

Case Number:	CM14-0076358		
Date Assigned:	07/18/2014	Date of Injury:	07/01/2010
Decision Date:	09/11/2014	UR Denial Date:	04/29/2014
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 Family Medicine and is licensed to practice in New Jersey. 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 worker is a 42 year old female who was injured on 7/1/2010. She was diagnosed with internal derangement of the knee, bilateral knee pain, left knee meniscal tear, femoral bursitis, edema bilaterally lower extremities, adjustment disorder mixed with anxiety and depression, chondromalacia of the left patella, left femoral bursitis, left hip pain, and chronic insomnia secondary to pain. The worker was treated with surgery (left knee, 2010, 2011, 2012, 2013), physical therapy, TENS unit, chiropractic treatments, topical lidocaine, medical foods (unknown specifics), and oral medications including NSAIDs and opioids. She was diagnosed with non-alcoholic steatohepatitis and stopped all medications approximately in 5/2013, but restarted Aleve and (occasional use) at a later date. A urine drug screen was completed on the worker on 3/6/14, which was negative for any tested medications. On 4/3/14, the worker was seen by her primary treating provider complaining of her left knee pain as well as less so her right knee, but also low back pain, and being tired due to the pain. She reported not tolerating the medical food or the lidocaine patches that she had been using. For the tiredness, she was prescribed a new medical food, Sentra AM, and for a replacement medication for her lidocaine patch, was recommended Flurbiprofen/Tramadol ointment. Also, she was given a vitamin B12 shot that day in the office (no explanation), and was referred to her orthopedic surgeon.

IMR ISSUES, DECISIONS AND RATIONALES

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

Urine drug screen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing AND Opioids Page(s): 43, 77, 78, 86.

Decision rationale: The Chronic Pain Guidelines state that urine drug screening tests may be used to assess for the use or the presence of illegal drugs. Drug screens, according to the California (MTUS), are appropriate when initiating opioids for the first time, and afterwards periodically in patients with issues of abuse, addiction, or poor pain control. The California (MTUS) lists behaviors and factors that could be used as indicators for drug testing, and they include: multiple unsanctioned escalations in dose, lost or stolen medication, frequent visits to the pain center or emergency room, family members expressing concern about the patient's use of opioids, excessive numbers of calls to the clinic, family history of substance abuse, past problems with drugs and alcohol, history of legal problems, higher required dose of opioids for pain, dependence on cigarettes, psychiatric treatment history, multiple car accidents, and reporting fewer adverse symptoms from opioids. In the case of this worker, there was no evidence of her using opioids recently leading up to the time of the request. Also, there was no evidence found in the notes available for review that would suggest she was at a high risk for drug abuse or addiction. Furthermore, the urine drug screen done only 1 month prior to the request was negative for any drugs. Therefore, the urine drug screen is not medically necessary.

Topical compound Fluribiprfen/Tramadol ointment: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are generally considered experimental as they have few controlled trials to determine efficacy and safety currently, especially combination products. Topical non-steroidal anti-inflammatory drugs (NSAIDs), specifically, have some data to suggest it is helpful for osteoarthritis and tendinitis for at least short periods of time, but there are no longterm studies to help us know if they are appropriate for treating chronic musculoskeletal pain. Topical NSAIDs have not been evaluated for the treatment of the spine, hip, or shoulder. Although some topical analgesics may be appropriate for trial as a secondary agent for neuropathic pain after trials of oral therapies have been exhausted, topical NSAIDs are not recommended for neuropathic pain. The only FDA-approved topical NSAID currently is Voltaren gel (diclofenac). Ketoprofen is not currently one of the topical NSAIDs available that is FDA approved, and it has a high incidence of photocontact dermatitis. All topical NSAID preparations can lead to blood concentrations and systemic effect comparable to those from oral forms and caution should be used for patients at risk, including those with renal failure and hypertension. In the case of this worker, it is unclear as to why the topical preparations of medication were being utilized (because of her liver disease?), which would be a reasonable

consideration if using medications that can affect the liver. However, using a combination product such as the one requested is not recommended over FDA approved Voltaren gel, and only for short-term use, not chronic use. Therefore, the Flurbiprofen/Tramadol ointment is not medically necessary at this time.

Sentra AM #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, Pain (Chronic).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG), Pain section, Medical food Physician Therapeutics, Sentra AM (<http://www.ptlcentral.com/medical-foods-products.php>).

Decision rationale: Sentra AM is a medical food product which contains various ingredients including choline, arginine, GABA, histidine, tryptophan, and serine, and is marketed for use to treat fatigue and cognitive disorders. The California Medical Treatment Utilization Schedule (MTUS) is silent regarding Sentra AM or its ingredients individually. The Official Disability Guidelines (ODG), however, states that medical food may be recommended in certain situations where there is a distinctive nutritional requirement. Choline, the primary ingredient in Sentra AM is only recommended for long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency, and is not generally recommended yet for other indications. Choline and these other amino acids are found in foods, which can be prescribed to patients as well, so there is no need for a specific product for most patients. Therefore, the Sentra AM in the case of this worker is not medically necessary.

Vitamin B-12 shot injection: 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 (ODG), Pain section, Vitamin B Other Medical Treatment Guideline or Medical Evidence: Langan RC, et. al., Update on vitamin B12 deficiency. Am Fam Physician. 2011 Jun 15;83(12):1425-30.

Decision rationale: The California Medical Treatment Utilization Schedule (MTUS) Guidelines do not address vitamin B12 injections. The Official Disability Guidelines (ODG), however, states that vitamin B supplementation is not recommended for the general treatment of chronic pain, particularly peripheral neuropathy, as the efficacy is not clear. However, in cases of specific deficiency of vitamin B12, such as in pernicious anemia, there is a clear benefit to supplementing (injected, sublingual, or oral). Studies over the past 20 or more years have suggested and confirmed that oral vitamin B12 supplementation is just as and even more effective at correcting vitamin B12 deficiency, even in cases of pernicious anemia and gastrectomy, and the cost is much cheaper to do it this way. Even if the worker had been diagnosed with vitamin B12 deficiency, which there was no evidence for such found in the documents available for review,

the more appropriate treatment would have been oral or sublingual dosing. Therefore, the vitamin B12 injection is not medically necessary.