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Re: Knee Orthoses Local Coverage Determination (LCD) Reconsideration Request

Dear DME MAC Medical Directors:

The American Orthotic & Prosthetic Association (AOPA) is the largest national orthotic and prosthetic trade association with a national membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a chronic disease or health condition. As a representative of the orthotic and prosthetic community we are asking for a review and revision of the current Medicare Local Coverage Determination (LCD) for Knee Orthoses (L33318).

AOPA believes that the current LCD does not adequately provide coverage for all Medicare beneficiaries who have been diagnosed with Osteoarthritis (OA). OA is the most common form of arthritis, and it impacts one in seven adults (approximately 32.5 million people) [1] and is most common among adults with other chronic conditions, such as heart disease, diabetes, and obesity. OA, according to the Centers for Disease Control and Prevention (CDC), is a degenerative joint disease, in which the tissues in the joint break down. Common symptoms of OA include pain, stiffness, decreased range of motion, swelling and eventual weaking and deforming of the joint.

The pain, stiffness, and swelling caused by OA may impact a beneficiary's ability to function normal tasks of daily living and limit their mobility. This decrease in mobility and ability to function reduces a beneficiary's quality of life and may impact their ability to work. It is estimated that $71.3 billion in annual earning losses can be attributed to OA[1] and OA may result in decreased physical activity, leading to an increase in related comorbidities. One in three adults with arthritis indicate they don't participate in any leisure time physical activity; and it has been shown that physical activity can reduce pain and improve physical function by 40%[2] . It is vital that Medicare beneficiaries suffering from pain and/or other symptoms of OA remain mobile and active.

Knee orthoses are an acceptable and established treatment modality for OA, especially in the earlier stages of the disease to help ensure that beneficiaries remain mobile, active and manage their knee pain. It has been shown that knee orthoses are an economical and effective treatment for knee osteoarthritis[3] and significantly improve a patient's quality of life, potentially delaying the need for surgery[3]. Medicare beneficiaries suffering from pain and/or other symptoms of OA in the knee(s) must have timely and appropriate access to quality knee orthoses and orthotic care to improve function, pain, and their quality of life; and to encourage and allow beneficiaries to be more active and possibly lower the risks of other comorbidities associated OA such as obesity, diabetes and heart disease.

The current Knee Orthoses LCD (L33318) doesn't allow for coverage of a knee orthosis solely for pain relief associated with OA, even though the Policy Article indicates that the primary purposes of OA bracing is to reduce pain. The *Coding Guidelines* portion of the current Knee Orthoses Policy Article (A52465) states that knee orthoses described by L1843 (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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise), L1844 (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, custom fabricated) and L1851 (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) "are designed to open the medial or lateral compartment of the knee **to provide pain relief due to osteoarthritis (emphasis added)"**.

AOPA is writing to formally request that the Durable Medical Equipment Administrative Contractors (DME MACs) review and revise the current Knee Orthoses LCD (L33318) to correct discrepancies in coverage for a select set of Medicare beneficiaries affected by osteoarthritis, and a select set of knee orthoses (L1843,L1844, L1845, L1846 L1851 and L1852) and to ensure the LCD is consistent with information found in the current Knee Orthoses Policy Article (A52465) and other DME MAC materials.

LCD Reconsideration Request: Revisions & Updates

The current Knee Orthoses LCD (L33318) allows for coverage of select knee orthoses (L1843, L1844, L1845, L1846, L1851 and L1852) under two very specific circumstances. The first is "if the beneficiary has had recent injury to or a surgical procedure on the knee(s). Refer to the diagnoses listed in the Groups 2 or 4 ICD-10 Codes in the LCD-related Policy Article." Even

though a recent surgery or injury is not defined in the LCD, the selected Groups 4 ICD-10 codes in the Policy Article does include diagnoses for OA.

The second circumstance does not require the beneficiary to have had a recent surgery or injury. The select knee orthoses (L1843, L1845, L1851 and L1852) are also "covered for a beneficiary who is ambulatory and has knee instability due to a condition specified in the Group 4 ICD-10 Codes in the LCD-related Policy Article…… knee instability must be documented by examination of the beneficiary and objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test)." As previously stated, the Group 4 ICD-10 Codes in the Policy Article does include diagnoses for OA.

However, these circumstances have inadvertently caused a hole in coverage for beneficiaries diagnosed with OA. It is very possible and common for a beneficiary to be diagnosed with and suffer from OA, but not have any objectively definable knee instability or joint laxity, and not have had a recent surgery or injury.

OA may be classified in four stages: minor, mild, moderate and severe. Knee instability is not always a symptom of OA, but rather a possible end result, and is typically not present until the fourth or severe stage, when surgery is the most common treatment modality. Requiring the presence of knee instability as the primary reason for coverage of knee orthoses used to treat OA, the LCD is significantly limiting Medicare coverage to only the most severe stages of OA rather than the early stages of the disease where symptoms of OA such as pain, stiffness, decreased range of motion, swelling and deformation of the joint may be effectively managed.

We respectfully request that the LCD be revised to allow for access and coverage for select knee orthoses (L1843, L1844, L1845, L1846, L1851 and L1852) during the earlier stages of OA. See Appendix A for new suggested LCD verbiage. Expanding Medicare coverage to include these knee orthoses in the early stages of OA will allow providers and suppliers to address common symptoms of OA such as pain, stiffness, decreased range of motion, swelling and deformation of the joint. This will increase or improve the quality of life for Medicare beneficiaries and may delay the need for surgery when OA has become more advanced. The earlier the orthosis can be provided the more effective it becomes. As previously stated, knee orthoses are proven to be an economical and effective treatment for knee osteoarthritis[3] and significantly improve a patient's quality of life and potentially delay the need for surgery[3].

The selected literature in Appendix C will provide information on the use of knee orthoses to treat pain, stiffness, and the other symptoms related to OA.

The reliance on the presence of objective documentation of knee instability as a condition of coverage for OA orthoses may have some other unintended consequences. First, it may place more of a finical burden on a beneficiary diagnosed with OA, as they may have to pay for non-covered knee orthoses out of pocket. Second, it increases the error rates in pre- and post-payment reviews as suppliers currently provide knee orthoses to treat all other symptoms of OA, not just knee instability and joint laxity. Lastly, it places a burden on the supplier as they must appeal the denials, often to the Administrative Law Judge level, or elect to pass the costs onto the beneficiary through the use of an Advanced Beneficiary Notice (ABN).

We are also requesting to update the language for testing requirements for knee instability/joint laxity. The current Knee Orthoses LCD states: "knee instability must be documented by examination of the beneficiary and objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test)." However, the DME MACs through various

educational materials and presentations have insisted that these are not the only acceptable tests and that others, including the posterior sag test, pivot shift test, apprehension test, or Lachman's test may also be used. We request that the LCD include these additional tests (posterior sag test, pivot shift test, apprehension test, or Lachman's test) and/or include the following statement "not all inclusive". See Appendix A for sample language. We are requesting this change because auditors and private payers, including Medicare Advantage, are asserting that the varus/valgus instability or anterior/posterior Drawer test are the only approved and acceptable tests. Revising the current LCD to include the new language will be consistent with existing DME MAC interpretations and published guidance, and reduce any confusion among suppliers, payers and auditors using the Medicare Knee Orthoses LCD as a basis for medical necessity and payment.

LCD Reconsideration Request Submission Criteria

To be considered a valid an LCD Reconsideration request, per the CMS Internet Only Manual, Publication 100-08, Program Integrity Manual, Chapter 13; the request must meet the following four requirements:

1) The LCD Reconsideration request must be submitted by any interested party doing business in a contractor's jurisdiction. AOPA represents over 1,900 orthotic and prosthetic suppliers and manufactures operating and treating beneficiaries in all four Durable Medical Equipment Medicare Administrative Contractor jurisdictions. Requirement met.

2) The LCD Reconsideration request must include the specific language that the submitter proposes to add/delete from a current LCD. See Appendix A. Requirement met.

3) The LCD Reconsideration request must include available evidence, including literature and references limited to published, full-text, peer reviewed evidence, indexed in PubMed of the US National Library of Medicine, National Institutes of Health. See Appendix C and See attachments. Requirement met.

4) The LCD Reconsideration request may only be for an LCD published in final form. The current Knee Orthoses LCD (L33318) is an active LCD and has been published and in final form since 01/01/2020. Requirement met.

LCD Reconsideration Request Summary

AOPA believes that this request has met all the requirements of an LCD Reconsideration and should be considered valid. We feel that the current Knee Orthoses LCD (L33318) does not meet the medical needs of all Medicare beneficiaries impacted by OA.

We request that that DME MACs review the attached literature, Appendix C, and revise the Knee Orthoses LCD (L33318), with the suggested language in Appendix A, to allow for coverage of knee orthoses (L1843, L1844, L1845, L1846, L1851 and L1852) when a beneficiary has knee pain, stiffness, decreased range of motion, swelling and/or a weak and deformed knee due to OA; but may not have documented instability/joint laxity or ligamentous injuries to the knee. While the use of "unloader' style knee orthoses (L1843, L1844 and L1851) are specifically described in the Knee Orthosis Policy Article (A52465) as an effective "option to open the medial or lateral compartment of the knee to provide pain relief due to osteoarthritis", the LCD

does not include pain relief as a Medicare covered condition. There is existing precedence for Medicare coverage of pain relief in other LCDs, specifically the LCD for Spinal Orthoses (L33790).

Secondarily, we request that that DME MACs review and revise the Knee Orthoses LCD (L33318) to update the joint laxity testing examples to be less exclusionary and more in line with current DME MAC guidance on the various types of acceptable tests and/or objective documentation methods.

AOPA is committed to working with CMS and its contractors to ensure Medicare beneficiaries have timely access to medically appropriate care, and to eliminate any undue burden and confusion among Medicare suppliers. These two changes would benefit those Medicare beneficiaries suffering from OA and increase their quality of life and lower their out-of-pocket expenses. The changes would also eliminate confusion among payers, auditors, and suppliers as to the types of tests which are acceptable for determining medical necessity, which will become increasingly important as Medicare Advantage plans are now required to adhere to all Medicare coverage policies and guidelines.

We look forward to your response and if we may provide any more information, or if you have any additional questions, please feel free to contact us.

Sincerely,

Joe McTernan
Director of Health Policy and Advocacy

Appendix A: Proposed Language to Add/Delete from the Current Knee Orthoses LCD (L33318)

Black text indicates the current LCD verbiage, the red text indicates the LCD Reconsideration request proposed language changes:

PREFABRICATED KNEE ORTHOSES (L1810, L1812, L1820, L1830, L1831, L1832, L1833, L1836, L1843, L1845, L1847, L1848, L1850, L1851, L1852):

"A knee immobilizer without joints (L1830), or a knee orthosis with adjustable knee joints (L1832, L1833), ~~or a knee orthosis, with an adjustable flexion and extension joint that provides both medial-lateral and rotation control (L1843, L1845, L1851, L1852),~~ are covered if the beneficiary has had recent injury to or a surgical procedure on the knee(s). Refer to the diagnoses listed in the Groups 2 or 4 ICD-10 Codes in the LCD-related Policy Article.

Knee orthoses L1832 and L1833, ~~L1843, L1845, L1851 and L1852~~ are also covered for a beneficiary who is ambulatory and has knee instability due to a condition specified in the Group 4 ICD-10 Codes in the LCD-related Policy Article.

A knee orthosis, Swedish type, prefabricated (L1850) is covered for a beneficiary who is ambulatory and has knee instability due to genu recurvatum - hyperextended knee, congenital or acquired (refer to the Group 5 ICD-10 Codes in the LCD-related Policy Article).

For codes L1832, L1833, ~~L1843~~, ~~L1845~~, and L1850, ~~L1851~~ ~~and L1852,~~ knee instability must be documented by examination of the beneficiary and objective description of joint laxity (such as, but not all inclusive, varus/valgus instability, anterior/posterior Drawer test, posterior sag test, pivot shift test, apprehension test, or Lachman's test).

A knee orthosis, with an adjustable flexion and extension joint that provides both medial-lateral and rotation control (L1843, L1845, L1851 and L1852) is covered if one of the following criterions are met:

1) The beneficiary is ambulatory and has knee instability due to a condition specified in the Group 4 ICD-10 Codes in the LCD-related Policy Article, and the knee instability must be documented by examination of the beneficiary and objective description of joint laxity (such as, but not all inclusive, varus/valgus instability, anterior/posterior Drawer test, posterior sag test, pivot shift test, apprehension test, or Lachman's test).; or

2) The beneficiary has had recent injury to or a surgical procedure on the knee(s) with a diagnosis listed in the Groups 2 or 4 ICD-10 Codes in the LCD-related Policy Article.; or

3) The beneficiary is ambulatory and has an osteoarthritis condition specified in the Group 6 ICD-10 Codes in the LCD-related Policy Article, and the osteoarthritis of the knee must be documented by examination of the beneficiary with an objective description of the arthritic changes to the knee joint (such as , but not

all inclusive, joint space narrowing, bone spurs, or cysts) identified through radiograph, MRI, X-ray, or CT report.; or

4) The beneficiary is ambulatory and has an osteoarthritis condition specified in the Group 6 ICD-10 Codes in the LCD-related Policy Article with changes in the knee with a documented increase of mild to severe pain (as indicated by the Kellgren and Lawrence classification system or something comparable).

Claims for L1832, L1833, L1843, L1845, L1850, L1851 or L1852 will be denied as not reasonable and necessary when the beneficiary does not meet the above criteria for coverage. ~~For example, they will be denied if only pain or a subjective description of joint instability is documented~~."

If these changes are accepted as written, there would be no need to revise or update the current LCD language for custom fabricated knee orthoses. Below is the current LCD (L33318) language for custom fabricated knee orthoses:

CUSTOM FABRICATED KNEE ORTHOSES (L1834, L1840, L1844, L1846, L1860):

"Custom fabricated orthoses (L1834, L1840, L1844, L1846, L1860) are not reasonable and necessary in the treatment of knee contractures in cases where the beneficiary is nonambulatory.

A custom fabricated knee immobilizer without joints (L1834) is covered if criteria 1 and 2 are met:

1. The coverage criteria for the prefabricated orthosis code L1830 are met; and
2. The general criterion defined above for a custom fabricated orthosis is met.

If an L1834 orthosis is provided and both criteria 1 and 2 are not met, the orthosis will be denied as not reasonable and necessary.

A custom fabricated derotation knee orthosis (L1840) is covered for instability due to internal ligamentous disruption of the knee (refer to the Group 3 ICD-10 Codes in the LCD-related Policy Article).

A custom fabricated knee orthosis with an adjustable flexion and extension joint (L1844, L1846) is covered if criteria 1 and 2 are met:

1. The coverage criteria for the prefabricated orthosis codes L1843, L1845, L1851 and L1852 are met; and
2. The general criterion defined above for a custom fabricated orthosis is met."

If these changes are accepted as written, there would be a need to revise the current Knee Orthoses Policy Article (A52465) ICD-*10-CM Codes that Support Medical Necessity* section. Per the suggested language a new Group 6 would need to be added. The ICD-10-CM Codes in Group 6 are already present in Group 4 and are comprised of the osteoarthritis diagnoses.

The revised *ICD-10-CM Codes that Support Medical Necessity* section of the Knee Orthoses Policy Article (A52465) would be:

Group 6 *(9 Codes)*

Group 6 Paragraph

For HCPCS Codes L1843, L1844, L1845, L1846, L1851 and L1852:

Group 6 Codes

Code	Descriptor
M17.0	Bilateral primary osteoarthritis of knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified

Appendix B: Bibliography

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Appendix C: Literature & References

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