Notice of Independent Review Decision

DATE OF REVIEW: 11/25/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Left Knee ACL Reconstruction with meniscus repair

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

This case was reviewed by a physician who is a board certified Orthopedic Surgeon and is currently licensed and practicing in the state of Texas.

REVIEW OUTCOME

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

☒ Upheld  (Agree)
☐ Overturned  (Disagree)
☐ Partially Overturned  (Agree in part/Disagree in part)

EMPLOYEE CLINICAL HISTORY [SUMMARY]:

The patient is a female who sustained an injury on xx/xx/xx, the knee went forward and not the foot. The patient has been treated with the use of hinged brace and crutches, ice application, physical therapy and steroid injections on 08/04/2014. Medication treatment includes Amoxicillin 500, Bystolic 5 mg, Chlorhexidine Gluconate 0.12 percent mouthwash, Hydrocodone-acetaminophen 10/325 mg, Ketorolac 10 mg, Ondansetron 8 mg, Promethazine 25 mg and propylthiouracil 50 mg. Past medical history was significant for Graves' disease, anterior cruciate ligament and meniscus repair of the left knee in 1997 and anterior cruciate ligament and meniscus repair of the right knee in 2006. MRI of the left knee dated 06/23/2014 documented that anterior translation of the tibia associated with absent anterior cruciate ligament tear and or resorption. There was no intact anterior cruciate ligament fibers demonstrated. There was a diffuse abnormal signal intensity in the medial meniscus consistent with myxoid change and/or degenerative tear. There was tricompartmental osteoarthritis most significant in the medial compartment. There was mild prepatellar soft tissue edema. There was tiny joint effusion.
The most recent office note dated 09/22/2014 documented the patient had pain in the left knee. The pain was described as burning with moderate severity. The pain improve with rest and narcotics and worse with walking, bending, squatting and weight bearing, there was associated weakness. Objective findings on examination include morbidly obese, the patient arrived in knee brace and was limping. There was tenderness over the superior and inferior pole patella and medial collateral ligament origin pain. The knee range of motion was decreased bilaterally by pain. There was positive anterior drawer sign. The Lachman’s and reverse Lachman’s test were positive with grade +. There was positive McMurray’s test and positive squat. The patient was diagnosed with rupture of the anterior cruciate ligament, strain of the knee and tear of the meniscus of the knee. The treating provider recommended left knee arthroscopy with anterior cruciate ligament reconstruction.

An initial denial dated 10/27/2014 indicates the plan for third anterior cruciate ligament (ACL) reconstruction has high risk for failure, stiffness, worsening of the arthritis and the need for revision surgery and therefore the request does not meet evidence based guidelines.

A second denial dated 11/04/2014 indicates the request is denied because the left knee MRI showed an absent ACL, but also osteoarthritis. Ms. has a BMI of 42. The meniscus abnormality is not confirmed as a tear and maybe myxoid or postoperative changes. The need for another ACL reconstruction and meniscus resection is not confirmed by these records.

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

The patient is a female who had a previous history of a hamstring ACL reconstruction LEFT knee and sustained re-injury in xx/xxxx. Subsequent MRI left knee revealed an absence of ACL graft, tricompartmental osteoarthritis, and increased signal medial meniscus consistent with myxoid degeneration versus tear. Physical exam by treating surgeon confirmed anterior laxity consistent with an ACL deficient knee.

The ODG was reviewed as it applies to this case. Unfortunately, the ODG does not specifically cover recommendations for ACL revision. An ACL revision carries significantly higher risk for failure and poor clinical outcomes compared with primary ACL reconstruction, and the criteria for proceeding with primary ACL reconstruction as determined by ODG are insufficient to extend to the setting of revision. This patient carries additional increased risk for a poor outcome with morbid obesity and existing tricompartmental arthritis. While ACL revision may reasonably help her instability and slow her arthritic progression, a surgery of that nature should only be undertaken after conservative modalities have been completely exhausted. The supplied records state that the patient was preauthorized for 12 sessions of physical therapy; however, no physical
therapy records were submitted for review. Non-operative treatment should also be considered for this patient, especially in light of her arthritis and obesity. As the patient has not undergone an adequate course of conservative treatment which would include a full course of physical therapy, I would agree with the previous adverse determination and find this case noncertified.

**ODG – Knee & Leg- Acute and Chronic**

**ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION**

Recommended as indicated below. An examination of all studies that compared operative and conservative treatment of anterior cruciate ligament (ACL) rupture found that outcomes in the operative groups were generally better than in the conservative groups for younger patients. (Hinterwimmer, 2003) (Linko-Cochrane, 2005) Females are more likely than males to have a narrow A-shaped intercondylar notch, and special surgical considerations are required in such cases. Following ACL reconstruction, female athletes are more likely than male athletes to rupture the contralateral ACL; however, males and females are equally likely to rupture the reconstructed knee. Although self-reported outcomes in the first 2 years following reconstruction are worse for females than for males, longer-term studies demonstrate no difference between males and females. (Sutton, 2013) Morbidity is lower for hamstring autografts than for patellar tendon autografts used for ACL reconstruction. (Bialau, 2006) 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) Most of the roughly 100,000 ACL reconstructions performed each year are for younger patients. Although age has been considered a relative contraindication for ACL surgery in the past, active older patients may respond well to this surgery and should not be ruled out as surgical candidates based solely on their age. It is important to look at their comorbidities, e.g., malalignment and osteoarthritis, because they predict potential problems. (Wulf, 2008) In patients with ACL injury willing to moderate activity level to avoid reinjury, initial treatment without ACL reconstruction should be considered. All ACL-injured patients need to begin knee-specialized physical therapy early (within a week) after the ACL injury to learn more about the injury, to lower the activity level while performing neuromuscular training to restore the functional stability, and as far as possible avoid further giving-way or re-injuries in the same or the other knee, irrespectively if ACL is reconstructed or not. (Neuman, 2008) Patients with anterior cruciate ligament (ACL) injuries may not need surgery. At 2-5 years after injury, muscle strength and function were similar in patients treated with physical therapy and surgical reconstruction or physical therapy only. ACL injuries are associated with the development of osteoarthritis (OA) in the long term, and some studies suggest that there is no evidence to suggest that reconstruction of the ACL prevents or reduces the rate of early-onset OA. On the contrary, the prevalence of OA may be even higher in patients with reconstructed ACL than in those with nonreconstructed ACL. (Ageberg, 2008) A recent meta-analysis, however, suggests the opposite in some circumstances. The results of the analysis support the proposition that ACL injury predisposes knees to osteoarthritis, but concludes that ACL reconstruction surgery has a role in reducing the risk of developing degenerative changes at 10 years. However, returning to sports activities after ligament reconstruction may exacerbate the development of arthritis. (Ajued, 2013) Immediate surgical reconstruction may not be needed for ACL tears, according to the results of an RCT in the *New England Journal of Medicine*. Some patients who are not elite athletes can function with an ACL-deficient knee, but it is difficult to predict which patients will have symptoms of instability that require surgery. (Frobell, 2010)
**Age:** Outcomes are worse in older patients (age beyond 50-60 years) but still may justify the procedure. ACL reconstruction can be successful in appropriately selected, motivated older patients with symptomatic knee instability who want to return to participating in highly demanding sport and recreational activities. (Legnani, 2011) Age alone should not exclude ACL-deficient patients from undergoing reconstructive surgery. (Gee, 2013) Patients aged 40 years and older with an ACL injury can have satisfactory outcomes after reconstruction. (Brown, 2013) Optimal surgical results can in fact be achieved even in older patients. (Desai, 2013)

**Autograft vs. allograft:** While it should be surgeon preference, and there should also be shared decision making involving benefits vs. risks to the patient, both patient and surgeon should be aware that there is some evidence of significantly higher allograft graft-failure rates for active patients under age 30, but the evidence is not absolutely conclusive. Starting with this study, ACL reconstruction using an allograft had a high failure rate in young, active adults. While there are obvious benefits of using the cadaver ligament, like avoiding a second surgical site on the patient, a quicker return to work and less postoperative pain, for the young patient who is very active, it may not be the right choice. (Luber, 2008) In this study military cadets who had ACL allograft reconstruction were almost seven times as likely to need a second surgery compared to autograft reconstruction. (Pallis, 2012) An analysis of over 16,000 patients with ACL surgeries (42% primary allografts) performed over a 6 ½ year period concluded that lower rates of graft survival were identified in younger patients and those with allografts. (Maletis, 2013) A 6-year follow-up of 980 primary ACLR patients resulted in an 18.9% re-operation rate with the conclusion that younger age at the index surgery and the use of allografts were predictors (risk factors) for subsequent surgery. (Hettrich, 2013) An earlier study involving the same Multicenter Orthopaedic Outcomes Network (MOON) cohort specifically concluded that graft rupture rate more than doubled with each 10 year age decrease and that the odds of allograft rupture was 4-times that of autograft. (Kaeding, 2011) Another MOON cohort author analyzed outcome data and reported that Revision ACLR and use of allograft predicted worse outcomes on the IKDC and both KOOS subscales. Choosing autograft rather than allograft, not smoking, and having normal body mass index are advised to improve long-term outcomes. (Spindler, 2011) No improvement in outcomes was noted in a 50 patient subset of the MOON cohort who had received platelet-rich plasma in conjunction with an allograft. (Magnussen, 2013) AAOS clinical practice guidelines also express some concern regarding use of allografts in young or highly active patients, but they conclude that that strong evidence supports the use of autograft and allograft equally. (AAOS, 2014) In this large study, improved sports function and patient-reported outcome measures were obtained when autograft was used, and use of autograft showed a decreased risk in graft rerupture at 2-year follow-up. (MARS, 2014) However, according to this systematic review, the current best available evidence suggests no differences in rupture rates and clinical outcomes. (Mascarenhas, 2014) And this meta-analysis also found no statistically significant difference in outcome between patients undergoing ACL reconstruction with hamstring autograft and soft-tissue allograft. (Cvetanovich, 2014) While use of autograft does not require much additional OR time (as little as 10 minutes for experienced surgeons), autograft does cause permanent hamstring deficiency of active knee flexion strength, which is an ACL dynamic agonist, or potential saphenous neurona pain, or significant incidence of anterior knee pain, superficial numbness, or potential patella fracture with patellar tendon bone-tendon-bone (BTB) graft. The length of time to cluch-free ambulation and transition to less restrictive activity is significantly less in allograft cases as is initial pain and narcotic use. There are trade-offs and graft decisions should be up to clinicians and their patients to discuss and decide the optimal choice.

**ODG Indications for Surgery™ -- Anterior cruciate ligament (ACL) reconstruction:**
1. **Conservative Care**: (This step not required for acute injury with hemarthrosis.) Physical therapy. OR Brace. PLUS

2. **Subjective Clinical Findings**: Pain alone is not an indication for surgery. Instability of the knee, described as "buckling or give way". OR Significant effusion at the time of injury. OR Description of injury indicates rotary twisting or hyperextension incident. PLUS

3. **Objective Clinical Findings (in order of preference)**: Positive Lachman's sign. OR Positive pivot shift. OR (optional) Positive KT 1000 (>3-5 mm = +1, >5-7 mm = + 2, >7 mm = +3). PLUS


For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

**MENISCETOMY**

Recommended as indicated below for symptomatic meniscal tears for younger patients and for traumatic tears. Not recommended for osteoarthritis (OA) in the absence of meniscal findings, or in older patients with degenerative tears until after a trial of PT/exercise. (Kirkley, 2008) (Khan, 2014) Meniscectomy is a surgical procedure associated with a high risk of knee osteoarthritis (OA). One study concludes that the long-term outcome of meniscal injury and surgery appears to be determined largely by the type of meniscal tear, and that a partial meniscectomy may have better long-term results than a subtotal meniscectomy for a degenerative tear. (Englund, 2001) Another study concludes that partial meniscectomy may allow a slightly enhanced recovery rate as well as a potentially improved overall functional outcome including better knee stability in the long term compared with total meniscectomy. (Howell-Cochrane, 2002) The following characteristics were associated with a surgeon's judgment that a patient would likely benefit from knee surgery: a history of sports-related trauma, low functional status, limited knee flexion or extension, medial or lateral knee joint line tenderness, a click or pain noted with the McMurray test, and a positive Lachmann or anterior drawer test. (Solomon, 2004) Our conclusion is that operative treatment with complete repair of all torn structures produces the best overall knee function with better knee stability and patient satisfaction. In patients younger than 35, arthroscopic meniscal repair can preserve meniscal function, although the recovery time is longer compared to partial meniscectomy. Arthroscopy and meniscus surgery will not be as beneficial for older patients who are exhibiting signs of degenerative changes, possibly indicating osteoarthritis, and meniscectomy will not improve the OA. Meniscal repair is much more complicated than meniscal excision (meniscectomy). Some surgeons state in an operative report that they performed a meniscal repair when they may really mean a meniscectomy. A meniscus repair is a surgical procedure done to repair the damaged meniscus. This procedure can restore the normal anatomy of the knee, and has a better long-term prognosis when successful. However, the meniscus repair is a more significant surgery, the recovery is longer, and, because of limited blood supply to the meniscus, it is not always possible. A meniscectomy is a procedure to remove the torn portion of the meniscus. This procedure is far more commonly performed than a meniscus repair. Most meniscus tears cannot be treated by a repair. See also Meniscal allograft transplantation. (Harner, 2004) (Graf, 2004) (Wong, 2004) (Solomon-JAMA, 2001) (Chatain, 2003) (Chatain-Robinson, 2001) (Englund, 2004) (Englund, 2003) (Menetrey, 2002) (Pearse, 2003) (Roos, 2000) (Roos, 2001) Arthroscopic debridement of meniscus tears and knees with low-grade osteoarthritis may have some utility, but it should not be used as a routine treatment for all patients with knee osteoarthritis.
(Siparsky, 2007) Asymptomatic meniscal tears are common in older adults, based on studying MRI scans of
the right knee of 991 randomly selected, ambulatory subjects. Incidental meniscal findings on MRI of the
tear are common in the general population and increase with increasing age. Identifying a tear in a person
with knee pain does not mean that the tear is the cause of the pain. (Englund, 2008) Arthroscopic meniscal
repair results in good clinical and anatomic outcomes. (Pujol, 2008) Whether or not meniscal surgery is
performed, meniscal tears in the knee increase the risk of developing osteoarthritis in middle age and
elderly patients, and individuals with meniscal tear were 5.7 times more likely to develop knee
osteoarthritis. (Englund, 2009) AHRQ Comparative Effectiveness Research concluded that arthroscopic
lavage for osteoarthritis, with or without debridement, does not improve pain and function for people
with OA of the knee. (AHRQ, 2011) The repair of meniscal tears is significantly improved when performed
in conjunction with ACL reconstruction. (Wasserstein, 2011) In patients with a nontraumatic degenerative
medial meniscal tear and no knee osteoarthritis, arthroscopic partial meniscectomy is no better than sham
surgery according to a high quality RCT. While arthroscopic partial meniscectomy is the most common
orthopedic procedure performed in the U.S., rigorous evidence of its efficacy is lacking. While the results
may argue against the current practice of performing arthroscopic partial meniscectomy in patients with a
degenerative meniscal tear, the study did not compare meniscectomy with no treatment, because in the
sham surgery group, they inserted an arthroscope and put fluid through the knee. (Sihvonen, 2013)

**Physical therapy vs. surgery:** In older patients with degenerative tears and symptoms caused by
osteoarthritis, PT/exercise may be an appropriate first option and it may be possible to reserve surgery for
those who do not benefit from PT alone. A high quality RCT, the Meniscal Tear in Osteoarthritis Research
(METEOR) trial, found similar outcomes from PT versus surgery for meniscal tears in older individuals.
Researchers at seven major universities and orthopedic surgery centers around the U.S. assigned 351
people with arthritis and meniscus tears to get either surgery or physical therapy, nine sessions on average
plus exercises to do at home. After six months, both groups had similar rates of functional improvement,
and pain scores were also similar. While 30% of patients assigned to physical therapy wound up having
surgery before the six months was up, often because they felt therapy wasn’t helping them, they ended up
the same as those who got surgery right away, as well as the rest of the physical therapy group who stuck
with it and avoided having an operation. These results suggest that physical therapy may be an
appropriate first option for many patients with osteoarthritis and meniscal tears and that it may be
possible to reserve surgery for those who do not benefit from physical therapy alone. (Katz, 2013) Another
RCT comparing meniscectomy to strengthening exercises in patients presenting with degenerative medial
meniscus tear and no clear evidence of osteoarthritis (Kellgren-Lawrence grade 0-1) found no significant
between-group differences in function, pain, or patient satisfaction scores. (Yim, 2013) Arthroscopic
surgery for knee osteoarthritis offers no added benefit to optimized physical and medical therapy,
according to the results of a single-center, RCT reported in the *New England Journal of Medicine*. The
study, combined with other evidence, indicates that osteoarthritis of the knee (in the absence of a history
and physical examination suggesting meniscal or other findings) is not an indication for arthroscopic
surgery and indeed has been associated with inferior outcomes after arthroscopic knee surgery. However,
osteoa rthritis is not a contraindication to arthroscopic surgery, and arthroscopic surgery remains
appropriate in patients with arthritis in specific situations in which osteoarthritis is not believed to be the
primary cause of pain. (Kirkley, 2008) In this RCT, arthroscopic partial medial meniscectomy followed by
supervised exercise was not superior to supervised exercise alone in terms of reduced knee pain, improved
knee function and improved quality of life, after non-traumatic degenerative medial meniscal tear in
ninety patients, mean age 56 years. (Herrlin, 2007) (Marcus, 2002) (Moseley, 2002) See also Arthroscopic surgery for osteoarthritis.

**ODG Indications for Surgery**

**Meniscectomy:**

*Criteria* for meniscectomy or meniscus repair (Suggest 2 symptoms and 2 signs to avoid scopes with lower yield, e.g. pain without other symptoms, posterior joint line tenderness that could just signify arthritis, MRI with degenerative tear that is often false positive). Physiologically younger and more active patients with traumatic injuries and mechanical symptoms (locking, blocking, catching, etc.) should undergo arthroscopy without PT.

1. **Conservative Care**: (Not required for locked/blocked knee.) Exercise/Physical therapy (supervised PT and/or home rehab exercises, if compliance is adequate). AND ( Medication. OR Activity modification [eg, crutches and/or immobilizer].) PLUS

2. **Subjective Clinical Findings** *(at least two)*: Joint pain. OR Swelling. OR Feeling of give way. OR Locking, clicking, or popping. PLUS

3. **Objective Clinical Findings** *(at least two)*: Positive McMurray's sign. OR Joint line tenderness. OR Effusion. OR Limited range of motion. OR Locking, clicking, or popping. OR Crepitus. PLUS

4. **Imaging Clinical Findings**: (Not required for locked/blocked knee.) Meniscal tear on MRI (order MRI only after above criteria are met). (Washington, 2003)

For average hospital LOS if criteria are met, see Hospital length of stay (LOS).
A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)