MAXIMUS Federal Services

Case Number:	CM14-0073698		
Date Assigned:	07/16/2014	Date of Injury:	05/01/2012
Decision Date:	08/22/2014	UR Denial Date:	05/12/2014
Priority:	Standard	Application Received:	05/21/2014

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 & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Texas and Oklahoma. 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 33-year-old male who reported an injury on 05/01/2012 due to a slip and fall at work. The injured worker has diagnoses of right shoulder internal derangement, left shoulder internal derangement, left elbow internal derangement, lumbar spine radiculopathy, right ankle internal derangement, anxiety and depression as well as left knee internal derangement and right wrist sprain/strain. The injured worker's past treatment includes the use of a TENS unit, wrist brace, physical therapy, a cervical pillow and medication therapy. An EMG/NCV done on 12/18/2013 revealed carpal tunnel syndrome and radiculopathy. The injured worker complained of left knee pain that radiated upwards and downwards. He also complained of loss of strength in the left ankle with aching and constant repeating pain. The injured worker rated his pain at a 7-8/10. He stated that his right shoulder also had tightness and occasional pain as well. He rated that pain at a 10/10. The physical examination dated 04/17/2014 revealed that the left ankle was tender. The injured worker's foot was held in inversion with extreme tenderness at the distal tibia. The injured worker's left knee also revealed tenderness with extension of 10 degrees and flexion of 110 degrees. There were no medications documented in the submitted report. The treatment plan is for the use of Xolido 2% for pain. The rationale was not submitted for review. The Request for Authorization form was submitted on 05/06/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Xolido 2% For Pain, Topical Compounds: Terocin Flurbi, Somnicin, Laxacin, Gabacyclotram: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, SSRIs, Topical analgesics Page(s): 72, 107, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, treatment for insomnia Other Medical Treatment Guideline or Medical Evidence:WebMD (Tryptophan).

Decision rationale: The request for Xolido 2% For Pain, Topical Compounds: Terocin Flurbi, Somnicin, Laxacin, Gabacyclotram is non-certified. The injured worker complained of left knee pain that radiated upwards and downwards. He also complained of left ankle loss of strength with aching and constant repeating pain. The injured worker rated his pain at a 7-8/10. He stated that his right shoulder also had tightness and occasional pain as well. He rated that pain at a 10/10. The MTUS guidelines state that topical medications are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The MTUS guidelines recommend Lidocaine (Xolido) for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. It is not recommended for non-neuropathic pain. Guidelines also state any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials for this type of treatment modality has been inconsistent and most studies are small and of short duration. Terocin contains capsaicin/lidocaine/menthol/methyl salicylate. The guidelines state that lidocaine is not recommended in formulations other than Lidoderm. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. It also contains Menthol 4% and Methyl salicylate. The guidelines state that there are no other commercially approved topical formulation of lidocaine that are indicated for neuropathic pain other than Lidoderm. The same guidelines above can be used for the medication Gabacyclotram which consists of cyclobenzaprine 4% - gabapentin 6% - tramadol 8%. Given the above guidelines, the medication is not within MTUS guidelines. In regards to Flurbiprofen it is an NSAID and topical treatment can result in 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. The medication Somnicin is a combination of Magnesium Oxide, Melatonin, Oxitriptan and Tryptophan. Magnesium Oxide is an element your body needs to function normally. Magnesium Oxide can be used as an antacid to relieve heartburn, sour stomach, or acid indigestion, a dietary supplement when the amount of magnesium in the diet is not enough, a laxative for short-term, rapid emptying of the bowel. It should not be used repeatedly. Melatonin, according to the ODG is a melatonin agonist (MT1

and MT2) indicated for difficulty with sleep onset; is nonscheduled (has been shown to have no abuse potential). One systematic review concluded that there is evidence to support the short-term and long-term use of ramelteon to decrease sleep latency; however, total sleep time has not been improved. Oxitriptan, a type of antidepressant is not recommended as a treatment option for chronic pain, according to the MTUS. It has been suggested that the main role of antidepressants such as Oxitriptan, may be in addressing psychological symptoms associated with chronic pain. Tryptophan is an amino acid, a protein building block that can be found in many plant and animal proteins. Tryptophan is called an "essential" amino acid because the body can't make it. It must be acquired from food. Tryptophan is used for insomnia, sleep apnea, depression, anxiety, and facial pain. The submitted report lacked any quantified evidence as to whether the injured worker had tried and failed any conservative care, such as tricyclic or SNRI antidepressants. In regards to the Terocin, it shows that Terocin contains capsaicin, lidocaine, menthol and methyl salicylate. Seeing as that the proposed cream contains lidocaine, it is not medically recommended. Furthermore, there was a lack of subjective complaints of neuropathic pain. There was also no rationale as to why the injured worker would require a topical lotion versus any oral medications. Flurbiprofen is an NSAID which, with long-term use, can cause ulcers or GI problems to the injured worker. Referring to the medication Somnicin, which contains magnesium oxide, melatonin, Oxitriptan and tryptophan. The ODG recommends melatonin to be given as a first line of treatment for difficulty with sleep onset. It is non-scheduled, and there have been no signs of abuse. Oxitriptan is an antidepressant, which is not recommended according to the California MTUS Guidelines. Given the above guidelines, the request for all of these medications is not necessary. Furthermore, the request submitted did not include a dose, frequency or duration on any of these medications. As such, the request for Xolido 2% for pain; topical compounds: Terocin, Flurbi, Somnicin, Laxacin and Gabacyclotram is non-certified.