

<b>Case Number:</b>	CM15-0200661		
<b>Date Assigned:</b>	10/15/2015	<b>Date of Injury:</b>	05/07/2013
<b>Decision Date:</b>	12/18/2015	<b>UR Denial Date:</b>	09/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/13/2015

### 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: New York, California  
 Certification(s)/Specialty: Emergency Medicine

### 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 57 year old female sustained an industrial injury on 5-17-13. Documentation indicated that the injured worker was receiving treatment for right knee pain. Previous treatment included physical therapy, acupuncture, extracorporeal shockwave therapy, topical compound creams and medications. In a PR-2 dated 9-11-15, the injured worker complained of constant, moderate achy right knee pain. Physical exam was remarkable for right knee range of motion 0 to 130 with diffuse tenderness to palpation and positive McMurray's test. The injured worker walked with a mild antalgic gait with a mild limp. Right quadriceps motor strength was 5 out of 5. The physician documented that he agreed with a qualified medical evaluator's (3-6-15) impression of right knee arthritis with recommendation for future care to included right knee replacement. The treatment plan included initiating Norco, Ibuprofen and Flexeril and right knee stem cell injection with Lipogems system. On 9-17-15, Utilization Review noncertified a request for Ibuprofen 800mg #90 and right knee stem cells injection Lipogems System (a transplant of micro fractured adipose tissue) and modified a request for Norco 10-325mg #90 to Norco 10-325mg #81 and Flexeril 10mg #90 and Flexeril 10mg #81.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Right knee stem cell injection- Lipogems System A Transplant of Micro fractured Adipose Tissue x1: 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) Knee and Leg/ Stem cell autologous transplantation.

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

**Decision rationale:** CA MTUS is silent regarding this request. According to the ODG guidelines, Stem cell autologous transplantation for the knee is "under study for advanced degenerative arthritis, post-meniscectomy and microfracture chondroplasty (adult stem cells, not embryonic). Stem cell therapy offers future promise for rheumatoid arthritis, spinal injury, degenerative joint disease, autoimmune disorders, systemic lupus erythematosus, cerebral palsy, critical limb ischemia, diabetes, heart failure, multiple sclerosis, and other conditions. However, 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." As this treatment is not FDA approved and documentation does not support the IW is enrolled in a clinical trial, the request for a Stem cell autologous transplantation to the right knee is not supported by the guidelines and the request is not medically necessary.

**Ibuprofen 800mg, #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, specific drug list & adverse effects.

**Decision rationale:** According to CA MTUS chronic pain guidelines, non-steroidal anti-inflammatory agents are recommended as an option for short term symptomatic relief for the treatment of chronic pain. Further recommendations are for the lowest dose for a minimal duration of time. Specific recommendations for Ibuprofen (Motrin) state sufficient clinical improvement should be observed to offset potential risk of treatment with the increase dose. It is unclear from the records how the IW has been taking this medication. However, the documentation does not support improvement of symptoms with NSAIDs currently prescribed.

Additionally, the request does include frequency and dosing of this medication. The request is not medically necessary.

**Norco 10/325mg, #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids, dosing, Opioids, specific drug list.

**Decision rationale:** CA MTUS, chronic pain guidelines, offer very specific guidelines for the ongoing use of narcotic pain medication to treat chronic pain. These recommendations state that the lowest possible dose be used as well as ongoing review and documentation of pain relief, functional status, appropriate medication use and its side effects. It also recommends that providers of opiate medication document the injured worker's response to pain medication including the duration of symptomatic relief, functional improvements, and the level of pain relief with the medications. The included documentation fails to include the above recommended documentation. It is unclear from the documentation submitted how low the IW has been prescribed this opiate pain medication. There is no documentation to support improvement in symptoms or function with the use of this medication. There are not toxicology reports discussed in the record to support prescribing within the opiate prescribing guidelines. Additionally, the request does not include dosing or frequency. Without the supporting documentation or adherence to the guidelines, the request for opiate analgesia is not medically necessary.

**Flexeril 10mg, #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril).

**Decision rationale:** According to CA MTUS, Cyclobenzaprine is recommended as an option for short course of therapy. Effect is noted to be modest and is greatest in the first 4 days of treatment. The IW has been receiving this prescription for a minimum of 3 months according to submitted records. This greatly exceeds the recommended timeframe of treatment. In addition, the request does not include dosing frequency or duration. The IW's response to this medication is not discussed in the documentation. The request is not medically necessary.