Clear Resolutions Inc.

An Independent Review Organization
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Description of the service or services in dispute:

XX XX resurfacing, XX knee.

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

Board Certified Orthopedic Surgeon

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)

XXXX who was diagnosed with patellofemoral disorders, XX knee (M22.2X2) / XX knee patellofemoral arthritis and pain in the XX knee (M25.562). XXXX injury occurred on or about XXXX. There was a history of prior injury to the knee.

XXXX for XX knee pain. XXXX described the pain as throbbing, sharp, severe, continuous and rated at 10/10. XXXX also experienced clicking, instability, snapping / popping, swelling, night pain, pain with sports / activities, radiating pain, and daytime pain with rest. The symptoms were worse with weightbearing, standing, driving, squatting, kneeling, bending, climbing stairs, twisting, moving, walking, engaging in athletics, and lifting. XXXX used a walker and cane for assistance and symptom relief at the time. Review of systems was significant for weakness of the XX thigh and XX knee, difficulty sleeping, and joint pain. The XX knee examination showed an XX gait, minimal effusion, pain / tenderness of the patella, patellofemoral crepitus, and patellar grind. XXXX without restriction. XXXX was to remain weightbearing as tolerated.

An undated x-ray of the XX knee showed XX sclerosis, XX XX, and joint space narrowing. There was XX noted in the XX.

The treatment to date included ice and heat application; rest; medications including XXXX, XX, XX XX, and XX; physical therapy; assistive devices; immobilization; XX unit; and home exercises.

Per a utilization review decision letter dated XXXX and a peer review by XXXX, the request for XX knee XX resurfacing was denied. Rationale: "Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request is non-certified. Detailed evidence of reasonable and/or comprehensive nonoperative management treatment protocol trial and failure cannot be established. Submitted documents do not demonstrate evidence of adequate course of physical therapy or provision of other forms of conservative measures. Exceptional factors were not addressed."

Per a reconsideration review decision letter dated XXXX and a peer review by XXXX, the appeal request for XX knee XX resurfacing was not approved. Rationale: "Based on the clinical information submitted for this review and using the evidence-based, peer reviewed guidelines referenced above, this request is non-certified. There were limited objective significant findings in the recent medical report that would validate focal articular defects. There was no clear evidence of exhaustion of conservative treatments, as there were no therapy reports submitted with this request. There were no additional records submitted with significant findings that would overturn the prior denial of this request. Furthermore, the peer discussion with XXXX, it was stated that the patient has been treated "XXXX" for this problem. The patient has shots, and a knee scope, with no improvement. The provider states the knee makes a horrible noise when XXXX moves, there is a patellofemoral arthritis noted. The patient has had multiple images done over the years, it is stated. After this discussion, the provider affirmed the patient had extensive conservative treatment, with patellofemoral arthritis seen on imaging. Understanding the long course of treatment, this procedure does not fall within guidelines, as it is still unclear if this procedure will alleviate the pain. The request remains not medically necessary."

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

The ODG states that focal joint resurfacing of the knee is not recommended until quality studies are available. The available information indicates persistent XX knee pain approximately XXXX. It is noted that the symptoms persist despite treatment with ice, heat, rest, muscle relaxants, physical therapy, and assistive device, mobilization, XX, XX, a XX unit and home exercises. XX knee x-rays from XXXX demonstrate mild patellofemoral arthritis. There are no recent MRI findings documenting the state of the articular cartilage of the XX and XX. It is unclear why a patellofemoral resurfacing procedure is recommended in the setting of only mild XX. In addition, it is unclear if there are any degenerative changes in the medial or lateral compartments that would not support an isolated XX resurfacing. Based on the provided documentation and ODG recommendation, the XX knee focal joint resurfacing is not medically necessary.

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

☐ ACOEM-America College of Occupational and Environmental Medicine
☐ AHRQ-Agency for Healthcare Research and Quality Guidelines
☐ DWC-Division of Workers Compensation Policies and Guidelines
☐ European Guidelines for Management of Chronic XX Pain
☐ Interqual Criteria
☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards
☐ Mercy Center Consensus Conference Guidelines
☐ Milliman Care Guidelines
☑ ODG-Official Disability Guidelines and Treatment Guidelines

Knee and Leg Chapter

Focal joint resurfacing
Not recommended until quality studies are available. Focal resurfacing of a knee joint defect is a surgical procedure in which a limited amount of bone is removed from the surface of the joint and then replaced with a metal or metal/plastic implant. It is proposed as an alternative to unicompartmental knee replacement or total knee replacement, involving less removal of the bone and theoretically allowing more normal joint function. Candidates for resurfacing may be younger in age, physically active, and have focal articular defects (i.e., early stage OA changes that are isolated), or it may be advocated in middle aged and older patients. Patient selection criteria are not clear. The two FDA approved knee resurfacing prostheses are the XX knee resurfacing implant (XX). These devices were approved through the FDA 510(k) abbreviated approval process [meaning they are not entirely new devices], and they are intended to be used with bone cement.
Evidence in the peer-reviewed published scientific literature evaluating safety and efficacy of focal knee joint resurfacing using these devices is limited and based on low-quality studies, just case series. Although there was improvement in pain and function scores, the studies were limited by small populations, lack of control groups and short to mid-term outcomes. Published data regarding the safety, efficacy and improved health outcomes with the use of this technology is insufficient and precludes the ability to draw conclusions at this time. In this small case series, the device appeared to be an effective reconstructive treatment option after five years for large full-thickness cartilage and osteochondral lesions of the knee in middle aged patients. (Becher, 2011)
According to this case series, focal femoral condyle resurfacing demonstrated excellent results for pain and function in middle-aged, well selected patients with full thickness cartilage and osteochondral defects. Patient profiling and assessment of confounding factors (in particular, mechanical joint alignment, meniscal function, and healthy opposing cartilage surfaces) are important for an individual treatment approach and successful outcomes. Treatment options for localized full thickness defects of the femoral condyle are numerous in young patients, but they become increasingly challenging in middle aged and older patients. The conclusion was that the focal inlay resurfacing procedure may delay traditional joint replacement procedures and provide a soft tissue and bone sparing alternative. (Bollars, 2012) Focal femoral inlay resurfacing has been developed for the treatment of full-thickness chondral defects of the knee. This technique involves implanting a defect-sized metallic or ceramic cap that is anchored to the XX bone through a screw or pin. The use of these experimental caps has been advocated in middle-aged patients who have failed non-operative methods or biological repair techniques and are deemed unsuitable for

conventional arthroplasty because of their age. (Brennan, 2013)

- ☐ Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and Practice Parameters
- ☐ Texas ACADA 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)

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.