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| Case Number: | CM15-0124076 | | |
| Date Assigned: | 08/04/2015 | Date of Injury: | 08/13/2001 |
| Decision Date: | 09/24/2015 | UR Denial Date: | 05/27/2015 |
| Priority: | Standard | Application Received: | 06/26/2015 |

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 50 year old male injured worker suffered an industrial injury on 8-13-2001. The diagnoses included lumbar radiculopathy, failed back syndrome, and depression. The treatment included medications, spinal cord stimulator and lumbar fusion. On 5-13-2015, the treating provider reported lower back pain radiating to both legs. He had developed a deep vein thrombosis in the right leg. He reported the battery for the spinal cord stimulator needed replacement. The pain was rated 7 to 8 out of 10 with medications and 10 out of 10 without medications. There was stiffness, spasms of the left leg with burning, numbness and tingling. The provider started Theramine for chronic pain, Sentra AM and Sentra PM to help with energy. It was not clear if the injured worker had returned to work. The requested treatments included Theramine, Sentra AM, Sentra PM, and Terocin patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine Qty 180: 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) - Theramine.

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

Decision rationale: According to the ODG, Theramine is an FDA regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Its mechanism of action is the production of neurotransmitters that help manage and improve the sensory response to pain and inflammation. This medication contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa. There is no medical literature that supports the use of this medication for the treatment of chronic pain. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

Sentra AM Qty 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) - Medical food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Sentra Product Information.

Decision rationale: Sentra AM is a Medical Food that is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness and memory. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of the ingredients. Medical necessity for the requested item has not been established. The requested medical food is not medically necessary.

Sentra PM Qty 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) - Sentra PM.

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

Decision rationale: Sentra PM is a Medical food that is intended for use in the management of sleep disorders associated with depression. It is a proprietary blend of choline bitartate, glutamate, and 5-hydroxytryptophan. There is no support for the use of medical food in the treatment of chronic pain, and there was no indication for the need for supplementation of any of

the ingredients. Medical necessity for the requested item has not been established. The requested medical food is not medically necessary.

Terocin patches Qty 30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of anti-depressants and anti-convulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or anti-depressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, there is no documentation provided necessitating Terocin patches. This medication contains: lidocaine and menthol. The guidelines state that topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain. Topical lidocaine other than Lidoderm is not recommended per the MTUS. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.