KAISER PERMANENTE® Mid-Atlantic States	**Upper Extremity 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 VA Medicaid members, please refer to the appropriate government publications.

I. **Service: Upper Limb Orthosis**

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

III. Scope

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

IV. Clinical Indication

A. Shoulder, elbow, wrist and/or hand orthoses is considered medically necessary when the patient meets **any** of the following indication:
   1. Recent surgery to the upper extremity or cast removal (within 21 days of request) with a need for any of the following:
      a. To reduce pain by restricting mobility of the affected body part;
      b. To facilitate healing of the affected body part or related soft tissue;
      c. To support weak muscles and/deformity of the affected body part;
      d. To increase range of motion; or

e. To apply traction for correction or prevention of contractures
2. Sprain or strain of upper extremity;
3. Stable non-surgical fracture of the upper extremity requiring stabilization;
4. Stable fracture of the humerus, radius, ulna, carpal or metacarpal bones;
5. Acromioclavicular (joint) dislocation or fracture of clavicle;
6. Joint contractures due to burns;
7. Rheumatoid arthritis, carpal tunnel syndrome or tendonitis of the wrist or hand; or
8. Ehlers's Danlos syndrome for hypermobile joints or;
9. Neurological Conditions resulting in abnormal tone/spasticity

V. 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.

VI. Medical Documentation

The following documentation is required when requesting an upper limb orthosis:

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

B. Medical 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. Presence of any co-morbidities that may interfere with the use and function of orthosis; **and**
   4. Functional evaluation by a qualified practitioner with documentation of **all** of the following:
      a. Functional needs and functional impairments;
      b. The necessity to use an orthotic device and associated components to meet the functional needs of the patient including usability, control, and durability;
      c. The need for orthosis to perform activities of daily living (ADL), including job function if applicable; and
      d. That the use of orthosis is not intended for convenience, luxury, leisure, sports, or recreational activities.

C. The patient will be referred to qualified occupational or physical therapists for training on the proper

use of the orthosis after delivery.

VII. Coverage Limitation

A. Adjustment or Repair

Adjustment or repair of an orthosis is medically necessary if the patient meets **all** of the following:

1. Documentation that the orthosis continues to provide a medical need for the individual; **and**

2. Documentation of **any** of the following reason for adjustment or repair:
   a. Age and growth;
   b. Activity level;
   c. Change in physiologic condition;
   d. Normal wear and tear; or
   e. Current orthosis reasonable lifetime expectancy as established by the manufacturer.
      i. Confirmation that the device is no longer under manufacturer's warranty;
      ii. Request for repair is not necessary when orthosis' maintenance and repair are still covered under manufacturer's warranty; **and**
3. A back-up orthosis of any kind is not eligible for repair.

B. Replacement

Replacement of an orthotic device is considered medically necessary if the patient meets **any** of the following criteria:

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

VIII. Exclusions

A. Orthoses are considered not medically necessary and not covered for the following:
   1. When the orthosis is determined to be experimental, investigational, or unproven as current evidence does not establish its' safety, efficacy and/or long-term outcomes such as the following devices (the list is not exhaustive):
      a. Myoelectric upper extremity orthotic devices;

   b. Patient-actuated serial stretch (PASS); and
   c. Bi-directional static progressive (SP) devices for all indications
2. When the request for upper limb orthosis is for a clinical indication other than those listed in section IV including but not limited to the following exclusion:
   a. Orthosis intended to be used as a positioning device except for resting hand splint(s). They are an essential component of a UE rehab program for a neurological patient with abnormal tone/spasticity; or
   b. Orthosis to be used on an uninjured body part, does not treat any underlying physical condition or to prevent injury.
3. When the orthosis is not prescribed by a qualified physician or practitioner;
4. When the required documentation for orthosis referral is missing or incomplete;
5. When the requested item does not meet the definition nor description of an orthosis (see section VIII for description of orthosis).
6. When the request is for a custom-made orthotic device unless there is sufficient clinical documentation to support that a prefabricated or non-custom-made orthosis is not appropriate for the patient's condition or functional need;
7. A second or back-up orthosis with the same or similar medical purpose as the current or existing orthosis;
8. Orthotic device with upgraded or extensive functionality or feature(s) beyond what is clinically required for the management of the patient's current medical condition;
9. 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;
10. Spring-loaded orthotics and static progressive stretch devices when the conventional method of treating a stiff or contracted joint(s) have not been attempted; and
11. Spring-loaded orthotics longer than 3 months of use are not covered.

B. A requested item is not eligible for benefit coverage in the following circumstances:
   1. An item that does not meet the definition of orthosis nor qualify as an orthotic device, which must be a rigid medical item. Non-rigid or semi-rigid items are considered "**soft goods"** and excluded from benefit coverage (see section VIII for soft goods' description).
   2. Over the counter support items;
   3. When the orthosis or components of the orthotic device is primarily intended for:
      a. Convenience such as support pillows/cushions.
      b. Luxury, decorative, appearance or cosmetic;
      c. Leisure or recreation;
      d. Exercise or physiotherapy
      e. To enhance athletic performance or sport-related activities unless the orthotic is prescribed for the treatment of the initial or acute sports-related injury.
      f. Mainly 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.

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 splinting device is a form of manual-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 **"soft good"** items 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 and neoprene shoulder braces
- 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. The objective with the use of ULO is to attain at least one of the following functions:
- To improve function;
- To assist with motion;
- To improve alignment;
- To off load a joint or body part;
- To protect against injury;
- To stabilize a body part;
- To immobilize treatment areas during rest periods;
- To prevent or correct range of motion deficits (stiffness) or deformities;
- To allow for compensation of a motor deficit;
- To guide cutaneous healing

Some of the more common upper extremity orthoses are the following (the list is not exhaustive):
- Thumb-finger-hand orthoses
- Wrist-hand orthoses (WHOs)
- Elbow orthoses (EOs)
- Shoulder-elbow orthoses (SEO)
- Shoulder-elbow-wrist orthoses (SEWO)
- Splints and Immobilizer

References

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2. Medicare Claims Processing Manual, Ch. 20- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) §50- Payment for Replacement of Equipment; §110- General Billing Requirements - for DME, Prosthetics, Orthotic Devices, and Supplies https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf
3. Medicare Benefit Policy Manual, Ch. 16- General Exclusions from Coverage, §180- Services Related to and required as a Result of Services Which Are Not Covered Under Medicare https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf
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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
12/21/2023	12/21/2023

*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.