

<b>Case Number:</b>	CM13-0024379		
<b>Date Assigned:</b>	11/20/2013	<b>Date of Injury:</b>	07/15/2009
<b>Decision Date:</b>	03/18/2014	<b>UR Denial Date:</b>	09/03/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/13/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Interventional Spine, and is licensed to practice in California. 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 physician 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 patient is a 57-year-old male with a date of injury of 07/15/2009. The listed diagnoses per [REDACTED] dated 10/03/2013 are: 1. Bilateral knee pain. 2. Internal knee derangement, bilateral. 3. Osteoarthritis of bilateral knees. 4. Long-term use of medications. 5. Encounter for therapeutic drug monitoring. According to report 10/03/2013 by [REDACTED], the patient presents with continued bilateral knee pain and swelling. The patient was noted to be status post left knee arthroscopic debridement and meniscectomy dated 09/09/2012. The patient was also noted to have right knee aspiration dated 07/23/2013, "which gave him no relief." Physical examination shows the patient ambulates with a cane. Examination of the right knee showed range of motion flexion at 90 degrees and extension at 10 degrees. Examination of the left knee showed flexion at 110 degrees and extension at 5 degrees.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**BIONICARE KNEE DEVICE:** Overturned

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 1021-1022.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**Decision rationale:** This patient presents with continued bilateral knee pain and swelling. Treater requests Bionicare knee device and supplies "to improve patient's pain level, reduce medication, improve knee function, and ability to perform ADLs, and to defer right total knee replacement." Utilization dated 09/03/2013 denied request stating, "This is not a first line of treatment option in the care of knee disorders." The MTUS and ACOEM Guidelines do not specifically discuss Bionicare. However, ODG Guidelines has the following regarding Bionicare knee device, "recommended as an option for patients in a therapeutic exercise program for osteoarthritis of the knee who may be candidates for 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 TKA with the use of the Bionicare device." This patient has a long history of bilateral knee symptomatology. In this case, the treater is requesting the Bionicare device to deter total knee replacement. Given the request for the Bionicare knee device is in accordance with ODG Guidelines, the supplies that are needed for the device would be necessary. Therefore, recommendation is for approval.

**BIONICARE SUPPLIES #3:** Overturned

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 1021-1022..

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**Decision rationale:** This patient presents with continued bilateral knee pain and swelling. Treater requests Bionicare knee device and supplies "to improve patient's pain level, reduce medication, improve knee function, and ability to perform ADLs, and to defer right total knee replacement." Utilization dated 09/03/2013 denied request stating, "This is not a first line of treatment option in the care of knee disorders." The MTUS and ACOEM Guidelines do not specifically discuss Bionicare. However, ODG Guidelines has the following regarding Bionicare knee device, "recommended as an option for patients in a therapeutic exercise program for osteoarthritis of the knee who may be candidates for 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 TKA with the use of the Bionicare device." This patient has a long history of bilateral knee symptomatology. In this case, the treater is requesting the Bionicare device to deter total knee replacement. The requested Bionicare knee device is medically necessary, and recommendation is for approval