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Notice of Independent Review Decision

Date notice sent to all parties:

May 13, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Reconsideration for Custom Knee Brace

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Board Certified Orthopedic Surgeon

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who reported an injury to his right knee. The patient subsequently underwent x-rays and was instructed on the use of crutches. The note indicates the patient utilizing Motrin at that time. X-rays revealed no evidence of a fracture, bony lesion, or other significant osseous abnormalities. Soft tissue swelling was identified consistent with effusion. The MRI of the right knee dated xxxxx revealed a complete ACL disruption. A bucket handle tear was also identified involving the medial meniscus. The clinical note dated 11/18/13 indicates the patient complaining of a sharp, shooting, stabbing, and throbbing sensation at the

right knee. The patient stated that he was having difficulty with ambulation. The patient was recommended for a surgical intervention involving a right ACL reconstruction. The surgery note dated 12/10/13 indicates the patient undergoing a right knee arthroscopic medial meniscectomy and ACL reconstruction. The therapy note dated 12/18/13 indicates the patient showing strength deficits throughout the right lower extremity. The note indicates the patient having no complications with surgery. The patient was complaint with a postoperative use of a CPM. The clinical note dated 12/20/13 indicates the patient continuing with postoperative pain. The patient demonstrated no evidence of ligament laxity. The patient was able to demonstrate 5/5 strength throughout the lower extremities. Sensation was intact throughout the lower extremities as well. The therapy note dated 01/17/14 indicates the patient able to demonstrate 8 to 120 degrees of range of motion throughout the right knee. The note indicates the patient having undergone a full course of postoperative therapy. The clinical note dated 01/31/14 indicates the patient stating his postoperative pain was improving. The patient was able to demonstrate 5/5 strength throughout the lower extremities. Normal reflexes were identified with exam. No tenderness was identified upon palpation throughout the knee.

The previous utilization review dated 02/10/14 resulted in a denial for a custom knee brace as the patient has a normal Lachman's sign as well as a negative pivot shift. No instability had been identified on clinical exam.

The utilization review dated 03/14/14 resulted in a denial as no information was submitted confirming the patient's instability at the affected knee.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The documentation indicates the patient having undergone an ACL reconstruction at the right knee. A custom knee brace would be indicated provided the patient meets specific criteria to include significant instability confirmed by clinical exam, the patient has an abnormal limb contour; excessive redundant soft skin has been identified; the patient has severe osteoarthritis; maximal off-loading results in a painful response. No information was submitted regarding the patient's significant clinical findings indicating the likely benefit of a custom fabricated knee brace. Without information confirming the need for a custom knee brace, this request is not indicated. As such, it is the recommendation of this reviewer that the request for a custom knee brace is not recommended as medically necessary.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Knee brace
Recommended as indicated below. Recommend valgus knee braces for knee OA.

Knee braces that produce a valgus moment about the knee markedly reduce the net knee adduction moment and unload the medial compartment of the knee, but could be impractical for many patients. There are no high quality studies that support or refute the benefits of knee braces for patellar instability, ACL tear, or MCL instability, but in some patients a knee brace can increase confidence, which may indirectly help with the healing process. In all cases, braces need to be used in conjunction with a rehabilitation program and are necessary only if the patient is going to be stressing the knee under load. (Bengal, 1997) (Crossley, 2001) (D'hondt-Cochrane, 2002) (Miller, 1997) (Yeung-Cochrane, 2002) (Van Tiggelen, 2004) There are no data in the published peer-reviewed literature that shows that custom-fabricated functional knee braces offer any benefit over prefabricated, off-the-shelf braces in terms of activities of daily living. (BlueCross BlueShield, 2004) The use of bracing after anterior cruciate ligament (ACL) reconstruction cannot be rationalized by evidence of improved outcome including measurements of pain, range of motion, graft stability, or protection from injury. (Wright, 2007) Among patients with knee OA and mild or moderate valgus or varus instability, a knee brace can reduce pain, improve stability, and reduce the risk of falling. (Zhang, 2008) Patellar taping, and possibly patellar bracing, relieves chronic knee pain, according to a recent meta-analysis. Patellar taping may be preferred over bracing due to the fact that there is much more evidence for taping than bracing, and also because taping produces better clinical results in terms of reductions in pain than patellar bracing, plus patients are more active in their rehabilitation with taping than with bracing. (Warden, 2008) This study recommends the unloader (valgus) knee brace for pain reduction in patients with osteoarthritis of the medial compartment of the knee. (Gravlee, 2007) Evidence that knee braces used for the treatment of osteoarthritis mediate pain relief and improve function by unloading the joint (increasing the joint separation) remains inconclusive. When knees with medial compartment osteoarthritis are braced, neutral alignment performs as well as or better than valgus alignment in reducing pain, disability, muscle cocontraction, and knee adduction excursions. Pain relief may result from diminished muscle cocontractions rather than from so-called medial compartment unloading. (Ramsey, 2007) (Chew, 2007) The results of this systematic review suggest that knee braces and foot orthoses are effective in decreasing pain, joint stiffness, and drug dosage, and they also improve proprioception, balance, Kellgren/Lawrence grading, and physical function scores in subjects with varus and valgus knee osteoarthritis. They should be cautiously considered as conservative management for relief of pain and stiffness and improving physical function for persons with knee osteoarthritis. (Raja, 2011) The knee adduction moment has an integral role in the development and progression of knee OA. A number of conservative biomechanics-based interventions can reduce the knee adduction moment effectively via different mechanisms. Many of these conservative biomechanical strategies could be employed in early stage OA and might help to prevent and/or delay disease progression. Valgus knee braces secured around the thigh and lower leg and worn throughout the day are a conservative treatment strategy for patients with medial knee OA. The underlying rationale for use of a valgus knee brace is the application of a valgus moment (knee abduction moment) to the knee joint, which could reduce the knee adduction moment during walking and unload the medial compartment of the knee. Valgus knee braces reduce the net knee adduction moment during walking in healthy young

adults and in patients with medial knee OA. Pain is a symptom of knee joint OA, and a valgus knee brace substantially reduces pain immediately upon use, and after continuous wear for durations ranging between 2 weeks and 12 months. Improvements in function have also been reported in patients with OA following valgus knee bracing for durations of between 6 months and 12 months. Although valgus bracing achieves effective unloading of the medial compartment of the knee and offers potential for improving the clinical outcome in patients with knee OA, the success of this intervention relies upon the patient being prepared to wear the knee brace continually. Valgus knee braces are bulky, potentially uncomfortable and might not be a practical daily solution for many patients. (Reeves, 2011) Knee bracing after ACL reconstruction appears to be largely useless, according to a systematic review. Postoperative bracing did not protect against reinjury, decrease pain, or improve stability. (Kruse, 2012)

Criteria for the use of knee braces:

Prefabricated knee braces may be appropriate in patients with one of the following conditions:

1. Knee instability
2. Ligament insufficiency/deficiency
3. Reconstructed ligament
4. Articular defect repair
5. Avascular necrosis
6. Meniscal cartilage repair
7. Painful failed total knee arthroplasty
8. Painful high tibial osteotomy
9. Painful unicompartmental osteoarthritis
10. Tibial plateau fracture

Custom-fabricated knee braces may be appropriate for patients with the following conditions which may preclude the use of a prefabricated model:

1. Abnormal limb contour, such as:
    a. Valgus [knock-kneed] limb
    b. Varus [bow-legged] limb
    c. Tibial varum
    d. Disproportionate thigh and calf (e.g., large thigh and small calf)
    e. Minimal muscle mass on which to suspend a brace
2. Skin changes, such as:
    a. Excessive redundant soft skin
    b. Thin skin with risk of breakdown (e.g., chronic steroid use)
3. Severe osteoarthritis (grade III or IV)
4. Maximal off-loading of painful or repaired knee compartment (example: heavy patient; significant pain)
5. Severe instability as noted on physical examination of knee