MEDICAL EVALUATORS
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Notice of Independent Review Decision

DATE OF REVIEW: 01/10/2014

DATE AMENDED: 02/12/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Right total knee replacement

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

The reviewer of this case is a board certified orthopaedic surgeon and has been licensed in the State of Texas since 2010. The reviewer has current hands on experience in the type of treatment/services being requested.

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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

EMPLOYEE CLINICAL HISTORY [SUMMARY]:

This is a male who sustained right knee injury on xx/xx/xx. Subsequently, he had right knee arthroscopic surgery with partial medial meniscectomy, chondroplasty, and injection on xxxxx. He continued to report constant right knee pain and weakness, A note indicates he had a fall a few weeks prior due to his right knee giving out. On right knee exam, there was minimal swelling, moderate medial joint line tenderness, and full ROM. Treatment history includes unsuccessful trial of physical therapy, injections, and medications. His past medical and surgical history includes hypertension, GERD, right shoulder surgery, cervical fusion, and chronic back and bilateral leg pain for which he had thoracic laminotomy and SCS placement in May 2006. He followed up on 10/07/2013 with worsening of right knee pain medially that was described as constant, moderate, and achy

that was exacerbated by stairs and standing from seated position. On physical exam, there was tenderness noted over medial capsule, no swelling or erythema, patellofemoral crepitus, positive patellar grind test, negative McMurray and Lachman tests, ROM was full in flexion and extension. No knee instability. Radiographs on 10/07/2013 showed patellofemoral and medial joint space narrowing. A follow up note dated 11/19/2013 indicates the examinee complained of significant pain and difficulty walking and his knee was giving out. On exam, he had antalgic gait, right knee range of motion was 0-100 degrees with varus deformity, crepitation and pain. The right knee radiographs on 11/19/2013 showed moderate degenerative changes, varus deformity, joint space narrowing, subchondral sclerosis, and arthritis medially. He was diagnosed with traumatic arthropathy and was recommended right total knee replacement.

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

In applying the ODG indications for surgery for this case, I think it is reasonable to conclude that this patient has failed an extended trial of conservative treatments. He has received both steroid and Synvisc injections, taken numerous medications, and completed physical therapy (2008) and aquatic therapy (2007). There were 2 previous adverse determinations based on the lack of a recent trial of therapy, however the ODG does not mandate that therapy trials be within a defined time period.

He has clearly limited ROM 0-100 with crepitus and pain, has had no pain relief with conservative modalities, and has obvious limitation in his current functional limitations displayed by his inability to return to work. Objectively, the patient is a male with a BMI of 46 (302 lbs). Imaging studies reveal varus deformity with notable medial and patellofemoral arthritis. Additionally, the patient had grade 2-4 chondromalacial changes noted on previous arthroscopy in 1997.

The sole contraindication in the ODG that I see for surgery in this patient is his obesity which has been correlated in traditional literature with increased perioperative and postoperative complications as well as a higher revision rate. However, numerous recent studies cited below clearly support the use of TKA in obese patients, and I think that rigid application of the ODG may be impractical for this particular case.

- The rate of failure of total knee implants, at least up to 5 years after surgery, and the time to failure, were not influenced by patients' BMI, except for subjects affected by morbid obesity, but this group had a small sample size. Based on this evidence, however, it does not appear justified to give low priority to obese subjects for total knee arthroplasty, which would, as a result of restored ability to move, lead to weight loss. (Bordini, 2009)
- A 2-year review of knee and hip replacement surgeries found that complication rates in obese patients were low, supporting doing the procedures even in the heaviest patients, but the review did show that

hospital stays were longer in those who were obese than in those who were not. (Parks, M 2010 “Complication Rates, Long Hospital Stays With Joint Replacement in Obese. National Medical Association (NMA) 2010 Annual Convention and Scientific Assembly: Presented August 1, 2010”)

- Obese patients may have clinically significant weight loss after total joint arthroplasty, since their osteoarthritis had limited their mobility and ability to exercise. When weight was corrected for natural gain, the overall study population had a trend toward weight loss, and 19.9% of the study population had clinically significant weight loss. (Stets, 2010)
- Obese patients are nearly twice as likely to incur infection after a total knee replacement, more than 2 times likely to incur deep infection, and slightly more likely to require a surgical revision than those who are not obese, according to a meta-analysis, but even with an elevated complication rate, total knee replacements provide an important improvement for patients with a high BMI. (Kerkhoffs, 2012)

In conclusion, the orthopedic literature completed in the past 10 years has trended heavily towards an evidence based support of TKA in obese patients. This can potentially result in significant subsequent improvements in pain, increased function, and weight loss. So interpreting the ODG guidelines as they apply to this case as well as the current peer reviewed literature, I would therefore disagree with the previous adverse determination.

ODG CRITERIA FOR KNEE JOINT REPLACEMENT:
Recommended as indicated below. Total hip and total knee arthroplasties are well accepted as reliable and suitable surgical procedures to return patients to function. The most common diagnosis is osteoarthritis. Overall, total knee arthroplasties were found to be quite effective in terms of improvement in health-related quality-of-life dimensions, with the occasional exception of the social dimension. Age was not found to be an obstacle to effective surgery, and men seemed to benefit more from the intervention than did women. (Ethgen, 2004) Total knee arthroplasty was found to be associated with substantial functional improvement. (Kane, 2005) Navigated knee replacement provides few advantages over conventional surgery on the basis of radiographic end points. (Bathis, 2006) (Bauwens, 2007) The majority of patients who undergo total joint replacement are able to maintain a moderate level of physical activity, and some maintain very high activity levels. (Bauman, 2007) Functional exercises after hospital discharge for total knee arthroplasty result in a small to moderate short-term, but not long-term, benefit. In the short term physical therapy interventions with exercises based on functional activities may be more effective after total knee arthroplasty than traditional exercise programs, which concentrate on isometric muscle exercises and exercises to increase range of motion in the joint. (Lowe, 2007) Accelerated perioperative care and rehabilitation intervention after hip and knee arthroplasty (including intense physical therapy and exercise) reduced mean hospital length of stay (LOS) from 8.8 days before implementation to 4.3 days after implementation. (Larsen, 2008) In this RCT, perioperative celecoxib (Celebrex)

significantly improved postoperative resting pain scores at 48 and 72 hrs, opioid consumption, and active ROM in the first three days after total knee arthroplasty, without increasing the risks of bleeding. The study group received a single 400 mg dose of celecoxib, one hour before surgery, and 200 mg of celecoxib every 12 hours for five days. (Huang, 2008) Total knee arthroplasty (TKA) not only improves knee mobility in older patients with severe osteoarthritis of the knee, it actually improves the overall level of physical functioning. Levels of physical impairment were assessed with three tools: the Nagi Disability Scale, the Instrumental Activities of Daily Living Scale (IADL) and the Activities of Daily Living (ADL) Scale. Tasks on the Nagi Disability Scale involve the highest level of physical functioning, the IADL an intermediate level, and the ADL Scale involves the most basic levels. Statistically significant average treatment effects for TKA were observed for one or more tasks for each measure of physical functioning. The improvements after TKA were "sizeable" on all three scales, while the no-treatment group showed declining levels of physical functioning. (George, 2008) This study showed that total knee replacement is second the most successful orthopaedic procedure for relieving chronic pain, after total hip. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. Hip replacement reduced pain to levels normal for age, reduced physical functioning to within 75% normal levels, and restored quality of life to virtually normal levels. Total knee replacement was the next most successful procedure, and it all but eliminated pain, improved physical functioning to 60% normal, and restored quality of life to within 65% of normal. (Hansson, 2008) A 6-week program of progressive strength training targeting the quadriceps femoris muscle group substantially improves strength and function following total knee arthroplasty for treatment of osteoarthritis, compared to patients who received standard of care therapy; however, addition of neuromuscular electrical stimulation (NMES) to the strength training exercise did not improve outcomes. (Petterson, 2009) Knee replacement surgery is expensive but worth the cost, especially if performed by experienced surgeons, according to a recent study. Some $11 billion is spent on 500,000 total knee replacements each year in the United States, and the number is projected to multiply seven times by 2030 because of the aging, overweight population. Over 90% knee replacements are successful, knee pain goes away and patients become more mobile. In the study, knee replacement surgery and subsequent costs added up to $57,900 per patient, which was $20,800 more than was spent on those who did not get the surgery. Those who got artificial knees lived more than a year longer in good health than those who did not, and the researchers calculated the added cost per year of good-quality life at $18,300. (Losina, 2009) In a 7-year prospective study, patients with severe osteoarthritis who had total knee replacement had significant improvements in health-related quality of life, but health outcomes were negatively influenced by obesity and postdischarge complications, and women typically did not get as much benefit from surgery as do men. Overall, 76.8% were satisfied or very satisfied with their total knee replacement, and 79.5% said they would have the surgery again in similar circumstances. (Núñez, 2009) More than 95% of patients report that they are satisfied with the outcome of their total knee replacement 1 year after surgery. Factors that increased risk for dissatisfaction were younger age, being

female, valgus alignment of the knee, and posttraumatic arthritis. (Ayers, 2010) Patients undergoing total knee arthroplasty (TKA) should receive ongoing COX-2 Inhibitor therapy for 6 weeks after their procedure, according to this unpublished RCT. (Schroer, 2011) In deciding who should have knee joint replacement surgery for osteoarthritis, we need to balance potential benefits against potential risks, using the concept of capacity to benefit, that the benefits of overcoming functional limitations should considerably outweigh any likely risks or unintended consequences in an individual by a considerable margin for it to be indicated for that person. (Dieppe, 2011) The prevalence of knee pain and knee replacement surgeries has risen substantially during the last 20 years, but the reasons for the increase remain obscure. The rise in knee surgeries may be linked more to an increased awareness of knee pain, as opposed to aging, increased obesity, or radiographic knee osteoarthritis. The authors recommend treating physicians carefully consider, from the signs and symptoms of the patient presenting with knee pain, a broad differential diagnosis, since not all knee pain in middle-aged and older adults is the result of osteoarthritis. (Nguyen, 2011) Knee replacement surgery is a success story of modern medicine, yet consensus is lacking about the precise indications for the procedure. The number of total knee replacements (TKRs) in the United States increased from 31.2 per 100,000 person-years in the period from 1971 to 1976 to 220.9 per 100,000 person-years in 2008, for a total that year of more than 650,000 procedures. Demand for knee replacement will continue to grow in light of aging populations and rising obesity rates, which both portend higher rates of osteoarthritis. Outcomes data break down into those for TKRs vs those for partial-knee replacements (PKRs). Surgeons and their patients sometimes will choose a PKR for the sake of a more normal-feeling knee, less extensive surgery, and a lower risk for infection, knowing that they have the option of converting to a TKR if need be. However, partial replacement has a higher risk for revision surgery than total replacement, and a conversion TKR is more likely to require more follow-up than a primary TKR, according to registry data. In addition to recommending better patient selection and better reporting of outcomes, particularly as it relates to individual implant devices, the authors also call for new strategies to treat early-stage osteoarthritis in younger patients that will avoid the need for major surgery altogether. (Carr, 2012) Since there is platinum level evidence that therapeutic exercise results in improved physical function for people with knee OA, this should be part of conservative care prior to knee arthroplasty. (Fransen, 2008) This systematic review concluded that PT interventions that empower patients to actively self-manage knee OA (such as aerobic, strength, and proprioception exercise) improved outcomes the best. (Wang, 2012) The latest AAOS Guidelines for Treatment of Osteoarthritis of The Knee, include a strong recommendation that patients with symptomatic osteoarthritis of the knee participate in self-management programs, strengthening, low-impact aerobic exercises, and neuromuscular education; and engage in physical activity consistent with national guidelines. (AAOS, 2013) Unicompartmental knee replacement: Recommended as an option. Unicompartmental knee replacement is effective among patients with knee OA restricted to a single compartment. (Zhang, 2008) In this RCT, the early results demonstrated that the unicompartmental knee replacement (UKR) group had less complications and more rapid rehabilitation than the total knee replacement (TKR) group. At five years there were an

equal number of failures in the two groups but the UKR group had more excellent results and a greater range of movement. The 15 years survivorship rate based on revision or failure for any reason was 89.8% for UKR and 78.7% for TKR. The better early results with UKR are maintained at 15 years with no greater failure rate. (Newman, 2009) Long-term studies are needed to appropriately define the role of less invasive unicompartmental surgical approaches. (Borus, 2008) Unicondylar knee arthroplasty (UKA) and total knee arthroplasty (TKA) are both recommended for the treatment of medial compartment osteoarthritis in the varus knee. Citing the arduous rehabilitation and bone loss associated with traditional knee arthroplasty, some opt for UKA, especially in young, high-demand patients. (McAllister, 2008) With appropriate patient selection, UKAs are a successful option for patients with osteoarthritis. (Dalury, 2009)

Bicompartmental knee replacement: Not recommended. See separate entry for Bicompartmental knee replacement.

Obesity: After total knee arthroplasty (TKA) for osteoarthritis of the knee, obese patients fare nearly as well as their normal-weight peers. A British research team reports that higher BMI (up to 35) should not be a contraindication to TKA, provided that the patient is sufficiently fit to undergo the short-term rigors of surgery. TKA also halts the decline and maintains physical function in even the oldest age groups (> 75 years). (Cushnaghan, 2008) In this study, the rate of failure of total knee implants, at least up to 5 years after surgery, and the time to failure, were not influenced by patients' BMI, except for subjects affected by morbid obesity, but this group had a small sample size. Based on this evidence, however, it does not appear justified to give low priority to obese subjects for total knee arthroplasty, which would, as a result of restored ability to move, lead to weight loss. (Bordini, 2009) Obese patients presented for and underwent joint replacement surgery at a younger age as compared to nonobese patients. (Gandhi, 2010) Adverse events (eg, perioperative complications, post-op wound infections) occurred in 14.2% of the non-obese, 22.6% of the obese and 35.1% of the morbidly obese patients after total knee replacement. (Dowsey, 2010) A 2-year review of knee and hip replacement surgeries found that complication rates in obese patients were low, supporting doing the procedures even in the heaviest patients, but the review did show that hospital stays were longer in those who were obese than in those who were not. (Parks, 2010) Obese patients may have clinically significant weight loss after total joint arthroplasty, since their osteoarthritis had limited their mobility and ability to exercise. When weight was corrected for natural gain, the overall study population had a trend toward weight loss, and 19.9% of the study population had clinically significant weight loss. (Stets, 2010) Obese patients are nearly twice as likely to incur infection after a total knee replacement, more than 2 times likely to incur deep infection, and slightly more likely to require a surgical revision than those who are not obese, according to a meta-analysis, but even with an elevated complication rate, total knee replacements provide an important improvement for patients with a high BMI. (Kerkhoffs, 2012)

Minimally invasive total knee arthroplasty: No significant benefit was seen in using a minimally invasive surgical technique over a standard traditional technique for total knee arthroplasty, but the study did not focus on quality-of-life outcomes (eg, length of hospital stay, reliance on pain medications, and the need for inpatient rehabilitation after

discharge), in which the minimally invasive approach is purported to show an advantage. (Wülker, 2010)
Bilateral knee replacement: The safety of simultaneous bilateral total knee replacement remains controversial. Compared with staged bilateral or unilateral total knee replacement, simultaneous bilateral total knee replacement carries a higher risk of serious cardiac complications, pulmonary complications, and mortality. (Restrepo, 2007)
Recommend that congestive heart failure and pulmonary hypertension be contraindications for bilateral total knee arthroplasty (BTKA), but not age per se. BTKA is seen as offering advantages over staged unilateral knee replacement surgery, including reduced time in the hospital, decreased costs, and a faster return to active life. The procedure also has been shown, however, to carry an increased risk for morbidity and mortality compared with unilateral knee replacement, with overall incidence of major in-hospital complications and mortality of 9.5%. Patients with the highest risk for adverse outcomes were those with congestive heart failure (odds ratio [OR], 5.5) compared with those without comorbidities, and those with pulmonary hypertension (OR, 4.1). Other risk factors included older age, with patients who were 65 to 74 years old or older than 75 years having about twice the likelihood of complications compared with patients 45 to 65 years old. Men also showed a 50% greater risk for complications than women. Older age, however, should not necessarily rule out patients who can otherwise benefit from bilateral knee replacement, and age by itself will be a risk factor in any kind of surgery. Factors that can increase the risk with congestive heart failure include bone particles and marrow entering the bloodstream to embolize in the pulmonary vasculature and other organs. (Memtsoudis, 2011)
Revision total knee arthroplasty is an effective procedure for failed knee arthroplasties based on global knee rating scales. (Saleh, 2002) It would be recommended for failure of the originally approved arthroplasty.
ODG Indications for Surgery -- Knee arthroplasty:
Criteria for knee joint replacement (If only 1 compartment is affected, a unicompartmental or partial replacement may be considered. If 2 of the 3 compartments are affected, a total joint replacement is indicated.):
1. Conservative Care: Exercise therapy (supervised PT and/or home rehab exercises). AND Medications. (unless contraindicated: NSAIDs ORVisco supplementation injections OR Steroid injection). PLUS
2. Subjective Clinical Findings: Limited range of motion (<90° for TKR). AND Nighttime joint pain. AND No pain relief with conservative care (as above) AND Documentation of current functional limitations demonstrating necessity of intervention. PLUS
3. Objective Clinical Findings: Over 50 years of age AND Body Mass Index of less than 35, where increased BMI poses elevated risks for post-op complications. PLUS
4. Imaging Clinical Findings: Osteoarthritis on: Standing x-ray (documenting significant loss of chondral clear space in at least one of the three compartments, with varus or valgus deformity an indication with additional strength). OR Previous arthroscopy (documenting advanced chondral erosion or exposed bone, especially if bipolar chondral defects are noted). (Washington, 2003) (Sheng, 2004) (Saleh, 2002) (Callahan, 1995)

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For average hospital LOS if criteria are met, see Hospital length of stay (LOS). See also Skilled nursing facility LOS (SNF)

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**

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

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☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**

☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**

☐ **TEXAS TACADA GUIDELINES**

☐ **TMF SCREENING CRITERIA MANUAL**

X **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**

☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**

1) Bordini B, Stea S, Cremonini S, Viceconti M, De Palma R, Toni A. Relationship between obesity and early failure of total knee prostheses. *BMC Musculoskeletal Disorder*. 2009 Mar 5;10:29.

2) Stets K, Koehler SM, Bronson W, Chen M, Yang K, Bronson MJ Weight and Body Mass Index Change After Total Joint Arthroplasty, Orthopedics June 2010, Volume 33, Issue 6:386

3) Kerkhoffs GM, Servien E, Dunn W, Dahm D, Bramer JA, Haverkamp D. The influence of obesity on the complication rate and outcome of total knee arthroplasty: a meta-analysis and systematic literature review. *J Bone Joint Surg Am.* 2012 Oct 17;94(20):1839-44. doi: 10.2106/JBJS.K.00820.