

Case Number:	CM15-0131705		
Date Assigned:	07/23/2015	Date of Injury:	08/12/2011
Decision Date:	09/17/2015	UR Denial Date:	06/22/2015
Priority:	Standard	Application Received:	07/07/2015

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: Anesthesiology

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 40-year-old female, with a reported date of injury of 08/12/2011. The mechanism of injury was the twisting of her right ankle while walking down a flight of stairs. The injured worker's symptoms at the time of the injury included right ankle pain. The diagnoses include bilateral lower extremity complex regional pain syndrome; malfunction, spinal cord stimulator; chronic pain syndrome; suspected complex regional pain syndrome of the upper extremities; and right ankle/foot sprain and strain. Treatments and evaluation to date have included implantation/revision of a spinal cord stimulator on 04/23/2015, oral medications, topical pain medications, physical therapy, injections, acupuncture sessions, and home exercise program. According to the medical report dated 04/10/2015, the diagnostic studies to date have included a CT scan of the right foot on 07/02/2012 which showed diffuse osteopenic changes of the right foot; and an MRI of the right lower joint on 10/03/2011 which showed mild sprain of calcaneonavicular ligament and suspect focal degenerative changes of the calcaneocuboid joint, with subcortical cyst on the cuboid side. The pain medicine re-evaluation dated 06/04/2015 indicates that the injured worker complained of neck pain, with radiation down the bilateral upper extremities, and frequent and severe muscle spasms in the neck area. She also complained of low back pain, with radiation of pain down the bilateral lower extremities and frequent and severe muscle spasms in the low back. There was also the complaint of pain in the left hip and foot, the right hip, bilateral thighs, knees, calves, legs, ankles, and feet, which was accompanied by numbness and tingling. The injured worker's pain was rated 5-6 out of 10 on average with medications since the last visit; and the pain was rated 9 out of 10 without medications since her

last visit. Her pain was reported as unchanged since her last visit. The injured worker reported constipation as moderate. It was noted that there was ongoing activities of daily living limitations due to pain. The physical examination showed hypersensitivity in the bilateral upper extremities, allodynia in the bilateral upper extremities, tenderness on palpation at the right foot, hypersensitivity in the bilateral lower extremities, and allodynia in the bilateral lower extremities. The injured worker's work status was documented as currently not working. The treating physician requested Tramadol 50mg #120, two bottles of TENS unit lotion aloe vera and vitamin E, Fosamax 70mg, Eszopiclone 3mg #30, Flector 1.3% patch #60, and Baclofen 10mg #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol 50mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list, Criteria for use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids and Tramadol (Ultram) Page(s): 74-96 and 113.

Decision rationale: The CA MTUS Chronic Pain Guidelines indicate that Tramadol (Ultram) is a centrally acting synthetic opioid analgesic which is not recommended as a first line oral analgesic. Multiple side effects have been reported including increased risk of seizure especially in patients taking selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and other opioids. Tramadol may also produce life-threatening serotonin syndrome. The injured worker has been taking Tramadol since at least 01/16/2015. The MTUS indicate that on-going management for the use of opioids should include the on-going review and documentation of pain relief, functional status, appropriate medication use, and side effects. The pain assessment should include: current pain, the least reported pain over the period since the last assessment, average pain, intensity of pain after taking the opioid, how long it takes for pain relief, and how long the pain relief lasts. Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. It was noted that the injured worker had a reduction in pain; was demonstrating an improvement in the level of function; was not experiencing any side effects; and is in compliance with the pain management agreement and there were no signs of medication abuse or diversion. It was also noted that her behavior and mood were appropriate. There is a pain contract on file, and she is monitored by periodic urinary drug testing and CURES reporting. There is no evidence of significant pain relief or increased function from the opioids used to date. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. The medical records included the urine toxicology reports dated 03/12/2015 and 04/21/2015, with consistent findings. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Therefore, the request for Tramadol is not medically necessary.

TENS unit lotion aloe vera & Vitamin E #2 bottles: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS unit Page(s): 114-121.

Decision rationale: In this case, there is no documentation of any subjective or objective functional benefit, a decrease in pain, or decrease in medication from usage of the TENS unit. Therefore, there is no rationale or indication for the TENS unit lotion (aloe vera & Vitamin E). Medical necessity for the requested item has not been established. The requested item is not medically necessary.

Fosamax 70mg #4: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Alendronate (Fosamax).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Bisphosphonates Page(s): 25. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Bisphosphonates.

Decision rationale: The CA MTUS Chronic Pain Guidelines recommend the treatment of bone resorption with bisphosphonate-type compounds as an option for patients with Complex Regional Pain Syndrome (CRPS) Type I. The injured worker has been diagnosed with CRPS of the bilateral lower extremities. MTUS indicates that "Alendronate (Fosamax) given in oral dosages of 40mg a day (over an 8 week period) produced improvements in pain, pressure tolerance and joint mobility." The treating physician prescribed Fosamax 70mg. Fosamax has been prescribed since at least 01/16/2015. According to the ODG, the use of bisphosphonate has been associated with complications including osteonecrosis of the jaw and possible increased risk of long bone fractures including the femur. The request does not meet guideline recommendations. Therefore, the request for Fosamax is not medically necessary.

Baclofen 10mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity drugs: Baclofen (Lioresa).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-66.

Decision rationale: The CA MTUS Chronic Pain Guidelines recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. The guidelines also indicate that the effectiveness of muscle relaxants appear to diminish over time and prolonged use of the some medications in

this class may lead to dependence. The medication has been prescribed since at least 01/16/2015. Baclofen is a muscle relaxant and used to treat muscle spasms. The guidelines indicate that Baclofen is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. There was no evidence that the injured worker had been diagnosed with either of those conditions. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). The side effects of Baclofen include sedation, dizziness, weakness, low blood pressure, nausea, respiratory depression, and constipation. There was documentation that it has been explained to the injured worker that this medication was not intended for continuous long term use. The injured worker has been taking this medication for at least 6 months. Therefore, the request for Baclofen is not medically necessary.

Eszopiclone 3mg #30: 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), Mental Illness and Stress-Eszopiclone (Lunesta).

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, Eszopiclone (Lunesta).

Decision rationale: Eszopiclone (Lunesta) is a prescription short-acting non-benzodiazepine sedative-hypnotic, which is recommended for short-term treatment of insomnia (two to six weeks). Benzodiazepine-receptor agonists work by selectively binding to type-1 benzodiazepine receptors in the CNS. Lunesta is indicated for the treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. According to the ODG guidelines, non-Benzodiazepine sedative-hypnotics are considered first-line medications for insomnia. All of the Benzodiazepine-receptor agonists are schedule IV controlled substances, which have potential for abuse and dependency. It appears that the non-benzodiazepines have similar efficacy to the benzodiazepines with fewer side effects and short duration of action. Eszopiclone has demonstrated reduced sleep latency and sleep maintenance and is recommended for short-term use. In this case, the injured worker has been taking Eszopiclone since at least 01/16/2015. It was noted that the injured worker has failed more conservative treatment modalities. According to the guidelines, "The FDA has lowered the recommended starting dose of Eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women." The treating physician prescribed Eszopiclone 3mg, which exceeds the guideline recommendations. Therefore, the request for Eszopiclone is not medically necessary.

Flector 1.3 percent patch #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic)-Flector patch (diclofenac epolamine).

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

Decision rationale: The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." They are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." Flector patch contains diclofenac, which is a non-steroidal anti-inflammatory drug (NSAID). The effectiveness in the clinical trials for topical NSAIDs have been inconsistent and most studies are small and of short duration. The guidelines also indicate that topical NSAIDs "may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety." It was noted that the Flector patch has been well-tolerated, and has been helpful in improving function and reducing pain while avoiding the need to increase opioid medications. There was documentation that the injured worker was unable to tolerate oral NSAIDs. The treating physician's request did not include the site of application, or directions for use. Medical necessity of the requested medication has not been established. The request for this topical analgesic is not medically necessary.