KAISER PERMANENTE® Mid-Atlantic States	**Spinal Orthosis and Soft Goods** **Medical Coverage 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.
- 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.
- For Maryland Medicaid and Virginia Medicaid members, please refer to the appropriate government publications.

I. **Procedure: Spinal Orthosis**

II. **Specialties:** DME, Rehabilitation, Orthopedic, Surgery

III. Scope

A. This policy is limited to Spinal Orthosis
B. The policy does not address Cranial Orthosis, Upper Limb Orthosis, Lower Limb Orthoses nor Dynamic and Static Progressive Manual Stretching Devices.
C. Related policies:
   - ❖ Cranial Helmet Medical Coverage Policy
   - ❖ Upper Limb Orthosis Medical Coverage Policy
   - ❖ Ankle-Knee-Foot Orthosis Medical Coverage Policy
   - ❖ Dynamic and Static Progressive Manual Stretching Device Medical Coverage Policy

IV. Clinical Indication

A. Cervical Orthoses (Rigid or semi-rigid cervical collars)

Cervical orthosis is considered medically necessary to provide cervical spine stabilization and /or immobilization for **any** of the following:

1. Post surgery of the spine or surrounding soft tissues (such as surgical fusion); or

2. Following trauma or injury to the neck or surrounding soft tissues (such as cervical whiplash-type injuries or upper cervical fractures).
3. Spinal Cord Injury
4. Head Drop issues due to neurological conditions (e.g., ALS, Parkinsons Disease)
5. Severe osteoarthritic or rheumatological conditions limiting cervical stability and function
6. Hypermobility syndromes

B. Prefabricated Lumbar Orthoses (LO), Lumbo-Sacral Orthoses (LSO) or Thoraco-Lumbo-Sacral Orthoses (TLSO)

Prefabricated Spinal Orthosis (brace) is considered medically necessary when the use of orthosis is intended for **any** of the following:

1. To reduce or control pain by limiting or restricting mobility of the spine; or
2. To stabilize and/or promote healing of the injured spine and surrounding soft tissues after sustaining trauma or injury; or
3. To support weak spinal muscles; or
4. To facilitate healing following surgical procedure of the spine or surrounding soft tissues such as:
   a. Post-operative control of fractures; or
   b. Post-surgical care after spinal fusion or reconstruction; or
   Note: Use of orthosis as a pre-operative diagnostic tool prior to lumbar fusion surgery is not considered medically necessary.

C. Custom-fitted prefabricated Lumbar Orthoses (LO), Lumbo-Sacral Orthoses (LSO) or Thoraco-Lumbo-Sacral Orthoses (TLSO)

Custom-fitted prefabricated spinal orthosis is considered medically necessary when **all** of the following requirements are met:

1. Any of the condition listed in section IV-B for prefabricated orthosis; **and**
2. To treat spinal deformities including but not limited to scoliosis, kyphosis or other neuromuscular-related deformities:
   a. To prevent spinal deformities; or
   b. To correct, control, or delay the progression of spinal deformities or
   c. To maintain, stabilize or correct spinal alignment; or
   d. To control spinal motion.

D. Custom fabricated or custom molded Lumbar Orthoses (LO), Lumbo-Sacral Orthoses (LSO) or Thoraco-Lumbo-Sacral Orthoses (TLSO)

Custom-fabricated spinal orthosis is considered medically necessary when **all** of the following criteria have been met:

1. The requirements for custom-fitted orthosis listed in section IV-C have been met; **and**

2. The orthosis is prescribed for the treatment of a skeletally immature patient with spinal deformity such as scoliosis; **and**
3. The patient has a body somatotype or an underlying deformity, precluding the use of a prefabricated device.

V. Documentation

The following documentation are required when requesting an orthosis:

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

B. Documentation addressing **all** of the following information:
   1. Medical diagnosis or condition requiring the need or use of an orthotic device; and
   2. Functional impairments and functional needs

VI. Adjustment, Repair and Replacement

A. Adjustment or Repair

1. Adjustment or repair of an orthosis is covered based on their medical necessity (such as age, activity level, growth and normal wear and tear) and their reasonable lifetime expectancy as established by the manufacturer of the device.
2. Request for repair is not necessary when the orthosis' maintenance and repairs are still covered under the device warranty.
3. A back-up orthosis of any kind is not eligible for repair.

B. Replacement

Orthotic device' replacement is medically necessary based on any of the following requirements:

1. Anatomical change or change in the patient's physical condition;
2. At the end of the device's reasonable useful lifetime expectancy as established by the orthosis' manufacturer;
   Note:
   Replacement of an orthosis prior to the device/appliance normal life span is covered only if the device was irreparably damaged, but not due to misuse, either intentional or non-intentional;
3. The cost of repair to the orthosis exceeds the purchase price;
4. Orthotic devices that are "worn out" are not eligible for replacement prior to their reasonable useful lifetime expectancy as established by the manufacturer; and
5. Replacement due to loss or theft will be considered on a case-by-case basis.
   Note: A police report is required if it has been determined that the orthosis is eligible for replacement due to theft.

VII. 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 IX for further description of soft goods.

VIII. Exclusion

A. Spinal orthosis is considered not medically necessary for **any** of the following:
   1. For any other indication except those listed in section IV, including but not limited to the following conditions:
      a. When the orthosis is intended for treatment of edema;
      b. When the orthosis is to be used to treat pressure ulcers; or
      c. When the orthosis is to be used on uninjured body part or to prevent injury;
   2. Orthoses that have been determined to be experimental, investigational, or unproven as current evidence does not establish its' safety, efficacy and/or long-term outcomes (such as but not limited to thoracic-lumbo-sacral orthotics that incorporate pneumatic inflation);
   3. Orthoses that are not prescribed by a qualified physician, practitioner or treating provider;
   4. When the required documentation for orthosis referral is missing or incomplete;
   5. Request for orthotic device with upgraded functionality or feature(s) beyond what is clinically required for the management of the patient's current medical condition; or
   6. When a second orthosis is requested with the same or similar medical purpose as the current or existing orthosis.

B. A requested device or appliance is considered not eligible for benefit coverage in **any** of the following circumstances:
   1. When the item does not meet the definition of an orthosis. Items that are not sufficiently rigid to be capable of providing the necessary immobilization or support to the body part for which it is intended to be used does not meet the description of an orthotic device (see section VIII for description of orthosis, spinal orthosis, and soft goods);
   2. Non-prescription over the counter support items;
   3. When the orthosis or component(s) of an orthotic device is intended primarily for the following:
      a. Convenience and do not treat the underlying physical condition such as but not limited to the following examples:
         i. Prophylactic elastic lumbar support (e.g., tool belts, lumbar belt); or
         ii. Inflatable lumbar support pillows/cushions; or

iii. Back rest support

b. Orthosis with luxury features (such as microprocessor component) when there is an existing appropriate standard alternative that will meet the patient's medical need or condition;
c. Luxury, decorative, appearance or cosmetic;
d. Leisure, recreation, exercise equipment, or physiotherapy;
e. To improve athletic performance or sport-related activities/participation unless the orthotic device is prescribed for the treatment of the initial or acute sports-related injury; or
f. Primarily intended for work-related activities

IX. 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.

Cervical orthosis is a rigid or semi-rigid non-invasive appliance applied on the neck for cervical spine immobilization.

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.

Low-load prolonged-duration stretch/spring-loaded devices or **dynamic splinting systems** are designed to provide low-load prolonged stretch (LLPS) to joints with reduced range of motion due to immobilization, dislocation, contracture, fracture, surgery, or other non-traumatic disorders while the patient is asleep or at rest. It is indicated for the following indication:

- Treatment of joint stiffness due to immobilization or limited range of motion after fractures, dislocations, tendon and ligament repairs, joint arthroplasties, tendon releases, head trauma, spinal cord injuries, burns, arthritis, hemophilia, cerebral palsy (CP), multiple sclerosis, and other traumatic and non-traumatic disorders.
- For the prevention or treatment of motion stiffness/loss in the knee, elbow, wrist, or finger during post-operative period
- It is not used for other joints such as the hip, ankle, or foot.
- Dynamic splinting systems include, but are not limited to, such products as Advance Dynamic ROM, Dynasplint, EMPI Advance Dynamic ROM, LMB Pro-glide, Pro-glide Dynamic ROM, SaeboFlex, SaeboReach, Stat-A-Dyne, and Ultraflex.

Orthosis is an externally applied, rigid or semi-rigid orthopedic appliance or apparatus, which is used to protect, restore, modify or improve the structural and functional characteristics of the neuromuscular and skeletal system through support, stabilization, immobilization, or alignment to prevent or correct deformities in the affected area.

Orthotic devices are designed for the purpose of:

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

Elastic materials, similar to a stretchable material or other fabric support garments (such as belt, strap, sleeve, protective body sock, covering of any type, garments including maternity support garments) with or without stays or panels (unless the supportive item is a component of the brace) do not meet the definition of an orthosis which must be rigid or semi-rigid appliance or device.

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), designed to provide support, stabilization, or immobilization of an injured, painful, or irritated part of the body.

- Soft good Items are not sufficiently rigid nor semi-rigid, to be capable of providing the necessary immobilization or support to the body part for which it is designed; and
- Elastic/stretchable materials or other fabric support garments (such as belt, strap, sleeve, garment, or covering of any type) with or without stays or panels are non-covered.

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

Spinal orthoses are sufficiently rigid or semi-rigid mechanical systems that apply external pressure at specific anatomical points capable of providing the necessary immobilization, correct spinal deformities or support the body part for which it is intended to be used.

Spinal orthosis has the following characteristics:

1. These orthoses are used to immobilize the specified areas of the spine:
   a. To control gross movement of the trunk and intersegmental motion of the vertebrae in one or more planes of motion:
      i. Lateral/flexion (side bending) in the coronal/frontal plane
      ii. Anterior flexion (forward bending) or posterior extension (backward bending) in the sagittal plane;
      iii. Axial rotation (twisting) viewed in the transverse plane; and
   b. To restrict the effect of the forces within a three-point pressure system.
2. These orthoses have intimate fit and are designed to be worn under clothing; and
3. These orthoses are not specifically designed for patients who are in wheelchairs.

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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
08/28/2024	08/28/2024

*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.