March 2008

Knee Orthoses
Response to Comments

PREFABRICATED KNEE ORTHOSES

In the draft Knee Orthoses LCD, L1831 and L1847 are denoted as used for and covered for flexion contractures. Request a revision of the descriptive language in the LCD and in allowing coverage in the cases of extension contractures as well as flexion contractures. Extension contractures may not be common but they do occur status post operatively or as a result of the Medicare beneficiary having been in the recumbent position for a prolonged period of time.

Response

The DME MAC Medical Directors agree. The final LCD covers extension as well as flexion contractures.

L1831 and L1847 should not be limited to only non-ambulatory patients.

Response

The DME MAC Medical Directors agree. The final LCD does not limit the use of L1831 and L1847 to only non-ambulatory patients.

In the treatment of knee contractures limiting the types of orthotics to "locking type" braces, L1831 and L1836, is a maintenance type approach and not one that prevents contractures from becoming worse.

Response

The DME MAC Medical Directors disagree. Treatment of knee contractures is not limited to "locking type" orthoses (L1831 and L1836). Coverage is allowed for L1830, L1832, L1843, L1845, and L1850 for patients with knee contractures who meet the specific requirements for coverage of the brace.

Criteria for L1843 should include diagnoses pertaining to fractures or ligamentous disruptions requiring knee bracing.

Response

The DME MAC Medical Directors agree. The final LCD includes these diagnoses.

The indications for coverage of L1830, L1832, L1843, L1845, and L1850 are limited and should either be eliminated or expanded.

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The DME MAC Medical Directors agree. The final LCD includes an expanded list of diagnoses.

Descriptions for codes L1843, L1844, L1845, L1846 refer to the orthotic joint as having both flexion and extension. Only extension is necessary to protect the anterior cruciate ligament which is what these braces are commonly used for by orthopedic surgeons.

Response

While the DME MAC Medical Directors agree with this comment, flexion and extension joints are part of the code definition and description for each of these orthoses.

CUSTOM FABRICATED KNEE ORTHOSES

Requiring suppliers that they "must consider" prefabricated alternatives before supplying a custom fabricated orthosis should be deleted. The statement "must consider" is vague and it is the physician who orders the orthotic, not the supplier. Suppliers should not be required to second guess the physician's prescription.

Response

The DME MAC Medical Directors disagree. There must be documentations in the physician's record or the supplier's record that supports the need for a custom fabricated orthosis in lieu of a prefabricated orthosis. This may include the supplier's "thought process" for selecting a custom fabricated product over a prefabricated product for that specific patient.

Recommend expanding the example situations that meet the criteria for coverage of a custom fabricated orthosis to include, but not limited to, the following:

1. Deformity of the leg or knee that precludes fitting with a prefabricated orthosis.
2. Disproportionate size of thigh and calf or atypical thigh and calf dimensions due to obesity (body mass index greater than or equal to 30 kg/m^2).
3. Minimal muscle mass upon which to suspend an orthosis.
4. Documented neurological, circulatory, or cutaneous status precludes a prefabricated orthosis.
5. Intimate fit is required for ligament protection or off-loading indication.
6. Material ordered or manufacturing process precludes a prefabricated orthosis.

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7. The patient requires an off-loading knee brace and one of the above criteria for code L1843 is met, provided that the patient also meets one of the above criteria for a custom fabricated orthosis.

Response

The DME MAC Medical Directors disagree. The list outlined in the draft Knee Orthoses LCD was presented as an example of common situations where a custom fabricated knee orthosis might be utilized. It was not intended to encompass the myriad of clinical scenarios where one might consider a custom fabricated device. The main point of the coverage criterion is that a custom fabricated orthosis is covered when there is a documented physical characteristic which requires the use of a custom fabricated orthosis instead of a prefabricated orthosis. The clinical reasoning for the selection of a custom fabricated orthosis over a prefabricated orthosis must be documented in the patient's medical record.

The draft LCD eliminates coverage for a custom fabricated KO for the treatment of knee contractures in the case of post surgery, cerebral palsy, or total brain injury patients.

Response

The DME MAC Medical Directors agree. The final LCD includes consideration of coverage of custom fabricated orthoses for patients with knee contractures who are ambulatory.

The definition for custom fabricated should be more specific, taking into account the percent use of prefabricated components in the composition of a custom fabricated orthosis.

Response

The DME MAC Medical Directors disagree. The Knee Orthoses LCD does take into account the use of prefabricated components when defining custom fabricated knee orthoses; however, providing a specific percent use of prefabricated components when constructing a custom fabricated orthosis is not necessary and too limiting. A custom fabricated orthosis is one which is individually made for a specific patient (no other patient would be able to use this orthosis) starting with basic materials including; but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as vacuum forming, cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item.

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There should be a higher reimbursement for custom fabricated orthosis made from a cast or digital image to patient model compared to an orthosis that is only "custom" enough to meet the definition of a custom fabricated L code.

Response

The DME MAC Medical Directors disagree. There are a number of production technologies or fabrication techniques that can be used in making a custom fabricated orthotic. The existing, varying technologies were taken into consideration at the time the custom fabricated "L codes" were created. A custom fabricated orthosis is one which is individually made for a specific patient (no other patient would be able to use this orthosis) starting with basic materials including; but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as vacuum forming, cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item.

Recommend including "made to measurements" in the definition of "molded to patient model".

Response

The DME MAC Medical Directors agree. The final LCD includes this verbiage in the definition of "molded to patient model".

ADDITION CODES

Inclusion of the all addition codes into the prefabricated base codes is inappropriate. Some addition codes or devices should be separately payable and not included in the base code unless the reimbursement is increased to reflect such.

Response

The DME MAC Medical Directors agree. The final LCD expands the list of addition codes that may be considered for separate payment with the base orthosis code. In addition, the list of addition codes that are considered bundled , not separately payable or not medically necessary was also expanded.

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Recommend creating an addition code for adjusting the orthosis to increase or decrease valgus or varus force on the knee in cases of osteoarthritis.

Response

The DME MAC Medical Directors disagree. Capability of valgus or varus force adjustment is a feature that was taken into consideration when creating and pricing the codes for those types of orthoses. Fitting and adjustment (e.g., increasing or decreasing the amount of valgus or varus force) are also included in the reimbursement for the base code and are not separately reimbursable.

The draft Knee Orthoses LCD restricts the use of certain L-codes to a "replacement only" status. Knee orthosis codes L2320, L2330, L2335, and L2340 (non-molded and molded lacers, anterior swing band and pretibial shell, respectively) are restricted to being billed as replacement items. These items should be allowed for separate billing and separate payment.

Response

The DME MAC Medical Directors disagree. Devices that incorporate codes L2320 and L2330 (non-molded and molded lacers, respectively) had those codes included in the pricing of the base knee orthosis code; therefore, separate billing and reimbursement of those codes would be appropriate only when used as replacements. Note that codes L2335 and L2340 are not compatible with knee orthoses and were removed from the policy.

Criteria for coverage of L2755 should be expanded to include consideration of musculoskeletal and/or angular deformities requiring a "high strength" component to prevent potential patient injury and to lower the weight limit to 120 lbs.

Response

The DME MAC Medical Directors disagree. Custom fabricated orthoses incorporating these types of materials are primarily designed for high impact/high stress activities and work environments. In the absence of these conditions, the only additional consideration would be coverage for patients exceeding 300 lbs. in weight. Below 300 lbs., standard (i.e., "non high strength") materials should suffice.

L2770 should be made a valid code.

Response

The DME MAC Medical Directors disagree. Code L2770 describes "any material, per bar or joint" which is a generic description and does not allow for the

establishment of reasonable coverage or reimbursement. Therefore, it is considered invalid for Medicare coverage.

Eliminating L2795 as a prefabricated knee orthosis addition code in the management of contractures would eliminate the third point of pressure which has a fundamental purpose with the use of bracing for contracture management.

Response

The DME MAC Medical Directors disagree. Applying pressure on the knee using a full kneecap device (L2795) is not an effective way to treat a knee contracture and therefore not considered medically necessary.

L2800 should be allowed and paid separately as an addition code with L1846 and L1858. L2800 provides additional control of the knee cap.

Response

The DME MAC Medical Directors disagree. The addition of L2800 is considered not medically necessary with L1846 because L1846 has medial/lateral and rotation control. Effective on January 1, 2008, L1858 has been deleted and cross walked to L1846..

L2780 (addition to lower extremity orthosis, non-corrosive finish, per bar) should not be omitted from the list of codes allowed to be added to custom devices.

Response

The DME MAC Medical Directors disagree. A non-corrosive finish (L2780) is considered a standard in the orthotic manufacturing process and therefore included in coverage of the base device.

There should be separate coverage for L2840 and L2850. These types of socks are helpful in reducing skin irritation and breakdown.

Response

The DME MAC Medical Directors disagree. Codes L2840 and L2850 are statutorily excluded from coverage because they are not by definition a brace.

L2860 (addition to lower extremity joint, knee or ankle concentric adjustable torsion style mechanism, each) should not be considered invalid for claim submission. E1810

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(dynamic adjustable knee extension/flexion device, includes soft interface material) is a different type of device and should not be required for claims billing of L2860.

Response

The DME MAC Medical Directors disagree. Code L2860 has been invalid for submission to Medicare since November 1997 and has been cross walked to E1812. Devices that include this feature are to be billed using E1812.

Not allowing separate payment of code L2999 with prefabricated devices is seen as limiting patient access to new devices and discourage the development and marketing of new technology.

Response

The DME MAC Medical Directors disagree. Code L2999 is nonspecific and rarely would be eligible for separate payment as an addition code to a prefabricated device. If a provider bills for L2999 and the claim is denied, the appeals process is available for reconsideration of the claim. Alternatively, if a manufacturer or provider feels they have a unique product that should be allowed for separate payment, they may contact the SADMERC for information on how to apply for a new HCPCS code.

There are benefits to the incorporation of an air bladder into a knee orthosis and it should be covered separately.

Response

The DME MAC Medical Directors disagree. No published, clinical literature supporting the incorporation of an air support chamber into a knee orthosis was received. Moreover, there is no addition code for an air support chamber. Providers who desire to utilize a knee orthosis with an air support chamber should consider code L1847 (KO, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, includes fitting and adjustment).

Patients should not have to wait one year after the initial date of service to obtain a replacement soft interface (K0672). Replacement covers should be available with the initial order due to the fact that many patients are incontinent and require frequent laundering.

Response

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The DME MAC Medical Directors disagree. Pricing for the base device includes 2 interfaces - 1 that is part of the initial brace and 1 additional interface (so called "one to wash and one to wear").

DOCUMENTATION REQUIREMENTS

The KX modifier should not be required and applied to all codes listed in the Knee Orthoses LCD.

Response

The DME MAC Medical Directors disagree. Clinical documentation supporting the use of any knee orthosis listed in the LCD is required in order for the device provided and billed to be covered under the Medicare DMEPOS benefit. Use of the KX modifier to denote supporting clinical information has been documented and on file is an appropriate requirement.

A telephone order from a physician should suffice as long as the appropriate information is in the order.

Response

The DME MAC Medical Directors disagree. A written order is required for every item of DMEPOS as stated in the CMS Medicare Program Integrity Manual, Chapter 5.

REASONABLE USEFUL LIFETIME

The useful lifetime of L1832 should be reduced to 6 months because the materials use to manufacture the device do not generally last up to 2 years.

Response

The DME MAC Medical Directors disagree. There are a number of products included in this code that are constructed to last for at least 2 years with typical daily use.

The reasonable useful lifetime for L1845, a prefabricated knee orthosis, should be considered 1 year and not 3 years. These are not indestructible and it is unrealistic to think an L1845 will last 3 years.

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Response

The DME MAC Medical Directors disagree. There are a number of products included in this code that are constructed to last for at least 3 years with typical daily use.

Reasonable useful lifetime of 2 years for a prefabricated post operative brace (L1832) or 3 years for a custom fabricated knee orthosis (L1836, L1843, L1845) is unrealistic, too limiting and does not allow replacement in the patient who "legitimately wears out the brace".

Response

The DME MAC Medical Directors disagree. The reasonable useful lifetime limits are considered reasonable for the general Medicare population. Replacement prior to the expiration of the reasonable useful lifetime may be considered when there has been a significant change in the patient's medical condition or the orthosis has been lost or irreparably damaged. If the brace is no longer functional due to wear and tear, a request for repair may be made and allowed if reasonable and necessary, not exceeding the cost of replacement. The medical necessity for the replacement item or repair (if prior to the expiration of the reasonable useful lifetime) must be documented in the patient's medical record and available upon request.

Coverage of a different knee orthosis should be allowed when there has been a "physiologic change". During the course of treatment a patient may be started with one type of knee orthosis, L1830, and after a few days or weeks need a change to a L1832 or L1845 or possible a custom fabricated orthosis. The fact that a patient has received one type of knee orthosis, (i.e., prefabricated) should not preclude him or her from getting a different prefabricated knee orthosis or a custom orthosis.

Response

The DME MAC Medical Directors agree. One of the instances when Medicare regulations allow for replacement of items prior to the expiration of the reasonable useful lifetime is when there has been a change in medical necessity. This requirement is typically met when the patient has a change in medical condition or there has been a significant "physiologic change. Providers should document in the patient's medical record the specific reason(s) for new device.

MISCELLANEOUS

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An individual list of products and classification of those products should be developed by the DME PSCs to define specifically what is a prefabricated vs a custom fabricated orthosis.

Response

The DME MAC Medical Directors agree. Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

The Kellgren-Lawrence Scale should not be used due to questionable reliability.

Response

The DME MAC Medical Directors agree. The Kellgren-Lawrence Scale has been removed from the final LCD.

We received multiple comments regarding qualified providers for custom fabricated knee orthoses.

Response

Specific accreditation and/or licensure requirements of qualified providers designated for reimbursement under Medicare for custom fabricated knee orthosis is required in statute to be determined through the negotiated rule making process. Negotiated rule making was conducted but there was not a unanimous agreement regarding the definition and criteria of qualified providers. Therefore, this section is not included in the final LCD.