MAXIMUS Federal Services

Case Number:	CM14-0194880		
Date Assigned:	12/02/2014	Date of Injury:	05/07/2004
Decision Date:	01/16/2015	UR Denial Date:	10/21/2014
Priority:	Standard	Application Received:	11/20/2014

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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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:

This is a 63-year-old female with a 5/7/04 date of injury, when she fell off from a stepladder and injured her neck and lower back. The patient was seen on 10/7/14 with complaints of severe pain in both knees and troubles sleeping. The patient stated that her pain was 8/10 without medications and 5/10 with medications. Exam findings revealed blood pressure 146/92, pulse 78, and respirations 12 and weight at 209 pounds. The provider requested Sentra PM for the patient's insomnia, Tramadol, Lyrica and Norco was discontinued due to denied authorizations in the past. The diagnosis is cervicalgia, cervical radiculitis, chronic pain syndrome, depression, insomnia, neuropathic pain, myofascial syndrome and lumbar radiculitis. Treatment to date: work restrictions, physical therapy and medications. An adverse determination was received on 10/21/14. The requests for Sentra PM #60 with 1 refill and Percura #120 with 1 refill were denied given that the medical necessity was not established and that the Guidelines did not recommend medical foods for treatment of chronic pain. The request for Lyrica 75mg #90 with 1 refill was modified to #16 for a lack of documentation indicating clinical evidence of neuropathic pain and reduction in the patient's pain. The request for Norco 10/325mg #180 with 1 refill was modified to #30 for a lack of functional improvement, reduction in pain and that the recent UDS (urine drug screen) tests were inconsistent and weaning was recommended.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Prescription of Sentra PM, #60 with 1 refill: 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), Sentra PM, Sleep disorders

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, Medical Foods

Decision rationale: CA MTUS does not address this issue. ODG states that Sentra PM is a medical food and is intended for use in management of sleep disorders associated with depression. The progress note dated 10/7/14 stated that Sentra was prescribed for the patient's insomnia. However, there is a lack of documentation indicating that the patient tried and failed other medications for insomnia. In addition, the Guidelines state that there are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Lastly, there is no rationale indicating the necessity for this specific medication for the patient's insomnia and contraindications for other medications for insomnia. Therefore, the request for 1 Prescription of Sentra PM, #60 with 1 refill was not medically necessary.

1 Prescription of Lyrica 75mg, #90 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lyrica Page(s): 19.

Decision rationale: CA MTUS states that Lyrica has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Peer-reviewed literature also establishes neuropathic pain as an indication for Lyrica. However, there is a lack of recent documentations indicating that the patient suffered from neuropathic pain or postherpetic neuralgia. In addition, there is a lack of documentations indicating subjective and objective functional gains from prior use of Lyrica. Lastly, the UR decision dated 10/21/14 modified the request for Lyrica 75mg, #90 with 1 refill to #16 for weaning purposes. Therefore, the request for Lyrica 75mg, #90 with 1 refill was not medically necessary.

1 Prescription of Percura #120 with 1 refill: 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), Medical Foods

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, Medical Foods FDA Medical Foods

Decision rationale: Percura is a medical food. CA MTUS does not address medical foods. ODG states that 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. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. However, the FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. In addition, there is no rationale or indication provided for the treatment with the requested medications. Therefore, the request for 1 Prescription of Percura #120 with 1 refill was not medically necessary.

1 Prescription of Norco 10/325mg, #180 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for the use of Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opiates Page(s): 78-81.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. However, given the 2004 date of injury, the duration of opiate use to date is not clear. There is no discussion regarding non-opiate means of pain control, or endpoints of treatment. The records do not clearly reflect continued analgesia, continued functional benefit, a lack of adverse side effects, or aberrant behavior. Although opiates may be appropriate, additional information would be necessary, as CA MTUS Chronic Pain Medical Treatment Guidelines require clear and concise documentation for ongoing management. In addition, several UDS tests revealed inconsistency with prescribed medications. Additionally, the progress note dated 10/7/14 indicated that Norco was discontinued and Tramadol was prescribed for the patient. Lastly, the UR decision dated 10/21/14 modified the request for Norco 10/325mg, #180 with 1 refill to #30 for weaning purposes. Therefore, the request for 10/325mg, #180 with 1 refill was not medically necessary.