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IRO REVIEWER REPORT

April 10, 2018

IRO CASE #: XXXXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Denial of intra-articular corticosteroid injection to subtalar joint

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

This case was reviewed by a Board-certified Orthopedic Surgeon who is considered to be an expert in their field of specialty with current hands on experience in the denied coverage

REVIEW OUTCOME:

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

X Overturned (Disagree)

PATIENT CLINICAL HISTORY [SUMMARY]:

This patient is a XX who sustained injury to XX on XXXX as a result of XX. XX sustained a right ankle dislocation and was subsequently treated with open reduction internal fixation. Due to persistent pain, XX later underwent ankle arthroscopy, debridement, and biopsy via arthrotomy and then finally ankle arthrodesis with Achilles lengthening and excision of superficial peroneal neuroma on XXXX. XX has undergone conservative treatments including physical therapy, home exercises, oral pain medications, and injection of the superficial peroneal nerve with partial relief on XXXX. At office visit with XX dated XXXX, XX had complaints of persistent activity-related right ankle pain over the lateral ankle and equinus deformity. Physical exam revealed a weight of XX, mild equinus deformity, right ankle swelling, right lateral ankle tenderness, decreased subtalar motion with some pain, and decreased sensation over the dorsum of the foot. The provider recommended injection of the subtalar joint by radiology to evaluate possible secondary arthritis resulting from his dislocation and fusion. This case has undergone 2 previous adverse determinations secondary to lack of support from ODG for intraarticular corticosteroid injection.

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

The ODG (Official Disability Guidelines) generally does not support the use of corticosteroid injections in the joints of the foot and ankle; however, “this does not preclude diagnostic anesthetic injections”. The ODG further indicates that, “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”. This individual sustained a severe right ankle injury that required ankle fusion at XX. Based on this, XX is at high risk for degeneration of adjacent joints, namely the subtalar joint. Given XX, injury severity, and body weight, it is very likely that XX subtalar joint is involved. It is the opinion of this reviewer that a single, diagnostic injection would be of great utility in determining if the subtalar joint is indeed involved. If XX pain is relieved or improved with the injection, this could guide further potential surgical treatment options. If the pain is unchanged, then the subtalar joint may not be the source of XX pain. Given the significant utility of a single subtalar corticosteroid injection for this atypical indication and the ambiguity of the ODG for this specific purpose, it is the opinion of this reviewer that the request for intra-articular corticosteroid injection to subtalar joint is reasonable and medically necessary. Therefore, the previous adverse determination is overturned.

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

Steroid intra-articular injections for foot and ankle conditions: How effective are they? Posted on June 30, 2016 by Mohammed KM Ali, Suhayl Tafazal, CA Mbah, D Sunderamoorthy. The Foot and Ankle Online Journal 9 (2): 7

Intraarticular foot and ankle injections to identify source of pain before arthrodesis. Khoury NJ1, el-Khoury GY, Saltzman CL, Brandser EA. AJR Am J Roentgenol. 1996 Sep;167(3):669-73.

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Ankle & Foot (Acute & Chronic) - (updated 02/13/18)

Corticosteroid injections

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)

Effect on glycemic control: Two SRs with 7 and 10 studies respectively confirmed that all CSI in diabetic patients resulted in mild to substantial elevation of blood glucose levels with transient post-injection hyperglycemia. Time to peak post-injection blood glucose is generally within 1 to 5 days, and return to baseline may take as long as 10 days. Higher post-injection blood glucose was found in patients with diabetes (both type I and insulin-dependent). Patient with diabetes should be advised of the risk of elevated blood glucose post injection. (Choudhry, 2016) (Waterbrook, 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)

Plantar fasciitis (heel pain): Not recommended. There has historically been no evidence for the effectiveness of injected corticosteroids for reducing plantar heel pain. (Crawford, 2002) Steroid injections, while being a popular treatment method only seemed to be useful in the short term and only to a small degree. (Crawford, 2003) In comparison only, CSI was better and much more cost-effective than electro-shock wave therapy (ESWT) for plantar fasciopathy. (Porter, 2005) An RCT concluded that a single ultrasound guided dexamethasone injection provides greater pain relief than placebo at four weeks but not beyond, possibly reducing swelling of the plantar fascia for up to three months, (McMillan, 2012) A Cochrane SR of CSI for plantar heel pain including 39 studies and 2492 adults found only low quality evidence for slight reduction of pain up to one month but not subsequently. Comparisons of CSI with other interventions including other types of injections were limited by very low quality evidence due to bias and imprecision. (David, 2017) An SR/MA of 10 studies and 517 patients comparing CSI with platelet-rich plasma (PRP) demonstrated no differences in pain or function at one, six-, or 12-months for either, suggesting further trials with longer follow-up. (Singh, 2017) Another SR/MA comparing CSI with autologous whole blood (AWB) injection noted marginal CSI superiority for plantar heel pain relief at 2-6 weeks, but conclusion was limited by bias risk. (Tsikopoulos, 2016) A very small (only 36 patient) multi-center RCT compared CSI, AWB, and no injection groups reporting more pain reduction for CSI at 4 weeks, with similar pain relief for both injectables at 12 weeks, but further studies with more patients and longer follow-up are still needed. (Karimzadeh, 2017)

Achilles tendinosis: Not recommended, along with other injection-based treatments. There is little information available from clinical trials to support any use of peritendinous steroid injection for treatment of acute or chronic Achilles tendinitis. (McLauchlan, 2000) Achilles tendon corticosteroid injections have been clearly implicated in Achilles tendon ruptures. (Coombes, 2010) CSI in the region of the Achilles tendon is contraindicated because it contributes to Achilles tendon ruptures. An SR noted little evidence to support any CSI efficacy, especially given concerns regarding tendon ruptures. (Metcalf, 2009) The literature surrounding all injectable treatments for Achilles tendinosis has inconclusive evidence regarding indications and mechanism of action. Better prospective studies are required to guide Achilles tendinosis treatment using injectable therapies. (Gross, 2013) A Cochrane SR of injection therapies for Achilles tendinopathy including 18 studies and 732 patients concluded that there was insufficient evidence from RCTs for any injection-based treatments for these conditions. (Kearney, 2015)

Morton's Neuroma: Not recommended. There are no RCTs to support CSI for the treatment of Morton's Neuroma. (Thomson, 2004) Alcohol injection of Morton's neuroma has a high success rate and is well tolerated. The results are at least comparable to surgery, but alcohol injection is associated with less morbidity, and surgical management may be reserved for non-responders. (Hughes, 2007) An RCT of 51 neuroma patients received 3 injections of either CSI with anesthetic or anesthetic alone. Pain and functional improvement were equivalent with or without corticosteroid at 3 and 6 months, and about half of both groups eventually had surgery. (Lizano-Díez, 2017) Although subcutaneous fat atrophy and injection site depigmentation have been reported for years following CSI, a case report of dramatic depigmentation following lymph vessels half way up the leg occurred after interdigital neuroma CSI. (van Vendeloo, 2016)