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| **Case Number:** | CM15-0059102 | | |
| **Date Assigned:** | 04/03/2015 | **Date of Injury:** | 11/23/2013 |
| **Decision Date:** | 05/11/2015 | **UR Denial Date:** | 03/17/2015 |
| **Priority:** | Standard | **Application Received:** | 03/27/2015 |

## 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 Jersey, Michigan, California
Certification(s)/Specialty: Neurology, Neuromuscular 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 34 year old male, who sustained an industrial injury on 11/23/2013. The current diagnosis is patella tendonitis. According to the progress report dated 2/27/2015, the injured worker complains of ongoing pain in the bilateral patellofemoral joints, left worse than right, despite platelet rich plasma injection. The current medications are Norco and Motrin. Treatment to date has included medication management, X-rays, physical therapy, cortisone injections, MRI of the right/left knees, and platelet rich plasma injection. The plan of care includes embryonic placental tissue injection.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Embryonic placental tissue injection Qty: 2.00:** 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), Knee and Leg, Stem cell autologous transplantation; Aetna Clinical Policy Bulletin: Osteoarthritis of the Knee: Selected Treatments.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Stem cell autologous transplantation. http://www.odg-twc.com/index.html.

**Decision rationale:** According to ODG guidelines, Stem cell autologous transplantation "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. At present, research on intervertebral disc regeneration is at the stage of animal studies, but studies have been conducted on regenerating intervertebral discs. Done as an alternative to fusion for lumbar intervertebral disc instability, this study, for the first time, performed therapeutic intervertebral disc regeneration therapy in patients and obtained favorable findings. (Yoshikawa, 2010)In a small pilot study in patients with chronic back pain diagnosed with lumbar disc degeneration and treated with autologous expanded bone marrow mesenchymal stem cells injected into the nucleus pulposus area, outcomes compared favorably with the results of other procedures such as spinal fusion or total disc replacement. (Orozco, 2011) Alternative graft options that combine mesenchymal stem cells (MSCs) and bone marrow aspirate (BMA) with synthetic or allograft scaffolds have been recently used in several animal and clinical studies, but the currently available evidence is insufficient to support the use of MSCs or BMA. (Khashan, 2013) This review focused on mesenchymal stem cells in spine fusion and the management of degenerative disc disease. They projected that recent advancements in stem cell-based technologies are promising and indicative that stem cells will play a major role clinically. These stem cells, growth factors, and scaffolds could replace diseased tissue in degenerative disc disease and enhance host tissue to achieve more reliable spine fusion, but further study is required. (Werner, 2014)"The patient developed chronic right knee pain that did not respond to previous therapies including platelets injections. There are no controlled studies supporting the use of stem cells for chronic knee pain. ODG guidelines do not recommend the use of stem cells for osteoarthritis and chronic knee pain. Therefore, the request for embryonic placental tissue injection Qty: 2.00 is not medically necessary.