MAXIMUS Federal Services

Case Number:	CM14-0197464		
Date Assigned:	12/05/2014	Date of Injury:	06/19/1995
Decision Date:	01/30/2015	UR Denial Date:	11/04/2014
Priority:	Standard	Application Received:	11/24/2014

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. The expert reviewer is Board Certified in Orthopedic Surgery and is licensed to practice in Minnesota. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 58-year-old male with a cemented total knee arthroplasty status post revisions with a figure-of-eight cable through the tibial tubercle replacing the patella tendon. The cable has migrated through the tibial tubercle and there is a 45 extensor lag reported which causes the injured worker to fall almost on a daily basis despite using a brace. The provider is considering revision of the patella tendon reconstruction with V-Y shortening and possible iliotibial band augmentation along with stem cell implantation. An extensor allograft is not being considered because of the history of infection in the past. The figure-of-eight cable will be adjusted to allow better extension and the knee will be immobilized in full extension postoperatively in a cast for 6-12 weeks. A request for stem cell implantation into the reconstructed patella tendon was noncertified by utilization review as it is experimental and not approved by FDA at this time. The provider had a discussion with the utilization review physician to the effect that this is the last thing to do for this patient prior to consideration for a below-knee amputation. However, based upon guidelines the request for stem cell implantation was still noncertified. Although the research for regenerative medicine is promising, the guidelines do not permit use of experimental techniques particularly because of the controversy with regard to the jurisdiction of FDA on stem cell implants.

IMR ISSUES, DECISIONS AND RATIONALES

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

Revision right patella tendon reconstruction, stem cell implantation during surgery:
Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Knee and Leg Procedure Summary

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

Decision rationale: California MTUS guidelines do not address this issue. Utilization review has certified the revision right patellar tendon reconstruction but noncertified the stem cell implantation during surgery. The noncertification with regard to the stem cell implantation was based upon ODG guidelines. The guidelines indicate that stem cell therapy offers future promise for various conditions; however, research is currently very preliminary, especially in the United States. Major issues remain unanswered re: best stem cell type and origin, cell dosage, timing, single versus multiple treatments and carrier biomaterials. There is a concern about safety although it has not been a problem thus far. However, FDA approval has not been granted and jurisdictional issues remain since stem cells are not considered drugs. Autologous stem cell transplantation has potential for regeneration of tissues including cartilage, tendon and bone. However, it is still considered experimental by guidelines and as such the medical necessity of the request for stem cell implantation during surgery is not established.