HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Illinois, California, Texas
Certification(s)/Specialty: Orthopedic Surgery

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This injured worker is a 47-year-old female who sustained an industrial injury on 8/17/15, relative to a trip and fall. Records indicate that she was diagnosed with a fractured navicular and underwent surgical repair of peroneal longus and brevis tendon tears. Conservative treatment had included physical therapy, activity modification, and orthotics. The 7/14/15 right lower extremity MRI impression documented an osteochondral lesion of the medial talar dome measuring 7x10 mm. There were no MRI findings to suggest an unstable lesion. There was moderate cartilage thinning and surface irregularity of the subjacent medial tibial plateau without a focal osteochondral lesion. The anterior talofibular ligament was attenuated, however intact, suggestive of a chronic partial tear. There was marked thickening and intrasubstance signal within the peroneal tendons which may reflect post-surgical change. There was no full thickness tear or retraction of the peroneal tendons. There was a mild amount of fluid within the peroneal tendon sheath. The 7/17/15 treating physician report cited persistent right foot and ankle pain. Pain was reported frequent grade 2-3/10, increasing to occasional moderate depending on the level of activity. Strapping was temporarily helping the right foot pain. Physical exam documented tenderness to palpation to the anterior talofibular (ATF) ligament, talar dome, lateral gutter of the right ankle, and the peroneal tendons from the retromalleolar groove to the 5th metatarsal base for the peroneus brevis and to the peroneal groove on the cuboid for the peroneus longus. Pain was elicited by inversion and eversion. The diagnosis included right ankle ATF sprain, osteochondritis dissecans (OCD), and peroneus longus/brevis tendinopathy. Imaging confirmed ATF attenuation, peroneal tendinopathy and an OCD of the medial talar dome. The
treatment plan indicated that arthroscopic surgery and injection of placental amniotic fluid under ultrasound guidance was recommended. Authorization was requested for repair of ATF graft, arthroscopic exam and debridement osteochondritis dissecans, injection of the peroneus longus under ultrasound guidance, injection of peroneus brevis under ultrasonic guidance, and application of allograft for the right ankle. The 9/16/15 utilization review non-certified the ATF graft, arthroscopic exam and debridement osteochondritis dissecans, injection of the peroneus longus under ultrasound guidance, injection of peroneus brevis under ultrasonic guidance, and application of allograft for the right ankle as there was no documentation of ankle instability via stress testing to support surgical intervention and associated injections and allografts. The 9/24/15 treating physician report cited persistent right ankle pain. The new pair of custom orthotics were reported very helpful and comfortable. Physical exam and imaging findings were reported unchanged from 7/17/15. The treating physician reported that he was unable to obtain radiographic stress testing due to potential liability concerns. He stated that the MRI findings indicated a chronic partial tearing of the ATF and this should be sufficient to warrant authorization of this procedure. There was a 10x7 OCD of the medial talar dome on MRI with corresponding joint pain that supported arthroscopic exam and debridement. There was imaging evidence of peroneal tendon interstitial tearing to support surgical repair. A revised surgical plan was submitted for authorization including repair of the ATF ligament, arthroscopy exam and OCD debridement, and repair of the torn peroneal tendons. The 10/12/15 utilization review modified the surgical request and certified arthroscopic examination and debridement of the OCD. The request for repair of the ATF ligament was non-certified as there was an absence of stress testing. The request for injection was denied as there was no guideline support for injection of amniotic fluid. The request for allograft was not supported by guidelines.

**IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

**Repair of ATF Graft, Arthroscopic exam and debride ocd:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation

**MAXIMUS guideline:** Decision based on MTUS Ankle and Foot Complaints 2004, Section(s): Surgical Considerations. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ankle and Foot: Arthroscopy; Surgery for ankle sprains.

**Decision rationale:** The California MTUS guidelines recommend surgical consideration when there is activity limitation for more than one month without signs of functional improvement, and exercise programs had failed to increase range of motion and strength. Guidelines require clear clinical and imaging evidence of a lesion that has been shown to benefit in both the short and long-term from surgical repair. Repairs of ligament tears are generally reserved for chronic instability. The Official Disability Guidelines (ODG) provide specific indications for surgery for ankle include physical therapy (immobilization with support cast or brace and rehabilitation program). Subjective and objective clinical findings showing evidence of instability and positive anterior drawer are generally required. Imaging findings are generally required including
positive stress x-rays identifying motion at the ankle or subtalar joint. The ODG states there exists fair evidence-based literature to support a recommendation for the use of ankle arthroscopy for the treatment of osteochondral lesions. Guideline criteria have not been met. This injured worker presents with persistent activity dependent right foot and ankle pain. Clinical exam findings did not evidence instability. Anterior drawer test is not documented. Stress x-rays have not been performed. There is imaging evidence of a 7x10 mm OCD lesion on the medial talar dome. There is also imaging evidence of anterior talofibular attenuation with findings suggestive of a chronic partial tear. Detailed evidence of long term reasonable and/or comprehensive non-operative treatment without sustained improvement has been submitted. The 10/12/15 utilization review modified this request and certified the arthroscopic exam and debridement of the OCD lesion. Guidelines had not been met to support ATF repair relative to evidence of instability. There is no compelling rationale to support the medical necessity of additional certification at this time. Therefore, this request is not medically necessary.

**Injection of Peroneus Longus under ultrasound guidance:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Ankle & Foot Peroneal tendinitis/tendon rupture (treatment).

**MAXIMUS guideline:** Decision based on MTUS Ankle and Foot Complaints 2004, Section(s): Physical Methods. Decision based on Non-MTUS Citation Premera Blue Cross Medical Policy #7.01.149. Amniotic Membrane and Amniotic Fluid Injections. 7/14/15.

**Decision rationale:** The California MTUS guidelines state that injection procedures have no proven value in treating ankle and foot complaints, with the exception of corticosteroid injections for Morton's neuroma, plantar fasciitis or heel pain. Neither the MTUS nor Official Disability Guidelines provide recommendations for placental amniotic fluid injections. Current medical policy from Blue Cross state that literature on human amniotic membrane injection for regenerative medicine is at a very early stage, with only two pilot studies identified to date. These preliminary studies show promising results for the treatment of plantar fasciitis. Additional studies with larger sample sizes and longer follow-up are needed to permit conclusions regarding the effect of this treatment on plantar fasciitis pain. Also needed are randomized controlled trials in humans to evaluate the efficacy of amniotic membrane injections for the treatment of other conditions, including but not limited to tendonitis and osteoarthritis. Guideline criteria have not been met. This injured worker presents with persistent activity dependent right foot and ankle pain. Clinical exam findings document tenderness over the peroneal tendon with plausible imaging evidence of chronic partial thickness peroneus tendon tears. There is a lack of large volume, long-term peer-reviewed outcome studies to support the use of these injections. There is no compelling rationale presented to support the medical necessity of this request. Therefore, this request is not medically necessary.

**Injection of peroneus brevis under ultrasonic guidance:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain.
**MAXIMUS guideline:** Decision based on MTUS Ankle and Foot Complaints 2004, Section(s): Physical Methods. Decision based on Non-MTUS Citation Premera Blue Cross Medical Policy #7.01.149. Amniotic Membrane and Amniotic Fluid Injections. 7/14/15.

**Decision rationale:** The California MTUS guidelines state that injection procedures have no proven value in treating ankle and foot complaints, with the exception of corticosteroid injections for Morton's neuroma, plantar fasciitis or heel pain. Neither the MTUS nor Official Disability Guidelines provide recommendations for placental amniotic fluid injections. Current medical policy from Blue Cross state that literature on human amniotic membrane injection for regenerative medicine is at a very early stage, with only two pilot studies identified to date. These preliminary studies show promising results for the treatment of plantar fasciitis. Additional studies with larger sample sizes and longer follow-up are needed to permit conclusions regarding the effect of this treatment on plantar fasciitis pain. Also needed are randomized controlled trials in humans to evaluate the efficacy of amniotic membrane injections for the treatment of other conditions, including but not limited to tendonitis and osteoarthritis. Guideline criteria have not been met. This injured worker presents with persistent activity dependent right foot and ankle pain. Clinical exam findings document tenderness over the peroneal tendon with plausible imaging evidence of chronic partial thickness peroneus tendon tears. There is a lack of large volume, long-term peer-reviewed outcome studies to support the use of these injections. There is no compelling rationale presented to support the medical necessity of this request. Therefore, this request is not medically necessary.

**Application of Allograft for the Right Ankle:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Ankle & Foot Allograft for ankle reconstruction.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee and Leg: Osteochondral allograft (OCA) transplantation; Ankle and Foot: Osteochondral autologous transfer system (OATS).

**Decision rationale:** The California MTUS guidelines do not provide recommendations for osteochondral allograft (OCA) transplantation. The Official Disability Guidelines do not provide recommendations in the ankle for the OCA procedure state that the osteochondral autograft transplantation procedure is not recommended for ankle conditions. Guidelines state that the OATS technique may have promise in the ankle, but long-term outcome of the OATS procedure is not yet available. The ODG recommend the OCA procedure as an option to autograft transplantation in the Knee Chapter. This injured worker presents with persistent activity dependent right foot and ankle pain. There is imaging evidence of a 7x10 mm OCD lesion on the medial talar dome. Detailed evidence of long term reasonable and/or comprehensive non-operative treatment without sustained improvement has been submitted. The 10/12/15 utilization review certified the arthroscopic exam and debridement of the OCD lesion. There is no
compelling rationale to support the use of an allograft as an exception to guidelines. Therefore, this request is not medically necessary.