintering (SLS) uses lasers to cure or sinter a powdered material into the shape of an orthosis.

[2]*Library in this case refers to "pre-made" moulds that are not custom made from the individual contours of the patient's foot. These moulds are kept as a "library" of moulds of various foot shapes and sizes and are matched up and used as approximations of the patient's foot architecture.*

Chart 2
***Reference the Pedorthic Association of Canada Orthoses Design and Manufacture document**

Custom-made Foot Orthosis
Orthoses Design and Manufacture



The Pedorthic Journey:
Orthoses Finishing and Quality Control

Shell sizing: The shell or footbed is carved to the appropriate depth and length (20). See chart on page 11.

Further additions and excavations: Alterations such as metatarsal pads, horseshoe pads, and wells for bony prominences can be performed at this stage as well as during the manufacturing processes described above.

Posting: Thermoplastic material is heated and cemented in layers to the bottom of the shell, then carved to create the desired balance and pressure dispersion. This can be done manually or as part of the milling or 3D printing process described above.

Lining: A top cover material is cemented to the top of the shell to achieve the desired support and cushioning between the foot and the custom foot orthosis.

Quality Control: The custom foot orthosis is evaluated to ensure it fills the prescription lab order and meets the standards established by the lab.

The Pedorthic Journey:
Orthoses Fitting, Patient Education, and Follow-up

During the fitting appointment, a Canadian Certified Pedorthist ensures the proper fit and function of the foot orthosis to both the patient and the footwear. The pedorthist will make any necessary changes to the orthosis immediately in an onsite laboratory. Pedorthists will check the fit, condition, and function of the patient's footwear. In addition, they will provide the following information with respect to orthoses and footwear.

Orthoses:

- Care and expected longevity of the orthotic device;
- What the patient should and should not feel, initially and over the long term;
- Appropriate duration and necessity of wear – initially, short term, and long term; and
- Timelines and expectations for the relief of symptoms.

Footwear:

- Education on appropriate footwear fit, features, and choices; and
- Specific footwear recommendations based on the patient's needs and lifestyle.

They will also advise the patient on lower limb health and safety, injury prevention, and other considerations for treatment.

A Canadian Certified Pedorthist typically follows up with patients within 2–6 weeks to ensure that the implemented solution is working as intended. Any issues would be addressed at this time.

Our Position

Like all healthcare professionals, Canadian Certified Pedorthists believe that it is important to build long-term relationships with patients. As a patient's needs change over time, a trusted pedorthist can provide ongoing advice and support to the patient.

The Pedorthic Journey: Custom-made Orthoses

A custom-made orthosis is a highly effective shoe insert that is developed specifically for each individual patient.

The primary function of an orthosis is to redistribute forces applied to the foot in an effort to alleviate the pain and discomfort caused by a variety of conditions.

An effective custom-made orthosis can result only from a casting process that produces an accurate three-dimensional model designed to capture the contours of the patient's foot in the desired posture.

A wide variety of orthotic designs and material combinations are used, including polypropylene and graphite, to varying densities of ethyl-vinyl-acetate (EVA) foam and combinations of natural materials such as cork with soft, shock-absorbing polyurethane foams to name a few. The list of potential raw materials utilized in the fabrication of foot orthoses is extensive.

Custom-made foot orthotic devices are fabricated using different methods, materials, and technologies. They should be fabricated with consideration of the assessment findings and treatment plan for each individual patient. In designing an individual's orthotic device, the pedorthist must consider such factors as:

- foot structure and lower limb biomechanics;
- severity of deformity;
- fixed or flexible;
- presenting medical conditions;
- body weight;
- age;
- other health conditions: systemic diseases, (arthritis, diabetes, CMT, lymphedema);
- neurological or vascular issues, allergies;
- lifestyle (type of work, physical activity and intensity); and
- footwear options and choices.

Our Position

Only a trained professional using three-dimensional moulds of the foot can produce a highly effective custom-made orthosis. While over-the-counter orthoses have some value, only custom-made orthoses, created from three-dimensional models, can provide the specificity required to address an individual patient's needs.

The Pedorthic Journey: Orthopaedic Footwear

The Pedorthic Association of Canada (PAC) has recognized the importance of differentiating the types of orthopaedic footwear that are being used in treatment plans across Canada. In particular, we recognize the important balance between medical necessity and consumer demand. Regarding orthopaedic footwear, PAC shares many of the guidelines and definitions that can be referenced through the International Organization for Standardization-21064 (ISO). This section is designed to be a useful tool to encourage clarity when defining orthopaedic footwear.

PAC has identified the three most crucial points to consider when classifying footwear as orthopaedic:

- Medical need
- Practitioner qualification
- Justification

Medical need is determined by:

- Congenital deformity (e.g., clubfoot)
- Disease (e.g., diabetic ulcer)
- Trauma/post-surgical (e.g., triple arthrodesis)
- Developmental foot deformity (e.g., hallux valgus)

Practitioner qualification includes the following Canadian designations:

- Pedorthists (C. Ped (C), C. Ped MC & COFS)
- Orthotists (CO (c))
- Chiropodists (D. Ch)
- Podiatrists (DPM)

Note: Canadian Certified Pedorthists are among the few formally trained professionals who can:

- *Assess, cast, design, fit, and modify custom-made orthopaedic footwear*
- *Select, fit, and modify pre-fabricated/mass-produced (in-stock) orthopaedic footwear*

Justification refers to the clinician being responsible for providing an informed opinion as to why orthopaedic footwear is appropriate for use in a patient's treatment plan. PAC has created a checklist to help streamline orthopaedic footwear claims adjudication (see Appendix A: Orthopaedic Footwear Submission Checklist, page 23).

PAC defines "orthopaedic footwear" as footwear containing features that are specifically selected by a qualified footcare professional and that are used to "correct" or manage a medical condition. Orthopaedic footwear is used in treatment plans that require unique footwear management strategies that cannot be addressed by traditional footwear retailers.

There are two classifications of orthopaedic footwear:

- Pre-fabricated or mass-produced (in-stock)
- Custom-made

Note: Adding a custom-made orthosis does not re-classify the footwear as "orthopaedic". Custom-made orthoses are a separate matter and should be clearly itemized when billing.

Pre-fabricated/mass-produced (in-stock) orthopaedic footwear is not made for an individual patient, however it incorporates features that are applicable to specific medical needs. Pre-fabricated orthopaedic footwear is available in a range of lengths, widths, styles, and materials, but is not typically purchased at mainstream footwear stores or online. When pre-fabricated/mass-produced (in-stock) orthopaedic footwear is used, a qualified provider should be specific about how the selection of style and brand addresses their patient's individual medical need.

Considerations when defining pre-fabricated footwear as orthopaedic (not all features are required):

1. Full instep adjustable closure. (e.g., buckles, laces, Velcro)
2. Torsional stability (e.g., stiff shank)
3. Heel counter, which provides stability or decreased pressure on the heel
4. Upper, size, shape, and materials to accommodate and protect the feet. May include features such as:
   a. Soft, smooth, and protective interior lining
   b. Stretch and/or heat mouldable upper materials to accommodate deformity
   c. Extended openings
5. Outsole requirements:
   a. Size and shape match or exceed the width of the upper
   b. Material may provide greater stability, traction, or reduced friction
   c. Conducive to permanent modification(s)
6. Last shape matches the shape of the foot and supports treatment plan
7. Rearfoot and forefoot rocker soles and/or toe spring to promote a natural gait cycle
8. Footwear must be provided by a qualified professional
9. Footwear selection must be justified as forming an integral part of treatment with supporting documentation

Note: Permanent footwear modifications may be added to pre-fabricated footwear as part of the treatment plan and still fulfill the orthopaedic definition. For details, see our full document about modifications (www.pedorthic.ca/footwear-modification-guide).

Recommendation: When considering pre-fabricated orthopaedic footwear claims, we suggest that insurers require: copies of biomechanical assessments; footwear make, model, and size; and description of how footwear features address a patient's need (see Appendix A: Orthopaedic Footwear Submission Checklist).

Custom-made orthopaedic footwear is typically used for the most serious and complex cases where the client's foot shape or condition cannot be accommodated by existing **pre-fabricated/mass-produced (in-stock) orthopaedic footwear**. Providing such footwear is a highly technical endeavour that requires a 3D cast of the patient's foot. From this cast, a precise and unique "last" is then produced which serves as the foundation in which patterns are cut and assembled from raw materials as designed by the practitioner to address the patient's individual need. Custom-made orthopaedic footwear may cost, on average, approximately $1,200 – $2,700 per pair of shoes, while custom-made boots may range from $3,000 to $3,500 per pair. Custom-made sandals would be in the range of $600 – $1,000 and could possibly exceed this amount in more complex cases. Custom-made orthopaedic footwear is used to:

- Accommodate foot deformity(ies)
- Accommodate extreme foot shape and size
- Compensate for severe limb discrepancy
- Compensate for foot biomechanical deficiencies
- Accommodate vulnerable (at risk) feet

Recommendation: When considering custom-made orthopaedic footwear claims, we suggest that insurers require: copies of biomechanical assessments; photos of the patient's feet; design specifications; and information about the manufacturing process.

Summary

PAC has identified that the most crucial three points to consider when determining if footwear can be defined as "orthopaedic" are:

- Medical need
- Practitioner qualification
- Justification

The intention of this section is to provide the basis for consideration of footwear as orthopaedic, while also expanding the term's definition beyond features alone. Medical conditions can be highly variable and so, too, are their solutions. Due to this fact, defining orthopaedic footwear by one specific list of features is inadequate. Furthermore, as the footwear industry changes to address consumer needs and demands, we can expect that these changes will continue to create confusion when trying to identify footwear as "orthopaedic" by features alone. Styles, brands, makes, and models, will always come and go, but what will never change are medical conditions requiring solutions for treatment.

As demonstrated in the past, PAC will continue to lead the foot orthosis and footwear industry by constantly evolving to meet industry standards and ensuring our guidelines continue to be relevant to maximize patient protection.

The Pedorthic Journey: Over-the-counter (OTC) Products

A note on language: *The terms "over-the-counter" (OTC) and "off-the-shelf" (OTS) are used interchangeably to refer to products that are widely available on the market, to any customer, with or without the guidance or advice of a healthcare professional.*

An over-the-counter (OTC) product is typically mass-produced, available without prescription, and can be used independently by an individual with or without professional advice.

There are times when an OTC device is utilized by Canadian Certified Pedorthists, including:

Urgency: an acute medical condition – a diabetic ulcer, for example – might require immediate relief through the offloading of pressure. An OTC product might bring relief while a custom-made orthosis is being fabricated.

Temporary need: short-term use for growing children or pregnant women with less severe foot or lower limb issues.

Minor conditions: small abnormalities. More serious or chronic abnormalities, however, require custom-made products.

Minimal activity: for a patient who is not on his/her feet very much, or is bed- or wheelchair-bound and rises only occasionally to transfer from bed to chair or to washroom.

Cost factors: as an alternative for patients who are unable to afford a custom-made product.

As a first step: as a trial to determine how a patient might respond to custom-made products.

Pedorthists are required to clarify on billing statements whether a device was OTC or custom-made. If a pedorthist alters an OTC device, it can be described as a "modified" product, not a "custom-made" product.

Our Position

While there are times when an OTC product might provide a measure of relief for a patient with foot pain, it does not provide the support, control, or specificity of a custom-made product. In fact, pedorthists will often see patients who have already tried OTC products and have found no relief. Therefore, it is essential that the clinician's judgment be respected in addressing the patient's pedorthic needs.

Other points:

- OTC products cannot provide accurate biomechanical advantages to patients with severe misalignment.
- OTC products cannot be expected to be absolutely suitable for any given patient.
- The value of heat-mouldable OTC products is enhanced when moulded by a Canadian Certified Pedorthist.
- OTC products have a shorter lifespan than custom-made devices, and must be replaced frequently if used for a long-term or chronic condition.
- The material selection and properties of OTC devices, as well as the limited capacity to modify them, restricts a clinician's control over the product and can therefore affect patient outcomes.

Understanding Foot Conditions:
PAC's Clinical Practice Guidelines

To consider a recommendation for orthopaedic products, a Canadian Certified Pedorthist must consider medical need. This is determined by: (a) the medical condition or diagnosis; and (b) the structural abnormality or irregularity present.

A medical condition or diagnosis involves identifying a disease or disorder as the cause of a person's symptoms. Orthopaedic medical conditions are the result of three main causes:

- Congenital deformity;
- Disease process; or
- Injury/trauma/wound.

Identifying the structural abnormality or irregularity contributing to the dysfunction is also imperative when determining the medical need for an orthopaedic product. These orthopaedic abnormalities can be divided into three main categories:

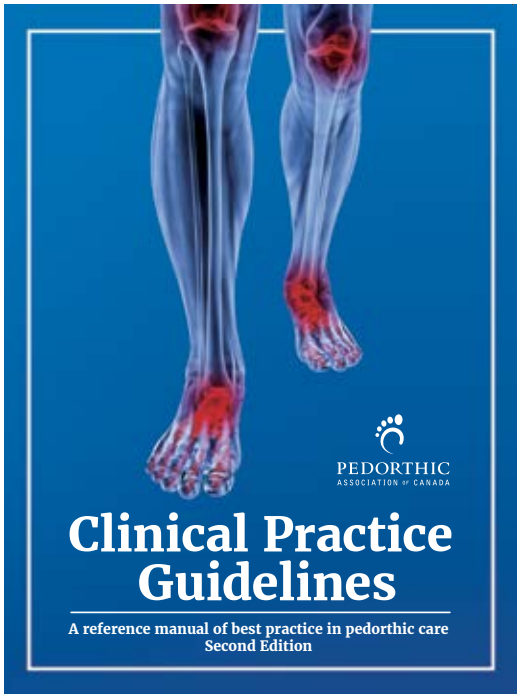
- Foot deformity;
- Foot, lower limb, and pelvis misalignment and dysfunction; and
- Neurological and vascular deficiencies.

These lists encompass a vast array of back, pelvis, hip, lower limb, and foot conditions.

In 2012, the Pedorthic Association of Canada released its first ever Clinical Practice Guidelines to identify evidence-based best practice and recent literature on a broad range of foot and lower limb issues. A team of over 100 Canadian Certified Pedorthists and other foot experts worked together to write and review guidelines for over 60 foot and lower limb conditions that pedorthists see in the course of their work.

While highly technical in nature, it is a very useful tool for understanding the range of work performed by Canadian Certified Pedorthists. With its extensive body of citations, the publication also demonstrates the extensive research and study that support pedorthic treatment.

In April 2018, PAC released the second edition of its Clinical Practice Guidelines. The new edition features updates, revisions, and seven new chapters.



Controlling Foot Care Benefit Costs in Canada

The Pedorthic Association of Canada values its relationship with insurers, and shares their frustration with respect to unethical and fraudulent practices within the industry. In addition to increasing costs, there are medical risks associated with incompetent, unqualified, and unaccountable providers dispensing orthopaedic medical products simply for financial gain.

PAC will continue to work closely with the insurance industry to assist insurers in making informed decisions when establishing policy and criteria relating to orthoses, footwear, modifications, and related appliances. PAC will continue to help the insurance industry to expose unethical and fraudulent behaviour.

Limiting Provision to Qualified Foot Care Professionals

PAC strongly feels that provision of orthopaedic products should be limited to those who:

1. are thoroughly educated in postural analysis, movement patterns, and musculoskeletal examination with a focus on the assessment of the lower limb anatomy, muscle and joint function, the interaction of the foot and lower limb with the rest of the body, as well as diseases and disorders that affect the foot;
2. are thoroughly educated in the fabrication of custom-made foot orthoses, footwear modification, custom-made footwear, and the provision of orthopaedic footwear;
3. have a professional designation from a Canadian certifying body (i.e., College) demonstrating that they have completed extensive competencies and passed a certification exam testing the competencies in the first two provisions;
4. have a Canadian governing body (i.e., College) that has Standards of Practice and a Code of Ethics written specifically to govern their professional practice in the competencies outlined in the first two provisions; and
5. have a professional association whose mandate is to develop and promote the study, practice, knowledge, and education in the competencies outlined in the first two provisions.

Limiting access to those professions that satisfy the five provisions listed above would not limit accessibility to plan members, but would direct them to qualified, accountable professionals.

Advances in Technology

As technology advances it becomes even more important to limit provision to qualified professionals. New technologies such as laser/optical scanners and 3D printing continue to change the way products are fabricated. It is important to understand that these technologies are simply tools utilized to design and fabricate these products but they play no role in the clinical assessment, biomechanical examination, and gait analysis that must be performed and interpreted by the qualified provider. An unqualified provider does not have the education, knowledge, or training to understand or differentiate among the various technologies, or recognize whether the orthopaedic product produced by them is appropriate.

Direct to Public Sales

With the advancement of technology and 3D printing specifically, fabrication companies are going directly to the consumer and bypassing the experienced healthcare provider. This raises a number of significant concerns such as:

- Who provides the clinical impression or medical diagnosis?
- Who performs the clinical assessment, biomechanical examination, and gait analysis to determine need?
- Who recognizes conditions that might be more sinister and require further investigation or other treatment?
- Who identifies, advises, and ensures appropriate treatment and compensations for joint, soft tissue, muscular, or neurological deficiencies or anomalies?
- Who ensures ideal casting posture?
- Who determines and provides the design, material, necessary components of the device (the orthosis prescription)?
- Who ensures the quality of the device?
- Who determines the appropriateness of the device?
- What happens if the device is uncomfortable, ineffective, or even detrimental?
- Who provides the footwear advice that is imperative to facilitate orthosis function?
- Who determines when the device needs modification or replacement?

Furthermore, advances in technology have enabled unqualified, unethical, and fraudulent providers to mislead plan members. Technology is impressive, but also confusing and overwhelming at times. Unqualified, unethical, and fraudulent providers can use technology to impress the public, enticing them into products and purchases that are unnecessary or even harmful. As technology plays an increasing role in the provision of these orthopaedic products, the importance of limiting provision to qualified providers becomes much more pronounced.

Limiting providers:

- offers clarity and helps to eliminate the current confusion by plan members as to who is qualified;
- prevents those providers who are unqualified and unethical from preying on unwitting plan members;
- raises the level of accountability of the qualified providers who risk losing their licence to practice and provide these orthopaedic products if they do not adhere to the Standards of Practice and Code of Ethics outlined by their Colleges; and
- enables the insurance industry to more effectively police, identify, and censure unethical or fraudulent providers within qualified professions.

Our Position

Limiting provision to qualified providers who share a common understanding would take us a step closer to standardizing the information provided to insurers to validate claims for orthopaedic products. This will be imperative as automation increases and data mining software is used to analyze claims in the future.

Glossary: Pedorthic Terminology

This glossary has been prepared by the Pedorthic Association of Canada for extended health benefits providers and third-party agencies. This glossary provides a list of key terms and definitions commonly used in pedorthic practice. Questions regarding specific products and services offered by a Canadian Certified Pedorthist – including items not listed here – should be discussed directly with the pedorthist.

Basic Terminology

Term	Definition
Cast	A three-dimensional (volumetric) model designed to capture the specific contours of the plantar aspect of the foot. Acceptable casting techniques are foam box casting, plaster slipper casting, a casting sock, wax slipper casting, contact digitizing, and optical/laser scanning. A two-dimensional footprint from a pedograph or pressure-sensitive mat does not qualify as a cast.
Custom-made	The term is reserved to define a product fabricated from a three-dimensional model of the foot which captures bony alignment and shape, and is manufactured from raw materials. A device must be fabricated from a "cast" and footwear must be fabricated from a "last" unique to the patient to qualify as custom-made.
Direct-moulded (non-casted)	Refers to a device moulded directly to the foot from raw materials that are warmed until soft. This device can be further modified and used to provide cushioning, deliver pressure relief, redistribute load, and accommodate deformity (a self-moulded product is not considered direct-moulded).
Gait analysis	The observation of the entire body with a focus on lower extremity to determine deviations in alignment, movement patterns, and symmetry during walking. This may be done visually or through video recording.
Last	A three-dimensional (volumetric) model designed to capture the specific contours of the entire foot. Acceptable techniques are plaster casting, casting sock, and optical/laser scanning. A two-dimensional footprint, foam cast, slipper cast, or contact digitizing are not acceptable techniques.
Modified	A mass-produced, pre-fabricated/over-the-counter device that has been altered by the addition or removal of material in order to modify movement or accommodate pain or dysfunction.
Pedorthic assessment	The assessment of lower limb bony alignment, posture, movement patterns, general function of the foot, and the interaction of the foot with the rest of the body. Typically a pedorthic assessment includes a history taking, postural analysis, musculoskeletal examination, functional testing, gait analysis, and footwear consultation.
Pre-fabricated OTC (over-the-counter) or stock	Refers to mass-produced devices and footwear that are not unique to the patient.
Self-moulded	Refers to a mass-produced, pre-fabricated/over-the-counter device that can be heated and moulded directly to the foot.

Products Provided

Term	Definition
Custom foot orthoses (orthotics)	An internal foot appliance that is manufactured from a three-dimensional image of the foot, and made from raw materials. A custom foot orthosis can accommodate bony deformities and/or modify the movement pattern of the foot and lower limb.
Custom-made footwear	Footwear that is manufactured from a three-dimensional mould of the foot and ankle, and made of raw materials. Custom-made footwear is specifically designed for each individual. It is usually needed when stock footwear will not fit due to deformity, or will not suit the patient due to significant dysfunction.
Custom-made toe splint	A device manufactured from a raw material (typically a silicon-like material) designed to re-align, separate, or support a deformed or deviated toe or toes.
Orthopaedic footwear	See expanded definition on page 14 of this guide.

Specialty Footwear/Braces/Splints

Term	Definition
Arch brace	Off-the-shelf device designed to support the medial longitudinal arch or metatarsal of the foot. Often used to replace taping or strapping. It can be useful for patients who do not need custom-made devices, or who are unable to wear footwear for specific activities.
Forefoot relief shoe	Single footwear device that decreases or eliminates external pressure to the plantar surface of the forefoot. Useful as a post-operative choice following forefoot surgery or as a device to protect an ulcerated area of the forefoot.
Overboot	Footwear designed to cover shoes, boots, and sandals to protect them from the elements; may also include insulating properties. An overboot allows the patient to continue their use of specific footwear and orthotic devices during inclement weather.
Plantar fasciitis (dorsiflexion) night splint	Off-the-shelf brace, fit for the patient and designed to maintain the ankle and forefoot in a dorsiflexed position during sleep. It is useful in the treatment of plantar fasciitis, Achilles tendinitis, and a number of other conditions involving the range of motion of the ankle. It can also be custom-made as per prescription.
Post-op shoe(s)	Footwear designed to accommodate swelling, dressings, and possible hardware present following an operation. Typically sold individually, post-op shoes may be used as a pair following bilateral surgery. May also be used to help establish equal heel heights when regular footwear cannot be worn.
Rearfoot relief shoe	Single footwear device that decreases or eliminates external pressure to the plantar surface of the rearfoot. Useful as a post-operative choice following rearfoot surgery or as a device to protect an ulcerated area of the rearfoot.
Rocker-soled walking brace	A walking boot designed to treat ankle and foot disorders resulting from a systemic disease or injury, as well as after surgery.
Toe alignment splint	Off-the-shelf device designed to re-align the great and lesser toes. Useful in the treatment of flexible deformities of the toes such as hammer toes, mallet toes, claw toes, bunions, and over-crossing toes.
Toe splints/pads/ cushions	Off-the-shelf devices designed to cushion, align, or accommodate bony deformities. These items are often used to stave off surgical intervention.

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Toe splints/pads/ cushions	Off-the-shelf devices designed to cushion, align, or accommodate bony deformities. These items are often used to stave off surgical intervention.

Stockings, Hosiery, and Specialty Socks

Term	Definition
Gel socks	Hosiery containing a layer of silicon-like material on the bottom. Often prescribed and used by individuals with diabetes, various forms of arthritis, and fat pad degeneration.
Medical compression stockings	The basic treatment for chronic venous insufficiency and lymphedema. Treatment of venous problems depends on the severity of the condition. The greater the severity, the higher the prescribed compression. Compression is graduated, strongest at the ankle with decreasing compression up the leg. This design compresses dilated veins to help move blood up the legs and back to the heart. If swelling of the foot and lower leg is not controlled, the fit of a shoe is compromised and could lead to additional complications.
Seamless socks	Hosiery that contains no seams exposed to the skin. Often prescribed and used by individuals with diabetes, various forms of arthritis, and dermatological conditions.

Appendix A: Orthopaedic Footwear Submission Checklist

Revised May 2018

Employee/Member Name: _____

Patient Name: _____

Policy/Plan Number: _____

Certificate/ID Number: _____

Patient DOB: _____

Information must be clear, concise, and legible. Proper medical terminology and anatomical terms must be included. If acronyms are used, there must be a legend explaining the terminology.

Clinical assessment findings

1. Diagnosis/clinical impression that necessitates orthopaedic footwear using appropriate anatomical and medical terminology

- Congenital deformity (e.g., clubfoot):_____

  _____

- Disease process (e.g., Charcot): _____

  _____

- Injury/trauma (e.g., stroke): _____

  _____

- Foot deformity: _____

2. Relevant clinical assessment/biomechanical examination/ gait analysis findings that necessitate footwear:

   _____

   _____

3. Date of assessment: _____

   Date of dispensing/fitting: _____

Pre-fabricated/mass-produced orthopaedic footwear

1. Make and model of footwear: _____

   _____

   a. Size and width: _____

2. If modifications performed, please list: _____

   _____

Custom-made orthopaedic footwear

1. Outline the manufacturing process: _____

   _____

   a. Foot capture/casting/scanning technique. If digital, include the brand name and model of the scanner:

   _____

   _____

   b. Materials used: _____

   _____

   c. Specific features to accommodate foot deformity: ____

   _____

The following must also be included with your submission:

i) Completed claim form

ii) Referral from a qualified prescriber

iii) Itemized paid receipt (including payment date and type)

iv) Copy of the lab/manufacturing facility packing slip or invoice including name, address, and phone number (copy of lab order in cases where the dispenser is the manufacturer)

v) Two sets of photos: (1) of patient's feet; and (2) of custom-made footwear dispensed **this is for custom-made footwear claims ONLY**

Provider information

Clinic name: _____

Address: _____

Phone: _____

Professional qualifications: _____

College registration number: _____ Date: _____

Canadian Certified Pedorthist
Name: _____

Signature: _____

For more information, contact the Pedorthic Association of Canada at 1-888-268-4404 or info@pedorthic.ca.

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