Enterprise Policy

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member’s policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member’s policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member’s policy, the Member’s policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) is covered exclusively for needs in the home setting. Mobility Related Activities of Daily Living (MRADLs) are exclusively within the home while Instrumental Activities of Daily Living (IADLs) can be in the home or outside of the home.

PacificSource covers medically necessary DMEPOS that is medically necessary and reasonable, can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is appropriate for use in the home.

Member should be evaluated by an independent trained clinician to determine the most appropriate DMEPO. To maintain objectivity, the trained clinician should not be associated with the DMEPO provider.

Medical necessity: means (in part) those services and supplies that are required to treatment of illness, injury, or disease that are:

- Consistent with the symptoms or diagnosis and treatment of the condition;
- Consistent with generally accepted standards of good medical practice in the subscriber’s policy’s state of issue, or expert consensus physician opinion published in peer-reviewed medical literature, or the results of clinical outcome trials published in peer-reviewed medical literature;
- As likely to produce a significant positive outcome as, and no more likely to produce a negative outcome than, any other service or supply;
- Not for the convenience of the member or provider of services or supplies;
- The least costly of the alternative services or supplied that can be safely provided.
Backup: PacificSource considers backup or duplicative DME or prosthetics not medically necessary including but not limited to the following:

- DME items specifically designed for outdoor use (manual wheelchairs designed for beach access, power mobility devices designed for rough terrain, manual wheelchairs for sports, etc.)
- Duplicate items of DME used for the same or similar medical purpose as the existing item, but not at the same time (e.g. for home, work, school or travel).
- Duplication or upgrade of a functional prostheses not used as the primary prosthetic.
- Prosthetics used for activities other than normal activities of daily living, including those utilized for sporting activities such as skiing, or swimming.
- Rental or purchase of two or more mobility devices (manual wheelchair, electric wheelchair, power operated vehicle (POV), transport chair, etc.)

Replacement: PacificSource covers a replacement DME when the member’s medical needs cannot be met by the current device. The current device is broken and cannot be repaired or the cost of the repair exceeds the cost of replacement. The device has been lost or stolen.

- EXCLUSIONS – repair or replacement of prosthesis for appearance, comfort, convenience or individual abuse, misuse, or neglect.

Repair: Suppliers must distinguish between repair and replacement. For repair, labor components are recorded in 15 minute increments. For replacement, there is no separate billing as the service is a component of the replacement item.

- EXCLUSIONS – Routine periodic servicing, such as testing, cleaning, and checking of device is not covered.

Hospital/SNF: Payment for DMEPOs provided to the member during the admission are included in the inpatient payment and are not separately reimbursable.

Description

This Health Services Policy includes coverage criteria on the following items:

1. Knee orthosis/brace
2. Lower limb prosthetic (foot, knee, ankle, hip, sockets)
3. Power wheelchair
4. Prosthetic shoe/Orthotic footwear
5. Spinal (Back) orthosis/brace
6. Upper limb prosthetic

Criteria/Exclusions

PacificSource follows CMS NCD/LCD coverage guidelines. For any item to be covered, it must be reasonable and necessary (medical necessity) for the diagnosis or treatment of an illness or injury, to improve the functioning of a malformed body member, and meet all other regulatory requirements. The purpose of the LCD is to provide information regarding “reasonable and necessary” criteria bases on Social Security Act §1862(a)(1)(A) provisions. In addition to “reasonable and necessary” criteria, other payment rules provided in the document must be met.

Noridian Healthcare Solutions, LLC, contract #19003 – DME MAC has jurisdiction over Idaho, Oregon, Montana, and Washington States (among others).
In cases where NCD/LCD is not available, MCG will be utilized.

1. Knee orthosis/brace
   a. PacificSource follows CMS Policy Article A52457 /LCD L33686 for coverage of ankle-foot, knee-ankle-foot orthosis
      i. EXCLUSIONS –
         1. Socks L2840, L2850 used in conjunction with orthoses is not covered
         2. There is no separate payment for CAD-CAM technology
   b. PacificSource follows CMS Policy Article A52465 /LCD L33318 for coverage of knee orthosis (braces)
      i. EXCLUSIONS –
         1. Knee braces for of the following indications are NOT considered medically necessary:
            a. When used primarily for improved athletic performance, sports participation, or recreational activities.
            b. To prevent injury in an otherwise uninjured body part.
         2. A9270 brace sleeves are not covered
         3. A9270 items not capable of providing immobilization or support are not covered

There is no separate payment for CAD-CAM technology

2. Lower limb prosthetic
   a. PacificSource follows CMS Policy Article A52496 /LCD L33787 for coverage of lower limb prosthesis to include feet, knees, ankles, hips, and sockets
      i. A determination of the medical necessity for certain components/additions to the prosthesis is based on functional ability.
      ii. Medical necessity for custom fitted versus off-the-shelf must be documented in sufficient detail to establish need
      iii. EXCLUSIONS – lower limb prosthetic
         1. For functional level 0 (zero)
         2. Water prostheses are considered a convenience and not medically necessary
         3. Powered lower limb prosthetics are considered experimental/investigational/unproven due to lack of evidence to support their effectiveness.
   4. The following restrictions apply to the codes listed below

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5671</td>
<td>Additional lower limb of suspension socket</td>
<td>Package includes pin(s), lanyard, or other components which are attached to the socket insert (cannot be unbundled)</td>
</tr>
<tr>
<td>L7700</td>
<td>Gasket or seal</td>
<td>Not separately reimbursable (unbundling)</td>
</tr>
<tr>
<td>L5962, L5964, L5966</td>
<td>Protective outer surface coverage</td>
<td>Not separately reimbursable when billed with L5704-L5707</td>
</tr>
<tr>
<td>L5620</td>
<td>BK Test Socket</td>
<td>Max allowable 2</td>
</tr>
<tr>
<td>L5629</td>
<td>BK, Acrylic Socket (resin)</td>
<td>Not separately reimbursable when billed with L5940 (unbundled)</td>
</tr>
<tr>
<td>L5637</td>
<td>BK, Total Contact</td>
<td>Not separately reimbursable -Is included in the payment for any molded socket (unbundling)</td>
</tr>
</tbody>
</table>
iv. EXCLUSION – Ankle-Foot/Knee-Ankle-Foot Orthoses
   1. L4396, L4397, L4398, L7394 are not covered when they are used for the sole treatment or prevention of pressure ulcers.
   2. A9283, A9285 are not covered because they do not act as a brace
   3. L2840, L2850 are not covered items

There is no separate payment for CAD-CAM technology

3. Power wheelchair
   a. PacificSource follows CMS Policy A52498 / LCD L33789 for coverage of power mobility devices.
   b. EXCLUSIONS –
      i. A custom motorized/power wheelchair base is not reasonable and necessary if the expected duration of need for the chair is less than three months (e.g., post-operative recovery).
      ii. Each Basic Equipment Package must include – (bundled package, not separately reimbursable)
         1. Lap belt
         2. Battery charger
         3. Complete set of tires and casters
         4. Leg rests
         5. Foot rests
         6. Arm rests
         7. Weight specific components
         8. Seat specific components
         9. Back rest specific components
         10. Controller and input devices
      iii. Ensure the level of service matches the level of need. DME is covered in a stepwise manner starting with the lowest level of service and moving up the continuum of care until the medical need is met.

iv. The following restrictions apply to the codes listed below

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9900</td>
<td>Universal Headrest Adaptor</td>
<td>Not separately reimbursable when billed with a Headrest (unbundled)</td>
</tr>
<tr>
<td>E2300</td>
<td>Seat elevation system</td>
<td>Not covered as does not meet definition of DME</td>
</tr>
</tbody>
</table>

4. Prosthetic shoe/orthopedic footwear
a. PacificSource follows CMS Policy Article A52481/ LCD L33641 for coverage of orthotic footwear.

b. Custom-fitted shoe insert L3000-L3031 are covered when medically necessary to treat conditions of the feet and ankles.
   i. There is no limit on the number of pairs of orthotics that can be ordered as long as all pairs are medically necessary.

c. Shoes and related modifications that are in integral part of covered leg brace are covered.

d. Shoes and related modification used for prevention of diabetic foot ulcers

e. EXCLUSIONS –
   i. Shoes that are put on over a partial foot prosthesis or other lower extremity prosthesis (L5010 – L5600).
   ii. Off-loading / supportive device A9283
   iii. All shoes and related modifications for treatment other than specified in this policy are non-covered

5. Spinal (Back) orthosis/brace

   a. PacificSource follows CMS Policy Article A52500 / LCD L33790 for coverage of TLSO and LSO braces
   i. EXCLUSIONS –
      1. spinal orthosis for the following indications are NOT considered medically necessary:
      2. When used primarily for improved athletic performance or sports participation.
      3. To prevent injury in an otherwise uninjured body part.
   ii. There is no separate payment for CAD-CAM technology

6. Upper limb prosthetic

   a. PacificSource follows MCG A-0701 for coverage of upper limb prosthetics
   i. Passive prosthetic – required manual repositioning typically with use of opposite arm
   ii. Body-powered prosthetic – uses a body harness and cable system to provide functional manipulation. The limb stump extends the cable and transmits the force of the terminal device.
   iii. Myoelectric prosthetic – uses muscle activity form the remaining limb for control of movement through electromyographic (EMG) signals.
      1. EXCLUSION – Myoelectric or hybrid systems will only be considered medically necessary when standard body-powered prosthetic devices cannot be used or are insufficient to meet the needs of the member in performing activities of daily living.

7. Neuromuscular electrical stimulation (NMES)

   a. PacificSource commercial and Medicare Advantage plans follow CMS policy NCD 160.12 for coverage of neuromuscular electrical stimulation for the treatment of muscle atrophy

   b. PacificSource Medicaid follows Oregon Health Plan (OHP) per Oregon Administrative Rules (OAR) 410-122-0515 for coverage of Neuromuscular Electrical Stimulation (NMES).

Medicaid

In addition, Medicaid plans are subject to Oregon Administrative Rules:
Other Documentation to support medical appropriateness should be provided by a clinician not associated with the DME provider.

Functional Levels

Clinical assessments of a member’s rehabilitation potential should be based on the following classification levels:

**Level 0:** Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.

**Level 1:** Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.

**Level 2:** Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.

**Level 3:** Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

**Level 4:** Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Definitions

**Activities of daily living (ADLs)** - basic personal everyday activities including, but not limited to, tasks such as eating, toileting, grooming, dressing, bathing, and transferring.

**CMS** – Center for Medicare & Medicaid Services

**DMEPOS** – durable medical equipment is any equipment that provides therapeutic benefits to a patient/member in need due to certain medical conditions and/or illness.

**Functional (knee brace)** – stabilize the knee for activities of daily living (ADLs). A functional brace may be used to support an unstable knee and decrease the stress on an osteoarthritic joint. Functional braces may be prefabricated or custom-fabricated.

**Instrumental Activities of Daily Living** - activities related to independent living. They include preparing meals, managing money, shopping for groceries or personal items, performing light or heavy housework, and using a telephone.

**LCD** – Local Coverage Determination
Prophylactic (knee brace) - are used on knees to prevent injuries in a relatively normal (stable) knee. Most contracts exclude durable medical equipment used primarily in athletic or recreational activities.

Mobility Related Activities of Daily Living - activities related to personal everyday activities within the home. They include feeding, toileting, dressing, and grooming.

NCD – National Coverage Determination

Rehabilitation (knee brace) – allow for moderate knee joint motion post-injury or post-surgery. They employ locking knee hinges and are usually prefabricated.

Unloading/Offloading (knee brace) - "unloads" some of the weight from the medial or lateral compartment of a painful osteoarthritic knee to reduce pain and help increase mobility by bracing the knee in the valgus position.

Related Policies

New and Emerging Technology Coverage Status

Unlisted and Unspecified Procedure Codes

References

American Orthotic & Prosthetic Association
https://www.aopanet.org/

Durable Medical Equipment Reference List. NCD 280.1. CMS

Appendix

Policy Number: [Policy Number]

Effective: 1/20/2020 Next review: 1/20/2021

Policy type: Enterprise

Author(s): [Authors]

Depts.: Health Services

Applicable regulation(s): N/A

External entities affected: N/A