

<b>Case Number:</b>	CM15-0141034		
<b>Date Assigned:</b>	07/30/2015	<b>Date of Injury:</b>	02/25/2008
<b>Decision Date:</b>	08/28/2015	<b>UR Denial Date:</b>	07/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/20/2015

### 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: California

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:

This injured worker is a 55 year old female who reported an industrial injury on 2-25-2008. Her diagnoses, and or impression, were noted to include: reflex sympathetic dystrophy in the lower limb; foot pain; and myofascial pain. Her treatments were noted to include ankle surgeries; injection therapy; physical therapy; home exercise program; pain psychology; medication management; rest from work. The progress notes of 5-18-2015 reported complaints of moderate left ankle pain with numbness and tingling, was aggravated by everything, not alleviated by anything, and was affecting all aspects of her life . Objective findings were noted to include: review of the diagnostic magnetic resonance imaging and x-ray reports; an antalgic gait due to left ankle-foot pain with preference to use the right lower extremity for ambulation; mild swelling and healed surgical scars over the left ankle-foot; allodynia to light touch and pinprick in the dorsum of the left foot; reduced left ankle range-of-motion; mild discoloration of the left foot; and colder left foot, compared to the right foot. The physician's requests for treatments were noted to include a stem cell injection to her left ankle for pain and bone non-union.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**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 Chapter.

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

**Decision rationale:** The requested Stem cell injection, is not medically necessary. CA MTUS is silent, Official Disability Guidelines, Ankle and Foot, Stem cell autologous transplantation noted: "Under study. See the Knee Chapter for more information and references. 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. In this review of diabetic Charcot patients who underwent foot and ankle reconstructive surgery with and without mesenchymal stem cells (MSC) grafting, the radiographic healing time parameter was most striking between groups, 6.4 versus 9.2 weeks. In both groups, there were non-unions, mal-unions, and/or delayed unions noted. Surgical application of MSC appears to be safe, and has the potential to be effective as an autograft substitute, but remains inconclusive." The injured worker has moderate left ankle pain with numbness and tingling, was aggravated by everything, not alleviated by anything, and was affecting all aspects of her life. Objective findings were noted to include: review of the diagnostic magnetic resonance imaging and x-ray reports; an antalgic gait due to left ankle-foot pain with preference to use the right lower extremity for ambulation; mild swelling and healed surgical scars over the left ankle-foot; allodynia to light touch and pinprick in the dorsum of the left foot; reduced left ankle range-of-motion; mild discoloration of the left foot; and colder left foot, compared to the right foot. The physician's requests for treatments were noted to include a stem cell injection to her left ankle for pain and bone non-union. This treatment is under study and currently inconclusive. The criteria noted above not having been met, Stem cell injection is not medically necessary.