MAXIMUS Federal Services

Case Number:	CM14-0075413		
Date Assigned:	07/16/2014	Date of Injury:	07/28/2013
Decision Date:	08/18/2014	UR Denial Date:	05/14/2014
Priority:	Standard	Application Received:	05/23/2014

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, has a subspecialty in Sports Medicine and is licensed to practice in New York and Texas. 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 44-year-old female with a reported date of injury on 07/28/2013. The mechanism of injury was not submitted within the medical records. Her diagnoses were noted to include left knee pain and degenerative joint disease. Her previous treatments were noted to include medications. The progress note dated 04/14/2014 revealed the injured worker complained of constant pain, rated 7 to 8 out of 10 to her left knee and it increased when bending her knee and standing on it for about an hour. The injured worker indicated elevating her leg relieved her pain. The injured worker complained of left ankle pain from the knee which radiated to the ankle along with a popping noise from the ankle. The physical examination to the left knee revealed mild edema and increasing pain along the medial joint line over the quadriceps. The range of motion was noted to be flexion was to 90 degrees and extension was to 0 degrees. The request for authorization form was not submitted within the medical records. The request is for a Bionicare and loader brace, however the provider's rationale was not submitted within the medical records.

IMR ISSUES, DECISIONS AND RATIONALES

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

Bionicare Unloader Brace: 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) ODG 2013 (knee).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Knee and Leg, Bionicare Knee Device.

Decision rationale: The request for a Bionicare unloader brace is non-certified. The injured worker complains of knee pain. The ODG recommend a Bionicare knee device as an option for patients in a therapeutic exercise program for osteoarthritis of the knee, who may be candidates for a total knee arthroplasty but want to defer surgery. This device received FDA approval as a TENS device, but there are additional claims of tissue regeneration effectiveness and studies suggesting the possibility of deferral of total knee arthroscopy with the use of the Bionicare device. The Bionicare device excessively attenuated knee osteoarthritis symptoms in patients who failed nonsurgical therapy. The guidelines state the outcomes are better with an unloader brace, used with Bionicare, than with Bionicare alone, which is a recommended treatment. In this case, an unloader brace was used with the Bionicare stimulator to obtain complimentary benefits, because it was thought the added effects of the brace would allow more patients to obtain the full 6 to 9 months of stimulator treatment that most patients require for full benefit, producing more rapid improvement and resulting in increased adherence and efficacy. The combined treatment was compared to the Bionicare only treatment and more patients achieved significant clinical improvement, at least 20% with combined treatment than with stimulator only treatment. There is a lack of documentation regarding the injured worker in a therapeutic exercise program for osteoarthritis of the knee to utilize the Bionicare knee device. Therefore, the request is not medically necessary.