

Case Number:	CM13-0057505		
Date Assigned:	12/30/2013	Date of Injury:	04/09/2010
Decision Date:	03/04/2015	UR Denial Date:	09/10/2013
Priority:	Standard	Application Received:	10/09/2013

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: Texas, California
 Certification(s)/Specialty: Family Practice

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 is a 55 year-old male patient, who sustained an injury on April 9, 2010, while performing regular work duties. He sustained the injury while pushing a heavy pallet in a trailer; his left knee gave way and twisted. The diagnosis includes status post left knee arthroscopic surgery. Per the doctor's note dated 6/24/2013, he had complaints of left knee pain and discomfort. Physical examination revealed joint line tenderness and painful range of motion of the left knee. On April 25, 2013, physical findings reveal the left knee showing full range of motion. The medications list includes naprosyn. He has undergone left knee arthroscopic surgery on 11/17/2010. The records indicate the injured worker has received treatment including icing, medications, surgery, radiological imaging, and left knee injections. The request for authorization is for a stem cell injection. On September 10, 2013, Utilization Review non-certified the request for a stem cell injection, based on ODG guidelines.

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 (ODG) OFFICIAL DISABILITY GUIDELINES- KNEE & IEG

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chapter: Knee & Leg (updated 02/05/15) Stem cell autologous transplantation

Decision rationale: Official Disability Guidelines (ODG); MTUS guidelines do not address this request. Per the ODG guidelines, stem cell autologous transplantation is "Under study for advanced degenerative arthritis, post-meniscectomy and microfracture chondroplasty (adult stem cells, not embryonic)". research is currently very preliminary, especially in the U.S. Major issues remain unanswered regarding best stem cell type and origin (peripheral blood, bone marrow, fat or even allogeneic umbilical cord), cell dosage, timing, single vs. multiple treatments, and carrier biomaterials (hyaluronic acid, tissue scaffolds). Although patient safety has not initially been a problem in short term studies (Pak, 2013), 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. Autologous hematopoietic stem cell (SC) transplantation can induce sustained remissions for more than 5 years in patients with severe autoimmune diseases refractory to conventional therapy. (Farge, 2010). There is no high grade scientific evidence to support the stem cell injection for this diagnosis. In addition, evidence of failure of conservative therapy including physical therapy and pharmacotherapy is not specified in the records provided. The medical necessity of stem cell injection is not fully established for this patient.