KAISER PERMANENTE® Mid-Atlantic States	**Lower Extremity and Foot Orthoses and Soft Goods** **Medical Coverage Policy**

2023 New Policy

UTILIZATION * ALERT*

- Prior to use of this MCP (Medical Coverage Policy) for evaluation of medical necessity and entering an orthotic referral, benefit coverage MUST be verified from the member's Evidence of Coverage (EOC) or other appropriate benefit documents to determine benefit availability and the terms, conditions, and limitations of coverage.
- Orthotic coverage varies widely for Commercial members due to state mandates and durable medical equipment DME) coverage allowances. Not all Commercial plans include orthotic coverage. Please review the member's plan Evidence of Coverage (EOC) for coverage prior to orthotic referral.
- If, after searching the Medicare Coverage Database, no NCD/LCD/LCA is found, please use this KP-MAS (Kaiser Permanente Mid Atlantic States) Medical Coverage Policy for coverage guidelines for Medicare members.
- As a benefit enhancement for Senior Advantage members, therapeutic shoes are covered for peripheral neuropathy & diabetic foot disease.
- Virginia Medicaid members have a benefit for therapeutic diabetic shoes when medical necessity criteria are met.
- For Maryland Medicaid and VA Medicaid members, please refer to the appropriate government publications.
- This MCP will replace the current MCP for Foot and Lower Extremity Orthotics for Adults Medical Coverage Policy which will be retired.

I. Procedure: Orthoses: Lower Extremity and Foot for Adult, Soft Goods

II. Scope

A. The policy is limited to Lower Limb Orthosis for Adults aged 18 and over.
B. The policy does not address Lower Limb Orthosis for Pediatrics, Mechanical Stretching Devices, Upper Limb Orthosis, Spinal Orthosis nor Cranial Orthosis.
C. Related policies:
   - ❖ Mechanical Stretching Devices Medical Coverage Policy
   - ❖ Upper Limb Orthosis Medical Coverage Policy; and
   - ❖ Spinal Orthosis Medical Coverage Policy

III. Knee-Ankle-Foot Orthotics, Knee Orthotics, Ankle-Foot Orthotics, Adult Foot Orthotics

Orthotics are appliances or apparatus that protect, restore, or improve the function of movable parts of the body through support and alignment to prevent or correct deformities.

The three primary categories of lower extremity orthotics are the following:

- Joint orthotics encompasses a joint proximal or distal to the injured, misaligned, or diseased area.
- Foot orthotics, which are primarily shoe inserts; and
- Therapeutic shoes which have integrated orthotic functions, and may include inserts

A. Joint Orthotics

Joint orthotics are appliances designed for the joint(s), proximal or distal to the injured, misaligned, or diseased area. Joint orthotic device is indicated when improvement in function is expected, and benefit coverage is available per member's benefit document.

Prefabricated devices (ready to use, custom fitted, or modified for a specific member) should always be considered prior to ordering a custom-made orthosis unless there is a documented failure, contraindication or intolerance to the prefabricated device. Coverage includes preparation, fitting, and basic additions such as bars and joints.

1. Ankle Orthotic

Ankle orthotic is a molded-to-patient or custom-fabricated. It is medically necessary if the patient could not be fit with a prefabricated ankle orthotic due to **any** of the following:

a. Ankle fractures; or
b. Ankle sprains; or
c. Any other ankle injuries requiring immobilization and/or stabilization.

2. Dynamic Ankle Foot Orthotic (AFO)

Dynamic AFO is clinically indicated during ambulation for ambulatory patients with weakness or deformity of the foot and ankle, requiring stabilization and expected to improve the function of the affected area.

a. **Prefabricated dynamic AFO** is medically necessary when **one** of the following criteria is met:
   i. The condition is expected to be permanent or of longstanding duration (more than 6 months), **or**
   ii. There is a need to control the knee, ankle, or foot in more than one plane, **or**
   iii. The member has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model/cast/positive image to prevent tissue injury, **or**
   iv. The member has a healing fracture, which lacks normal anatomical integrity or

anthropometric proportions.

b. **Custom molded-to-patient dynamic AFO** for ambulatory member is medically necessary when **one** of the criteria cited in prefabricated dynamic AFO clinical indication is met in addition to **any** of the following:
   - **i.** The member cannot be fitted with a prefabricated (off-the-shelf) AFO **or**
   - ii. The member has a documented neurological, circulatory, or orthopedic status that necessitates custom fabrication to prevent tissue injury.

3. **Static Ankle-Foot Orthotic (AFO)**

Static AFO is an orthotic device, not to be used during ambulation and indicated for **any** of the following:

a. Plantar fasciitis, associated with **all** of the following:
   - **i.** Significant pain that interferes with activities of daily living; **and**
   - ii. There is impaired gait, balance or mobility because of the condition; **and**
   - iii. Unresponsive to medical treatment (e.g., stretching, strengthening of calf muscles, taping, strapping, non-steroidal anti-inflammatory medications, reduced activity and physical therapy);

b. Plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least 10 degrees (such as a non-fixed contracture); **and**
   - i. There is reasonable expectation of the orthotic to correct the contracture; **and**
   - ii. Contracture is interfering or expected to interfere significantly with the member's functional abilities; **and**
   - iii. Orthotic is used as a component of a therapy program that includes active stretching of the involved muscles and/or tendons.

4. **Knee-Ankle-Foot Orthotic (KAFO)** or ankle contracture splints or foot drop splints

a. **Prefabricated KAFO** is clinically indicated when **one** of the following criteria is met:
   - i. The condition is expected to be permanent or of long-standing duration (> 6 months); **or**
   - ii. There is a need to control movement about the knee, ankle, or foot in more than one plane; **or**
   - iii. The member has a healing fracture that lacks normal anatomical integrity or anthropometric proportions.

b. **Custom molded-to-patient KAFO** for an ambulatory member is indicated when **one** of the prefabricated KAFO clinical indication is met, plus any one of the following:

i. The member cannot be fitted with a prefabricated (off-the-shelf) KAFO **or**
ii. Member has a documented neurological, circulatory, or orthopedic status that necessitates custom fabrication to prevent tissue injury.

5. **Knee Orthotics (KO)**
   a. Prefabricated KO is clinically indicated when **one** of the following criteria is met:
      i. The condition is expected to be permanent or of longstanding duration (> 6 months)**; or**
      ii. There is a need to control movement around the knee in more than one plane; **or**
      iii. The member has a healing fracture or surgery that lacks normal anatomic integrity.

   b. **Custom molded-to-patient KO** for an ambulatory member is indicated when **one** of the prefabricated KO criteria is met in addition to **any** of the following:
      i. The member cannot be fitted with a prefabricated knee orthotic **or**
      ii. The member has a documented neurological, circulatory, or orthopedic status that necessitates custom fabrication to prevent tissue injury.

6. **Hinged Knee Brace**
   Hinged knee brace is clinically indicated for **any** of the following:
   a. For the acute management of an acute knee fracture or an acute knee ligament injury (limited to Orthopedics/PMR**); or**
   b. For knee disability when the condition is chronic and permanent, and the brace is required to perform activities of daily living. Not covered for recreational use. (Request limited to Orthopedics/PMR).

B. Foot Orthotics (shoe inserts)

Custom fitted or custom fabricated foot orthotic for adults, arch supports, heel pads and heel cups, including repair and/or replacement of foot orthotic device is medically necessary and covered when **both** of the following criteria are met:

1. The orthotic is required for one of the following:
   a. The orthotic is applied immediately following surgery and/or is required as part of the post-operative care; **or**
   b. The foot orthotic is an integral part of a leg brace or therapeutic shoe as cited in section III A, C and D.
2. The member has a base or supplemental rider coverage for orthotics.

C. Foot Orthotics Integral to Ankle, Leg or Knee Brace

Foot orthotics are covered for members with orthotic plan coverage.
A **foot orthotic integral to a brace** is medically necessary when there is documentation by the ordering provider of the medical need for this device:

1. **Medical management requirements** are met for foot orthotics integral to a brace if **any** of the following are documented:
   - **a.** For acquired conditions, conservative medical management (non-steroidal anti-inflammatory medications, cold or heat therapy, active stretching, reduced activity, and physical therapy) has failed; **or**
   - **b.** The congenital or acquired condition is associated with significant pain that interferes with activities of daily living and there is impaired gait, balance, or mobility because of the condition; **or**
   - c. There is a reasonable expectation that the condition will improve, or function will be maintained with the use of the orthotic device.

2. Covered conditions for Foot Orthotics integral to a brace:
   - a. Calcaneal apophysitis or calcaneal spur;
   - b. Clubfoot;
   - c. Equinovalgus or equinovarus;
   - d. Limb length discrepancy;
   - e. Neurologic or neuromuscular conditions (e.g., cerebral palsy, hemiplegia, spina bifida) producing spasticity;
   - f. Neuroma;
   - g. Plantar fasciitis following failure of conservative medical management (e.g., stretching, strengthening of calf muscles, taping, strapping, non-steroidal anti-inflammatory medications, reduced activity, and physical therapy);
   - h. Posterior tibial insufficiency or dysfunction;
   - i. Sever's disease;
   - j. Status post foot surgery for continued correction (e.g., surgically treated fractures);
   - k. Symptomatic intractable plantar keratosis; **or**
   - l. Tibialis posterior tendonitis and other tendinitis conditions unresponsive to medical management.

D. Therapeutic Shoes

1. Therapeutic shoes, with or without inserts, are covered to support or protect the feet of members with impaired peripheral sensation or altered peripheral circulation. Coverage requirements vary by state mandate. Consult the member's Evidence of Coverage (EOC) for limitations and

requirements.
2. In general, therapeutic shoes are only replaced every 12 months for the following indication:
   a. Altered peripheral circulation such as diabetic foot disease; and
   b. Impaired peripheral sensation (such as peripheral neuropathy)
3. Shoes which replace a whole or partially amputated foot are categorized as "prosthetics" and are only included within this policy for clarification.
4. As with orthotics, external prosthetic coverage is excluded from some commercial plans. Please consult the member's EOC.
5. Prosthetic feet, whole or partial, used to compensate for a missing portion of the foot (e.g., amputation) are not limited to only diabetic conditions (as are therapeutic shoes in some jurisdictions).
6. Prosthetic feet, whole or partial, are considered medically necessary for members with any level of ambulation.
7. Coverage is provided for a pair of diabetic or therapeutic shoes even if only 1 foot meets requirements.

IV. Soft Goods

Medical soft goods are non-rigid items, constructed of non-durable materials to help support, stabilize and/or aid in the recovery of a part of the body from irritation, injury or after surgery.

Soft goods are considered DME benefit-specific exclusion and not eligible for coverage.
Please see section VIII for details on soft goods.

V. Documentation for Orthosis Referral

The following documentation are **all** required when requesting an orthosis:

A. Order/prescription from a qualified physician/practitioner or treating provider including the purpose of the orthosis**; and**

B. Documentation addressing **all** of the following:
   1. Member's medical condition requiring the need and use of an orthotic device; **and**
   2. Member's functional impairment in relation to completion of activities of daily living without the prescribed device; **and**
   3. Other treatment or devices that were tried and found to be ineffective, inadequate, or contraindicated to meet the member's functional needs.

VI. Coverage Limitation, Adjustment, Repair and Replacement

A. Coverage Limitation

1. KP does not cover orthotics for adults which are considered experimental, investigational or unproven, including the following devices (list is not all-inclusive):
   a. Custom-fabricated foot orthotics for the treatment of hallux valgus or hallux rigidus foot deformity;
   b. Magnetic, or copper insoles or orthotics with magnetic or copper foil; and
   c. Stance control orthotics
2. Coverage is limited to one orthotic per foot. Separate orthotics for multiple shoes is considered convenience items.
3. Foot and lower extremity orthosis are limited to adults;

B. Adjustment and Repair

1. Adjustment or repair is covered only when anatomical change or reasonable wear and tear renders the item non-functional, and the repair will make the equipment usable;
2. Request for repair of the device is not necessary when orthosis' maintenance and repair are still covered under the manufacturer's warranty; and
3. Repair of a back-up orthotic device of any kind is not covered.

C. Replacement

Replacement of an orthotic device is considered medically necessary based on **any** of the following criteria:

1. A change in the patient's physical condition or anatomical change (such as growth adjustments);
2. Reasonable wear and tear render the item non-functional and unrepairable);
   Note: KP (Kaiser Permanente) does not cover repair or replacement if the orthotic becomes unusable or non-functioning because of member misuse, abuse, or neglect.
3. At the end of the device's reasonable useful lifetime expectancy as established by the manufacturer)
   a. The usual replacement cycle or device normal life span are the following:
      i. Greater than one year for semi-rigid; and
      ii. Greater than two years for rigid orthotics;
   b. Orthotic devices that are "worn out" are not eligible for replacement prior to their reasonable useful lifetime expectancy established by the manufacturer.
   c. Replacement of an orthosis prior to the device/appliance normal life span is covered only if the item was irreparably damaged but not due to misuse, intentional or non-intentional;
4. Replacement due to loss or theft will be considered on a case-by-case basis.
   A police report is required, if the orthotic device is determined to be eligible for replacement due to theft; and
5. The cost of repair to the orthosis exceeds the purchase price).

VII. Exclusion

A. Orthoses are considered not medically necessary and not covered for **any** of the following:
   1. When the orthosis is not prescribed by a qualified physician or practitioner;
   2. When the requested item does not meet the definition of orthosis (see section VIII);
   3. When the required documentation for orthosis referral or replacement is missing;
   4. Orthotics to be used for treatment of any of the following:
      a. Edema;
      b. Uninjured body part;
      c. Prevent pressure ulcers; or
      d. Prevent injury.
   5. Foot orthotics and ankle/foot orthotics for treatment of any of the following:
      a. Back pain;
      b. Knee pain;
      c. Pronation;
      d. Corns and calluses; or
      e. Hammertoes
   6. Foot orthotics that are not integral to a brace or a therapeutic shoe, or are not a component of post-surgical care;
   7. Socks used in conjunction with orthotics;
   8. Ankle contracture and foot drop splints used solely as recumbent positioning devices for bedridden patients;
   9. Custom-made orthotic devices unless there is available clinical documentation to support that a non-custom-made orthosis is not appropriate for the patient's condition or diagnosis;
   10. A request for a second orthosis with the same or similar medical purpose as the current or existing orthosis;
   11. Orthotic device with upgraded functionality or feature(s) beyond what is clinically required for the management of patient's current medical condition;
   12. Orthosis with luxury features when there is an existing appropriate standard alternative that will meet the patient's medical need or condition;

B. The following items are not eligible for benefit coverage:
   1. Medical items that do not meet the definition of orthosis nor qualify as an orthotic device which must be rigid or semi-rigid. Non-rigid items are considered soft goods and excluded from benefit coverage (see section VIII for description of soft goods);
   2. Arch supports, shoe inserts, and other foot care products that can be purchased over the counter without a prescription;
   3. When the orthosis or components of the orthotic device is primarily intended for:

a. Orthosis with luxury features when there is an existing appropriate standard alternative that will meet the patient's medical need or condition;
b. Decorative, appearance or cosmetic;
c. Convenience, leisure, recreation, exercise equipment, or physiotherapy;
d. To improve athletic performance or for sport-related activities/participation; or
e. Primarily intended for work-related activities and not required for any other activities of daily living within the home.

VIII. Description

Off-the-shelf (OTS) orthosis are prefabricated devices, which may or may not be supplied as a kit upon delivery, requiring minimal assembly and minimal self-adjustment for fitting.

Custom prefabricated orthosis is a prefabricated device, may or may not be supplied as a kit upon delivery, require some assembly and require fitting-adjustment by a certified orthotist or an individual with specialized training in orthosis fitting.

Custom fabricated orthosis is a custom-made orthosis, fabricated from a mold through impression or measurements to specifically fit an individual patient.

Dynamic and static progressive mechanical stretching device is a form of mechanical-stretching, spring-loaded device, designed to provide a low load, prolonged stretch (LLPS) to joints that have reduced range of motion due to immobilization, contractures, fracture, dislocation, surgery, or other non-traumatic disorders.

Orthoses are externally applied, rigid or semi-rigid orthopedic appliances or apparatus, used to protect, restore, modify or improve the structural and functional characteristics of the neuromuscular and skeletal systems through support, stabilization, and alignment or to prevent or correct deformities in the affected area. Orthotic devices are designed for the purpose of:

- Supporting a weak or deformed body part or
- To restrict / limit mobility or motion of a diseased or injured part of the body; or
- To assist with the treatment of an illness or injury; or
- To improve the functioning of a malformed body part.

Non-rigid items that do not meet the definition of orthosis are considered **"soft goods"** and do not have benefit coverage.

Prefabricated Orthoses are orthoses fabricated for general size, such as small, medium, and large, and do not require adjustment by a skilled clinician. A prefabricated orthoses can be considered off the shelf.

Soft goods are non-rigid items, constructed of elastic/stretchable materials or inelastic materials and designed

to provide support, stabilization, or immobilization of an injured, painful, or irritated part of the body.
Soft goods are considered DME benefit-specific coverage exclusion. Example of soft goods include the following (the list is not exhaustive):

- Neck braces or collars – such as soft neck collar
- Shoulder immobilizers – such as shoulder slings
- Clavicle, arm, elbow, and wrist supports – such as neoprene braces for wrist, neoprene tennis elbow brace, tennis elbow bands.
- Abdominal and back supports or braces – such as abdominal binders, soft back braces with no rigid support (no stays)
- Knee, and ankle brace or supports - such as knee sleeve with patellar cut out, neoprene braces for knee and ankle, knee bands for runners.
- Elbow protectors
- Heel protectors – such as Prevalon boots, Foot Waffle
- Rib belts – such as gait belt
- Abduction pillows
- Positioners – such as foam wedges for positioning
- Other soft goods – such as:
  - Donut cushions
  - Other cushions for hemorrhoids
  - Cold therapy
  - Elastic bandages
  - Over the counter compression stockings

Upper Limb Orthoses (ULO) are prefabricated or custom-made devices/appliances, designed for the shoulder, elbow, wrist, hand and/or finger(s) using three points of pressure to achieve the therapeutic goal of functional motion while providing stability and support.

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
08/24/2023	08/24/2023

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any set of circumstances for an individual member.