IRO Express Inc.

Notice of Independent Review Decision

Case Number: XX Date of Notice: 3/4/2019 3:59:57 PM CST

IRO Express Inc.

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IRO REVIEWER REPORT Date: 3/4/2019 3:59:57 PM CST IRO CASE #: XX **DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:** XX Injection A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO **REVIEWED THE DECISION:** Orthopaedic Surgery **REVIEW OUTCOME:** Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be: ☐ Overturned Disagree ☐ Partially Overturned Agree in part/Disagree in part ☑ Upheld Agree

PATIENT CLINICAL HISTORY [SUMMARY]: XX. XX XX is a XX-year-old XX with date of injury XX. XX smashed XX XX XX when XX by XX XX. XX was status post XX XX open reduction XX XX and XX XX and removal of painful XX. On XX, XX evaluated XX. XX for a post-operative follow-up. XX was XX XX status post XX XX surgery. XX presented partial weight bearing (PWB) in a XX XX to the XX XX extremity. XX reported tenderness and swelling by the XX of the XX after working. XX rated XX pain at 1/10 at the time and 7/10 after working all day a day prior. The pain was well controlled on the ongoing regimen. XX XX XX examination of surgical site was normal. The diagnosis was delayed union of joint of the XX. XX. XX educated XX. XX on XX and its regenerative properties in tendon / ligament, bone, cartilage, and nerve healing. XX also discussed that this could aid in the reduction of pain, inflammation, scar tissue formation and that it might help

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delay or prevent surgery. XX. XX further opined that XX. XX had a delayed union of the fracture and XX sites and would benefit from XX. XX. XX was advised to remain partial weightbearing as tolerated in the XX XX extremity at times utilizing XX XX for XX to XX weeks, continue Bone XX, and XX therapy. On XX, x-ray of the XX XX showed bones in acceptable anatomical alignment. The XX demonstrated no evidence of loosening or failure. Moderate soft tissue edema was noted. There was no evidence of bone bridging between the graft and bone on the XX and XX aspect of the graft. Treatment to date included medications, XX XX surgery, hyperbaric oxygen therapy, bone XX, XX for ambulation, and XX XX. Per a utilization review summary by XX XX, XX dated XX, the request for XX injection was not certified. The Primary Reason(s) for Determination was, based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request was noncertified. Per review of related literature, clinical trials had demonstrated that patients treated with XX XX products had increased rates of wound healing compared with the standard of care. In this case, the patient was status post XX XX open reduction and internal fixation (ORIF) of the XX XX nonunion and ORIF of the malunion of the XX XX graft and removal of the painful XX. There was no guideline support for XX in pain control. The patient had no evidence of non-union on repeat x-ray.

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

The claimant is status post XX XX open reduction and internal fixation followed by removal of painful XX. The use of XX or XX derived products is still under investigation and the overall efficacy of its use following surgical procedures such as open reduction and internal fixation is still unclear. There is no clear evidence from randomized controlled trials or cohort studies demonstrating that the use of XX derived products results in improved post-operative outcomes as compared to patients who do not receive the treatment. There were no exceptional factors noted in the records to support the use of XX.

Therefore, it is this reviewer's opinion that medical necessity is not established and the prior denials are upheld.

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 & TREATMENT GUIDELINES Ankle and Foot XX-XX XX (PRP)