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| Case Number: | CM15-0032438 | | |
| Date Assigned: | 02/25/2015 | Date of Injury: | 08/22/1997 |
| Decision Date: | 04/15/2015 | UR Denial Date: | 01/21/2015 |
| Priority: | Standard | Application Received: | 02/20/2015 |

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 43 year old female who sustained an industrial related injury on 8/22/97 while transferring an obese patient. The injured worker had complaints of low back pain that radiated to bilateral legs and bilateral feet. Diagnoses included lumbar spine sprain/strain, discogenic low back pain, myofascial back pain, and fear avoidance behavior due to chronic pain. Treatment included epidural injections and the use of a TENS unit. Medications included Norco, Cymbalta, Motrin, and Aspirin. The treating physician requested authorization for Percura #120, Trepadone #120, Sentra PM #60, and Dilaudid 4mg #60. On 1/21/15 the requests were non-certified. Regarding Percura, Trepadone, and Sentra PM the utilization review (UR) physician cited the Official Disability Guidelines and noted 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. Regarding Dilaudid, the UR physician cited the Medical Treatment Utilization Schedule (MTUS) guidelines and noted published literature emphasized that use of high dose opioid therapy rarely results in satisfactory analgesia or improved function.

IMR ISSUES, DECISIONS AND RATIONALES

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

Percura #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (Pain Chapter).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain (Chronic), Percura.

Decision rationale: The patient presents with pain and weakness in her lower back and lower extremity. The request is for PERCURA #120. The MTUS and ACOEM guidelines are silent with regards to this product. However, the ODG guidelines, under medications, Percura Topic, does not recommend Percura. Percura is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid, choline bitartrate, L-arginine, L-serine, and other ingredients. It is intended for dietary management of metabolic processes associated with pain, inflammation and loss of sensation due to peripheral neuropathy. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." Until there are high quality studies of the ingredients in Percura, it is not recommended. In this case, Percura is noted in progress reports dated 09/23/14, 10/21/14 and 10/28/14. The treater, however, does not discuss the purpose of this prescription or the effectiveness of this medical food. There is lack of support from the guidelines for Percura, the request IS NOT medically necessary.

Trepadone #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (Pain Chapter).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain (chronic)chapter, Trepadone.

Decision rationale: The patient presents with pain and weakness in her lower back and lower extremity. The request is for TREPADONE #120. ODG guidelines, chapter 'Pain (chronic)' and topic 'Trepadone', states that the medical food is "Not recommended. 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. The guidelines also state that "There is insufficient evidence to support use for osteoarthritis or for neuropathic pain." In this case, Trepadone is noted in progress reports dated 09/23/14, 10/21/14 and 10/28/14. The treater, however, does not discuss the purpose of this prescription or the effectiveness of this medical food. Additionally, ODG guidelines do not support the use of this medical food for neuropathic pain. Hence, the request IS NOT medically necessary.

Sentra PM #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (Pain Chapter).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain Chapter, Medical Food website www.ptlcentral.com.

Decision rationale: The patient presents with pain and weakness in her lower back and lower extremity. The request is for SENTRA PM #60. Per www.ptlcentral.com, Sentra PM are capsules by oral administration, especially formulated prescription only medical food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the dietary management of the altered metabolic processes of sleep disorders associated with depression (www.ptlcentral.com). ODG, Pain Chapter, Medical Food states: "medical food: intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must meet the following criteria: 1. The product must be a food for oral or tube feeding. 2. The product must be labeled for dietary management of a specific medical disorder. 3. The product must be used under medical supervision." In this case, the treater requested Sentra PM for pain related insomnia. Sentra PM does not meet ODG criteria for medical foods, and currently there are no guidelines discussing this product. Therefore, the request IS NOT medically necessary.

Dilaudid 4mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78-81. Decision based on Non-MTUS Citation [http://www.americanpainsociety.org/uploads/pdfs/Opioid Final Evidence Report.pdf](http://www.americanpainsociety.org/uploads/pdfs/Opioid%20Final%20Evidence%20Report.pdf).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS Page(s): 76-78.

Decision rationale: The patient presents with pain and weakness in her lower back and lower extremity. The request is for DILAUDID 4MG #60. Per 10/14/14 progress report, the treater wants the patient to discontinue Nucynta and Norco. The patient rates her pain at 10/10 without medications and 5/10 with medications. Average pain is 7/10. Work status is not known. The patient underwent 6 urine drug screenings (UDS) between 09/02/14 and 12/09/14. The results of UDS are provided. The treater prescribes Dilaudid for the first time on 10/14/14. Regarding initiating opiates, MTUS guidelines page 76-78 recommend "the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." "Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS also states, "If partial analgesia is not obtained, opioids should be discontinued." In this case, the treater wants the patient to try Dilaudid because the patient "has not been getting any relief from her medication" such as Norco and Nucynta. There is discussion regarding what the problem with the other opioids such as Norco and Nucynta. The treater

provides partial analgesia with other opiates to consider another opiate. The trial of Dilaudid seems reasonable. The request IS medically necessary.