Becket Systems

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Notice of Independent Review Decision

Amended Letter 08/03/18

Description of the service or services in dispute:

Right Total Knee Replacement
Walker
Quad cane
Post-operative knee bracing
E0168 3-in-one commode
E0676 Mechanical deep vein thrombosis (DVT) prophylaxis
Physical therapy

Description of the qualifications for each physician or other health care provider who reviewed the decision:

Board Certified Orthopedic Surgery

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

- ☐ Overturned (Disagree)
- ☑ Upheld (Agree)
- ☐ Partially Overturned (Agree in part / Disagree in part)

Patient Clinical History (Summary)

Xx is a XX who was diagnosed with right knee complex patella fracture status post open reduction and internal fixation, right knee internal derangement and status post right knee surgery on XX with Dr. XX. XX had sustained a work-related injury to XX right knee on XX when XX fell XX XX.

On XX, XX was evaluated by XX, MD for a postoperative follow-up. XX was still having sharp pain. The pain score at rest was 6/10 and worse with ambulation. On examination, the right knee surgical incision was clean, dry, intact and healed. There was no drainage or redness. There was positive stiffness. Range of motion was 5-90 degrees with tenderness at the joint line with positive quadriceps atrophy. Gait was antalgic. Dr. XX opined XX would benefit from a right total knee replacement surgery, postoperative knee bracing, walker, quad cane, 3-in-1 commode, postoperative mechanical deep vein thrombosis prophylaxis with use of Venapro devices and postoperative right knee therapy three times per week for six weeks.

A right knee x-ray dated XX showed healed patella fracture with retained fracture.

The treatment to date included medications (XX) right knee surgeries; injections, orthotics and physical therapy sessions.

Per a utilization review determination letter by XX, MD dated XX, the requested services of total knee arthroplasty, knee orthosis, intermittent limb compression device and physical therapy were non-certified. Rationale: The claimant presents with right knee pain after XX fell XX XX while working as an XX. The claimant is status post a right patella removal of failed hardware performed on XX by Dr. XX. The claimant has trialed oral medications, injections, orthotics and an unknown amount of physical therapy. With all this, there is no evidence of degenerative changes seen on imaging affecting at least two of three knee compartments to warrant a total knee arthroplasty. Furthermore, there is no indication of BMI or when the last injection was given. I recommend non-certification of the request for a right knee total knee a1throplasty."

Per a utilization review adverse determination dated XX by XX, MD, the requested services were non-certified. Rationale: "Within the associated medical file, there is documentation of the XX UR Determination identifying that an adverse determination was rendered due to a lack of documentation of evidence of degenerative changes on imaging affecting at least two of three knee compartments, BMI, as well as the date of service from when the last injection was given. In addition, there remains documentation of subjective (stiffness, joint pain, and current significant functional limitations) and objective (XX) findings, and minimal pain relief with conservative care (including physical therapy and medications). However, despite a diagnosis of post-traumatic arthritis, there is no documentation of osteoarthritis on x-rays. In addition, there remains no documentation of evidence of degenerative changes on imaging affecting at least two of three knee compartments. Furthermore, there is no documentation that the patient has a Body Mass Index of less than 40. Therefore, I am recommending non-certifying the request for Recon: Right Total Knee Replacement. Given my recommendation for non-certification of the associated surgical request, I am recommending non-certifying the request for walker, quad cane,3-in-one commode, mechanical deep vein thrombosis (DVT) prophylaxis and physical therapy."

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

The ODG recommends knee joint replacement when there are persistent subjective findings despite conservative care, the individual is over XX, the individual has a body mass index of less than 40, and x-rays demonstrate significant loss of the chondral clear space in at least one of the three compartments. There is evidence of persistent right knee pain despite conservative treatment with oral medications, injections and physical therapy; however, there is no documentation of osteoarthritis on x-ray. In addition, the body mass index is not documented. Based on the lack of documented degenerative joint disease on x-ray, the right total knee replacement is not medically necessary. As the surgery is not medically necessary, the requests for a walker, quad cane, three-in-one commode, mechanical deep vein thrombosis prophylaxis, and physical therapy are not medically necessary. As such, the recommendation is to uphold the two previous denials.

A description and the source of the screening criteria or other clinical basis used to make the decision:

☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards

☑ ODG-Official Disability Guidelines and Treatment Guidelines

Knee and Leg Chapter

Durable medical equipment (DME) Recommended generally if there is a medical need and if the device or system meets Medicare's definition of durable medical equipment (DME) below.

See also specific recommendations here: Aquatic therapy; Bathtub seats; BioniCare® knee device; Bone growth stimulators; Braces; Canes; Cold/heat packs; Compression cryotherapy; Continuous-flow cryotherapy; Continuous passive motion (CPM); Crutches; Cryocuff; Cryotherapy; Dynamic splinting systems; Dynasplint; Electrical stimulators (E-stim); Electromyographic biofeedback treatment; ERMI knee Flexionater®/ Extensionater®; Flexionators (extensionators); Exercise equipment; Game Ready™ accelerated recovery system; Home exercise kits; Joint active systems (JAS) splints; Knee brace; Lymphedema pumps; Mechanical stretching devices (for contracture and joint stiffness); Motorized scooters; Neuromuscular electrical stimulation (NMES devices); Orthoses;Post-op ambulatory infusion pumps (local anesthetic); Power mobility devices (PMDs); RS-4i sequential stimulator; Scooters; Shower grab bars; TENS (transcutaneous electrical nerve stimulation); Therapeutic knee splint; Treadmill exerciser; Trekking poles; Unloader braces for the knee; Vacuum-assisted closure wound-healing; Vasopneumatic devices; Walkers; Walking aids (canes, crutches, braces, orthoses, and walkers); Wheelchair; Whirlpool bath equipment.

The term DME is defined as equipment that
(1) Can withstand repeated use, i.e., could normally be rented and used by successive patients;

(2) Is primarily and customarily used to serve a medical purpose;
(3) Is generally not useful to a person in the absence of illness or injury; and
(4) Is appropriate for use in a patient's home. (CMS, 2005)

Most bathroom and toilet supplies do not customarily serve a medical purpose and are primarily used for convenience in the home. Medical conditions that result in physical limitations for patients may require patient education and modifications to the home environment for prevention of injury, but environmental modifications are considered not primarily medical in nature. Certain DME toilet items (commodes, bed pans, etc.) are medically necessary if the patient is bed- or room-confined, and devices such as raised toilet seats, commode chairs, sitz baths and portable whirlpools may be medically necessary when prescribed as part of a medical treatment plan for injury, infection, or conditions that result in physical limitations. Many assistive devices, such as electric garage door openers, microwave ovens, and golf carts, were designed for the fully mobile, independent adult, and Medicare does not cover most of these items.

Intermittent pneumatic compression devices Recommended for short-term mechanical thromboprophylaxis for moderate- to high-risk perioperative surgical and hospitalized patients, especially following lower extremity trauma. Best practices involve use of simple, practical, and inexpensive lower leg-only devices, combined with pharmacological thromboprophylaxis when medically feasible. Although mechanical methods do reduce the risk of deep vein thrombosis [DVT], there is no evidence that they reduce the main threats, pulmonary embolism [PE], fatal PE, or total mortality. In contrast, pharmacological methods significantly reduce all of these outcomes. Not recommended for home use due to a lack of quality evidence, associated counter-productive immobilization, and patient non-compliance issues. See also Venous thrombosis, Compression garments and Vasopneumatic devices.

An intermittent pneumatic compression device (IPCD) is also referred to as a standard pneumatic compression device (SPCD) or a sequential compression device (SCD). This device is different from a lymphedema pump, also called an advanced pneumatic compression device (APCD), which is a more complex, durable, and expensive adjunct specifically designed for long-term home use. The distinction between standard devices for the prevention of DVT and complex devices for the treatment of chronic lymphedema are reflected in different billing codes, which should be appropriately used depending on prophylactic vs. chronic treatment indications (e.g., E0676 vs. E0650, E0651, and E0652).

A Cochrane systematic review (SR) of 22 trials (9137 participants) showed moderate quality evidence for combining IPCD and pharmacological prophylaxis, as compared to each alone; these results support most current guideline recommendations for the use of combined modalities in hospitalized patients, limited to patients with trauma or undergoing surgery. Evidence is also consistent that while symptomatic DVT has been reduced with IPCD alone, only anticoagulation or combined approaches have actually decreased the incidence of PE. (Kakkos, 2016) These findings are further supported by another meta-analysis (MA) of 16,164 hospitalized patients (70 trials) where IPCD was more effective than either no device use or compression stockings in reducing DVT incidence, with combined pharmacological thromboprophylaxis further reducing risk. (Ho, 2013) An MA of 9 studies and another SR of 14 RCTs both concluded that IPCD alone and chemoprophylaxis alone were equally effective but that a combined approach was superior for higher-risk surgical patients. (O'Connell, 2016) (Pavon, 2016) IPCDs have also been shown to be effective and inexpensive for DVT prophylaxis and improved survival in a large multi-center trial of hospitalized stroke patients. (Dennis, 2015)

Since current evidence guiding specific device selection remains limited, it has been suggested that flexibility and acceptance by nursing staff and patients, as well as costs, should be considered. Compliance with IPCDs has been problematic. An MA of 7 studies revealed 25% nonadherence during hospitalization with IPCDs. (Craigie, 2015) While home use of IPCDs still lacks any compelling evidence in the literature, it must be assumed that compliance would be even worse without nursing oversight. Different types of IPCDs for prevention of DVT after total hip replacement lack quality evidence due to a high bias risk, according to another SR. Making an informed selection regarding specific devices remains difficult due to differing compression garments, location of air bladders, patterns of pump pressure cycles, compression profiles, cycle length, duration of inflation/deflation times, and cycling modes. (Zhao, 2014) An RCT with and without a foot pump device in combination with anticoagulation failed to demonstrate any difference between groups regarding DVT incidence for total knee arthroplasty patients. (Sakai, 2016) This finding suggests that leg compression devices are preferable to foot-only models. Thigh/leg devices are more difficult to use, and there are no studies showing any superiority over standard leg models. Upon discharge from healthcare facilities, use of chemoprophylaxis alone for high-risk patients is best supported by existing evidence, unless medically contraindicated.

ODG, XX: Knee and Leg
Knee joint replacement
Recommended as indicated below. Both total hip and total knee arthroplasty (TKA) are well accepted as reliable and suitable surgical procedures to return highly symptomatic patients to better function. The most common indicated diagnoses are advanced osteoarthritis (OA) followed by rheumatoid arthritis. Recent population-based

studies have raised serious questions regarding the efficacy of TKA for individuals with only mild-to-moderate disease.
See also Computer-assisted navigation surgery; Customized knee joint replacement; Outpatient joint replacement; Robotic-assisted knee surgery; and Surgery for arthrofibrosis.
ODG Indications for Surgery™ -- Knee arthroplasty:
(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.)
Criteria for knee joint replacement:
1. Conservative Care:
(a) Exercise therapy (supervised PT and/or home rehab exercises) and
(b) Medications (unless contraindicated: NSAIDs OR Viscosupplementation injections OR Steroid injections) {Surgery should be delayed at least 6 months following any intra-articular corticosteroid injection due to the risk of infection}. AND
(c) Documented significant weight loss effort with BMI > 35 PLUS
2. Subjective Clinical Findings:
(a) Stiffness and
(b) Nighttime joint pain and
(c) Marked daily pain despite conservative care AND
(d) Documentation of current significant functional limitations including limited mobility. PLUS
3. Objective Clinical Findings:
(a) XX and
(b) Body mass index (BMI) < 40, as increased BMI poses elevated risks for post-op complications. {Pre-operative bariatric surgery is not supported, but may be otherwise indicated for unrelated medical (disease of life) reasons} PLUS
4. Imaging Clinical Findings: Osteoarthritis on either
(a) Standing X-ray (documenting significant loss of chondral clear space in at least one of the three compartments; varus or valgus deformity with medial or lateral loss of joint space) OR
(b) Previous arthroscopy (documenting advanced chondral erosion or exposed bone, especially if bipolar chondral defects are noted). (Washington, 2003) (Sheng, 2004) (Saleh, 2002) (Callahan, 1995)
For average hospital LOS if criteria are met, see Hospital length of stay (LOS). See also Skilled nursing facility LOS (SNF).

Appeal Information

You have the right to appeal this IRO decision by requesting a Texas Department of Insurance, Division of Workers' Compensation (Division) Contested Case Hearing (CCH). A Division CCH can be requested by filing a written appeal with the Division's Chief Clerk no later than 20 days after the date the IRO decision is sent to the appealing party and must be filed in the form and manner required by the Division.

Request for or a Division CCH must be in writing and sent to:
Chief Clerk of Proceedings Texas Department of Insurance
Division of Workers' Compensation P. O. Box 17787
Austin, Texas, 78744

For questions regarding the appeals process, please contact the Chief Clerk of Proceedings at 512-804-4075 or 512- 804-4010. You may also contact the Division Field Office nearest you at 1-800-252-7031.