

Case Number:	CM15-0176756		
Date Assigned:	09/17/2015	Date of Injury:	02/25/2008
Decision Date:	10/29/2015	UR Denial Date:	08/25/2015
Priority:	Standard	Application Received:	09/08/2015

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: New York, Tennessee

Certification(s)/Specialty: Emergency Medicine

CLINICAL CASE SUMMARY

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

The injured worker is a 55 year old female, who sustained an industrial injury on 2-25-2008. The injured worker was diagnosed as having left ankle recurrent dislocation. Treatment to date has included diagnostics, physical therapy, spinal cord stimulator, and multiple left ankle surgeries. Currently (8-06-2015), the injured worker "wants manipulation and stem cell". Objective findings documented stable left ankle and slight swelling. Her work status was not noted. The treatment plan included left ankle manipulation and stem cell injection, non-certified by Utilization Review on 8-25-2015. An additional progress report (8-10-2015) noted complaints of left ankle pain and foot with numbness and tingling. Pain was rated 4 out of 10 and aggravated by "everything" and not alleviated by "anything". She reported that pain impacted her activities of daily living and emotional status. It was documented that an x-ray showed "positive progression of healing". It was also documented that Agreed Medical Evaluation (7-13-2015) recommended "regenerative medicine injection for her left ankle". Current medications included Norco, Cyclobenzaprine, Diclofenac, Omeprazole, Terocin lotion, Atorvastatin, Topiramte, Venlafaxine, Theramine, Albuterol, and Naproxen. Exam of the left foot and ankle noted several surgical scars, mild swelling of the left foot-ankle, allodynia to light touch and pinprick in the dorsum of left foot, reduced range of motion of the left ankle, mild discoloration of the left foot, and temperature subjectively colder in the left compared to right foot. An assessment noted reflex sympathetic dystrophy of lower limb.

IMR ISSUES, DECISIONS AND RATIONALES

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

Left ankle manipulation: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ankle & Foot: Manipulation.

Decision rationale: Manipulation of the ankle is not recommended. There is limited evidence from trials to support the use of manipulation for treating disorders of the ankle and foot, although it is commonly done and there is anecdotal evidence of its success. In general, it would not be advisable to use this beyond 2-3 weeks if signs of objective progress towards functional restoration are not clearly demonstrated. Manual mobilization of the ankle has limited added value and is not recommended. Therefore, the request is not medically necessary.

Stem cell injection: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Ankle & Foot (updated 06/22/15), Stem cell autologous transplantation.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ankle & Foot: Stem cell autologous transplantation.

Decision rationale: Stem cell autologous transplantation is under study. Stem cell therapy has been used for osteoarthritis, rheumatoid arthritis, spinal injury, degenerative joint disease, autoimmune diseases, systemic lupus erythematosus, cerebral palsy, critical limb ischemia, diabetes type 2, heart failure, multiple sclerosis, and other conditions. Adult stem cells are harvested from many areas of the body, including the bone marrow, fat and peripheral blood, and they are purified and reintroduced back in the patient. According to the theory, stem cells isolated from a patient (i.e. from the bone marrow or fat) have the ability to become different cell types (i.e. nerve cells, liver cells, heart cells and cartilage cells), and they are capable of "homing in" on and repairing damaged tissue. Although patient safety has not initially been a problem in short term studies, there is still scientific concern about potential carcinogenic effects from these enhanced pluri-potent cells. FDA approval has not been granted and jurisdictional issues remain since stem cells are not considered drugs. In other words, these treatments remain experimental; techniques are inconsistent and should be limited to randomized controlled clinical trials. The lack of evidence does not allow determination of efficacy or safety. Therefore, the request is not medically necessary.