Case Number:	CM15-0194788		
Date Assigned:	10/08/2015	Date of Injury:	01/22/2010
Decision Date:	12/15/2015	UR Denial Date:	09/14/2015
Priority:	Standard	Application Received:	10/05/2015

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
Certification(s)/Specialty: Internal 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 is a 66 year old male who sustained an industrial injury on 1-22-2010. A review of the medical records indicates that the injured worker is undergoing treatment for right knee internal derangement, status post total knee replacement 2013, right knee pain and chronic pain related insomnia. Past medical history included hypertension. Medical records (3-5-2015 to 9-9-2015) indicate ongoing pain in the right knee and lower leg. He was unable to bend his right knee or ankle due to severe edema. He rated his average pain 8 out of 10 without medications and 5 out of 10 with medications. The physical exam (9-9-2015) revealed edema of right knee and calf. There were red pustules above the right ankle. Treatment has included surgery, injections and medications. Current medications (9-9-2015) included Trepadone, Gabadone, Clonidine and Dilaudid. The injured worker has been prescribed these medications since at least 3-5-2015. The request for authorization was dated 9-9-2015. The original Utilization Review (UR) (9-14-2015) non-certified requests for Trepadone, Gabadone, Clonidine and Dilaudid.

IMR ISSUES, DECISIONS AND RATIONALES

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

Trepadone, #120: 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), Pain - Trepadone.

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

Decision rationale: Trepadone is a prescription medical food formulated for the dietary management of pain. The California MTUS is silent regarding medical foods. The Official Disability Guidelines (ODG) does not recommend. Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa. There is insufficient evidence to support use for osteoarthritis or for neuropathic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "a food which is formulated to be consumed or administered internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain." According to the cited guidelines, Trepadone is not recommended. Therefore the request for Trepadone #120 is not medically necessary.

Gabadone, #60: 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), Pain - Gabadone.

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

Decision rationale: ODG state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG state that medical food is not recommended. Medical food is a food which is formulated to be consumed or administered internally under the supervision of a physician and which is intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Based on the currently available medical information for review, there is no documentation about the composition, of this medical food and why this particular medical food is requested, the medical necessity for Gabadone has not been established. The request is not medically necessary.

Clonidine 0.1mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Complex Regional Pain Syndrome (CRPS). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

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

Decision rationale: As per Official Disability Guidelines (ODG), Clonidine is not recommended except as an end-stage treatment alternative for selected patients for specific conditions, and only after a short-term trial indicates pain relief in patient's refractory to opioid monotherapy or opioids with local anesthetic. There is no recommendation for its use as there is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Within the submitted medical records there is no clear discussion about the reason for Clonidine prescription. The requested treatment: Clonidine 0.1mg, #60 is not medically necessary. Of note, discontinuation should include a taper to avoid withdrawal symptoms.

Dilaudid 4mg, #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Opioids.

Decision rationale: According to ODG and MTUS, Dilaudid is an opioid analgesic, and is in a class of drugs that has a primary indication to relieve symptoms related to pain. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics. These medications are generally classified according to potency and duration of dosage. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. There is no compelling evidence presented by the treating provider that indicates this injured worker, had any significant improvements from use of opioids. Also review of Medical Records do not indicate that in this injured worker, previous use of opioid, has been effective in maintaining any measurable objective evidence of functional improvement. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. The requested medication is not medically necessary.