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Notice of Independent Review Decision

January 2, 2018

IRO CASE #: XXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Right ankle steroid injection under fluoroscopy

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

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:
X Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a XXXXX XXXX who was injured on XXXXX. XXXX was diagnosed with the posttraumatic degenerative joint disease (DJD) of the right ankle, sprain of deltoid ligament of the right ankle, sprain of syndesmosis of the right ankle and fracture of the shaft of the right fibula. The exact mechanism of injury is not available.

On XXX, XXXX, M.D., evaluated the patient in a follow-up visit. The patient reported right ankle pain due to a work-related injury in XXX. XXXX had been lost to follow-up since XXXX. XXXX had been doing reasonably well. XXXX still had occasional pain in the ankle with activities. XXXX tried to remain active with lower impact activities. XXXX was not taking any medications. The history was notable for hypertension and open reduction, internal fixation (ORIF) of the right ankle fracture and syndesmosis in XXXX. On examination, the patient's BMI was 54.99. The patient ambulated on XXXX right lower extremity with a normal gait. The alignment was satisfactory. XXXX incisions had healed without signs of infection. There was some diffuse swelling around the ankle. There was no point tenderness. Light touch was intact, and there were good distal pulses. X-rays of the right ankle dated XXXXX, revealed postoperative changes. There were some posttraumatic degenerative changes in the ankle. There was a large posterior calcaneal spur with some Achilles calcification. Dr. XXXX diagnosed posttraumatic DJD of the right ankle, sprain of the deltoid ligament of the right ankle, sprain of syndesmosis of the right ankle and fracture of the shaft of the right fibula. Dr. XXXX recommended right ankle steroid injection under radiographic guidance for hopeful pain relief. The patient was advised to continue with all activities as tolerated.

On XXXX, a preauthorization request for right ankle steroid injection under fluoroscopy was submitted.

Per utilization review dated XXXX, XXXX, M.D., denied the request for right ankle steroid injection under fluoroscopy. Rationale: *"The available documents indicate that the claimant has chronic ankle pain and is doing relatively well, without complaints of loss of functionality, loss of time from work, decrease in physical activities, and is not taking any pain medications. There is no evidence based on the claimant's examination, nor history that the claimant will benefit from a right ankle steroid injection. In addition, ODG does not recommend steroid injections for the ankle/foot, as there is little evidence for any substantial effectiveness and a higher risk of harm. Therefore, based on the available documents and guideline recommendations, the request for right ankle steroid injection under fluro is recommended not certified".*

On XXXX, Dr. XXX appealed the denied services.

On XXXX, XXXX, M.D., completed a reconsideration review and upheld the denial based on the following rationale: "*Within the associated medical file, there is documentation of some diffuse swelling around the ankle. However, there is no point tenderness. Gait is normal. There are no additional documented deficits on the physical exam to warrant authorization for this injection. There is insufficient documentation contraindicating other guideline-supported treatment for the claimant's condition. Therefore, I am recommending non-certifying the request for Reconsideration: Right ankle steroid injection under fluoroscopy (CPT 20610, 76000)."*

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

ODG does not recommend intra-articular steroid injection of the ankle joint. The documentation provided by the requesting provider does not provide evidence-based references that may supersede ODG. The determination of NON-CERTIFICATION by the previous two reviewers appears to be accurate.

Per ODG:
Not recommended. Although corticosteroid injections (CSI) have very poor evidence for foot and ankle conditions with potential for harm, higher quality research also results in non-recommendation for most other forms of injection therapy. When approval occurs for individual patients beyond these guidelines, then only a one-time injection using lower corticosteroid doses and minimal-to-no intra-articular anesthetic would be advised. Specific conditions are discussed below.

See also Alcohol injections (for Morton's neuroma); Hyaluronic acid injections; Autologous blood-derived injections; Platelet-rich plasma(PRP); Sural nerve block; Percutaneous needle tenotomy (PNT).

A retrospective case series of 365 patients who received corticosteroid injections for a variety of foot and ankle conditions with 2-year follow up showed significant improvement in 86%, complete pain resolution in 66%, but only 29% remained asymptomatic at 2-years. Complications which included flare reactions and plantar plate ruptures were low (1.3%), with no infections reported. Better results were observed with ankle soft tissue impingement, but injections were ineffective for longer than 3 months for plantar fasciitis and hallux rigidus. (Grice, 2017) A systematic review (SR) of CSI for tendinopathies including 50 studies (13 human, 36 animal) noted good evidence that glucocorticoids caused significant negative effects on tendon cells in vitro, specifically causing reduction of cell viability, cellular

proliferation, and collagen synthesis. In vivo studies showed increased collagen disorganization and necrosis, with mechanical strength being significantly reduced. (Dean, 2014) Extracellular matrix synthesis, particularly type 1 collagen was reduced and inflammatory cells infiltrated tendon tissue. The authors suggested caution and sensible moderation when using CSI for select conditions. (Dean, 2016) In addition, CSI causes impaired fibroblast viability and depletion of stem cell pools, making it a questionable choice, especially for later-stage tendinopathies. (Abate, 2017)

Risks associated with IA corticosteroid injections are likely higher than historically believed. An analysis of 278 medico-legal cases involving complications following IA, paravertebral, intramuscular, and other site cortisone injections noted that almost 40% involved treatment errors including poor aseptic technique, lack of indications, excessive dosing, and too short time intervals between injections. The authors warned that patients should be better informed of potential risks for infection and tissue atrophy, especially with repeat injections, and that introduction of crystals into subcutaneous and adipose tissue should be avoided. (Holland, 2012) An SR including 40 studies indicated that methylprednisolone, dexamethasone, hydrocortisone, betamethasone, prednisolone, and triamcinolone all displayed dose- and time-dependent deleterious chondrotoxic effects, especially > 3 mg/dose or 18-24 mg/cumulative total dose in vivo. The authors recommended using the lowest possible doses and longer time intervals between injections. (Wernecke, 2015) The addition of local anesthetics, particularly 1% lidocaine and 0.25% (or higher) bupivacaine to corticosteroids further worsens the chondrotoxic effects in vitro. (Braun, 2012) An SR of 12 studies on the chondrotoxic effects of single doses of 4 different local anesthetics indicated that bupivacaine and lidocaine were significantly worse than mepivacaine and ropivacaine. Cytotoxicity caused by all 4 anesthetics was dependent on dose, time, and type of local anesthetic. Osteoarthritic cartilage is more vulnerable with destructive effects first in the superficial chondral layers, including loss of membrane integrity, mitochondrial DNA, and nuclear changes. (Kreuz, 2017)

Intra-articular corticosteroids: **Not recommended, although this does not preclude diagnostic anesthetic injections. See the discussion above. Most evidence regarding any efficacy of intra-articular CSI is limited to the knee (questionable benefit), with almost no trials addressing joints of the foot and ankle. No independent clinical factors were identified that could predict any reliable post-injection response and evidence remains limited. (Ward, 2008) A Cochrane SR of conservative treatments for osteoarthritis (OA) of the ankle identified several RCTs related to hyaluronic acid (HA) injections, but none for CSI. Overall, injection treatments for ankle OA has insufficient data to support it, with even the HA studies being low quality evidence. (Witteveen, 2015)**

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES