MAXIMUS Federal Services

Case Number:	CM14-0084037		
Date Assigned:	07/21/2014	Date of Injury:	03/15/2013
Decision Date:	08/29/2014	UR Denial Date:	05/27/2014
Priority:	Standard	Application Received:	06/05/2014

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 Physical Medicine and Rehabilitation and is licensed to practice in Illinois. 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 50-year-old female with a reported date of injury of 03/15/2012. The mechanism of injury was noted to be cumulative trauma. Her diagnoses were noted to include bilateral carpal tunnel syndrome, recurrent; status post carpal tunnel release procedure to the bilateral wrists; and bilateral elbow sprain/strain. Her previous treatments were noted to include physical therapy, surgery, and medications. A progress note dated 05/05/2014 revealed the injured worker complained of pain and discomfort to her left hand and wrist. The injured worker revealed the pain was constant, with hypersensitivity to her left wrist. The physical examination noted decreased range of motion of the left wrist, and stated that the injured worker was awaiting a left wrist carpal tunnel release. The progress note dated 05/06/2014 revealed the pain did not resolve completely following the previous bilateral carpal tunnel release surgery. The physical examination revealed no gross motor deficit of the extremities. The postoperative report dated 05/24/2014 revealed the injured worker had pre- and post-operative diagnoses regarding her left wrist and hand, and the operation was performed to her right wrist and hand. The Request for Authorization form dated 05/19/2014 was for an AmnioFix injection to the revision of the left carpal tunnel surgery to reduce inflammation, dramatically enhance healing time, and reduce scar tissue formation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Amnio Fix Injection to revision of left Carpal Tunnel Surgery: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://ryortho.com/breaking/fda-trips-up-high-flying-mimedx/.

Decision rationale: The request for an AmnioFix injection to the revision of the left carpal tunnel surgery is not medically necessary or appropriate. The injured worker underwent carpal tunnel surgery on 05/24/2014. The FDA wrote a letter regarding these products, including AmnioFix injectable, AccelShield injectable, and EpiFix injectable, all of which are intended for use, among other things, in reducing inflammation and scar tissue formation, as well as for enhanced wound healing of soft tissues. These micronized amniotic/chorionic-based products are manufactured from dehydrated composite amnion and chorion tissue and then have the end user re-suspend them in normal saline for injection into soft tissues. The micronized and injectable versions of allograft placental tissues, which are sold under several brand names including AmnioFix, AccelShield, and EpiFix, did not meet the requirement of minimal manipulation because, during the processing, the tissues were micronized. Micronizing the tissue, said the FDA, altered their original structural characteristics enough to push them from the allograft designation into a drug and biologic regulatory category. There is a lack of documentation regarding the necessity to use AmnioFix with the carpal tunnel surgery which was already been performed on 05/24/2014. Additionally, the FDA has not approved AmnioFix for utilization. Therefore, the request is not medically necessary or appropriate.