I. Description

The prevalence of osteoarthritis (OA) is constantly increasing, currently affecting 4.3 million adults in the United States, and making it the most prevalent of the chronic joint disorders worldwide. One contributing factor that may increase the severity of knee OA is knee malalignment. Studies have shown that an increased load in the medial compartment of the knee can cause an increase in knee degeneration. Unloader knee orthoses are specifically designed to reduce the pain and disability associated with osteoarthritis of the medial compartment of the knee by bracing the knee with a valgus directed force to unload the compressive forces on the medial compartment.

This policy addresses only knee orthoses for osteoarthritis. For all other indications, refer to the Noridian Healthcare Jurisdiction D Local Coverage Determination (LCD) and Local Coverage Article (LCA) for Knee Orthoses for specific criteria.

II. Criteria/Guidelines

A. A prefabricated unloader knee orthosis is covered (subject to Limitations and Administrative Guidelines) when all of the following criteria are met:

1. There is moderate to severe medial compartment osteoarthritis (see Appendix for definitions).
2. Grade 1 or less involvement of the lateral compartment
3. Patient has persistent knee pain limiting activities of daily living (ADL) despite the use of all of the following standard treatment modalities (unless contraindicated):
   a. Nonsteroidal anti-inflammatory drug (NSAID)
   b. Topical NSAID (if oral NSAID is contraindicated)
   c. Intra-articular corticosteroid injection
   d. Exercise program and strength training and/or physical therapy
   e. Counseling regarding weight management, if applicable

B. A custom-fabricated unloader knee orthosis is covered (subject to Limitations and Administrative Guidelines) when the following criteria are met:

1. The above criteria for a prefabricated knee orthosis are met
2. There is a documented physical characteristic which requires the use of a custom fabricated orthosis instead of a prefabricated orthosis, including, but not limited to:
   a. Deformity of the leg or knee
   b. Size of thigh and/or calf
   c. Minimal muscle mass upon which to suspend an orthosis

III. Limitations

A knee orthosis for the treatment of lateral or patellofemoral compartment osteoarthritis is not covered because it is not known to be effective in improving health outcomes.

IV. Administrative Guidelines

A. Custom fabricated knee braces require precertification. Complete HMSA’s Precertification Request and mail or fax the form as indicated. The following documentation from the patient’s medical records must be submitted:

1. Imaging reports supporting that the patient has medial compartmental osteoarthritis with no to minimal involvement of the lateral compartment.
2. Clinical notes supporting persistent pain affecting ADLs despite use of standard treatment modalities or that treatment modalities are contraindicated.
3. Documentation supporting that the patient has a physical characteristic which requires the use of a custom-fabricated orthosis.

B. Applicable codes:

<table>
<thead>
<tr>
<th>HCPCS code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K0901</td>
<td>Knee orthosis (KO), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf</td>
</tr>
<tr>
<td>K0902</td>
<td>Knee orthosis (KO), double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf</td>
</tr>
<tr>
<td>L1843</td>
<td>Knee orthosis, single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, includes fitting and adjustment</td>
</tr>
<tr>
<td>L1844</td>
<td>Knee orthosis, single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment; custom fabricated (Requires precertification)</td>
</tr>
<tr>
<td>L1845</td>
<td>Knee orthosis, double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment; prefabricated, includes fitting and adjustment</td>
</tr>
<tr>
<td>L1846</td>
<td>Knee orthosis; double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment; custom fabricated (Requires precertification)</td>
</tr>
<tr>
<td>ICD-9 Code</td>
<td>Description</td>
</tr>
<tr>
<td>715.16</td>
<td>Osteoarthrosis, unspecified whether generalized or localized, lower leg</td>
</tr>
</tbody>
</table>
V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes § 432E-1.4), generally accepted standards of medical practice, and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References


VII. Appendix

The Kellgren-Lawrence scale describes the severity of articular cartilage changes associated with osteoarthritis. Grade 3 or 4 on the grading scale is considered moderate to severe osteoarthritis:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Doubtful narrowing of joint space and possible osteophytic lipping</td>
</tr>
<tr>
<td>2</td>
<td>Definite osteophytes and possible narrowing of joint space</td>
</tr>
<tr>
<td>3</td>
<td>Moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends</td>
</tr>
<tr>
<td>4</td>
<td>Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone ends</td>
</tr>
</tbody>
</table>