MAXIMUS Federal Services

Case Number:	CM15-0020562		
Date Assigned:	02/10/2015	Date of Injury:	08/18/1994
Decision Date:	03/30/2015	UR Denial Date:	01/23/2015
Priority:	Standard	Application Received:	02/04/2015

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: Montana
Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 67 year old female, who sustained an industrial injury on 8/18/1994. The diagnoses have included post-laminectomy syndrome of lumbar region and lumbar disc degeneration. Past medical history included hypertension, hypercholesterolemia, asthma and hypothyroidism. Treatment to date has included pain medications and lumbar fusion at L4-5 and L5-S1. According to the progress note dated 12/18/2014, the injured worker had a chief complaint of low back pain. She reported sharp pain down the lower extremities, severe nerve pain in the feet at night, becoming fatigued easily and severe back aches. The injured worker reported that her legs felt heavy and she had pins and needles along the bottom of her feet. The injured worker's pain continued to worsen and her activity was declining.Use of pain medication had increased. Toxicology screening done at the last visit was noted to be within normal limits for her current medications. Authorization was requested for medication refills for Oxycodone and Opana. On 1/23/2015, Utilization Review (UR) non-certified a request for Opana ER 20mg one tablet orally every twelve hours #60. The Medical Treatment Utilization Schedule (MTUS) was cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Opana ER 20mg 1 tablet orally every 12 hours #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids-Criteria for use Page(s): 76-80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Oxymorphone Page(s): 74-80 and 93. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Drug formulary, Opana

Decision rationale: Opana ER is an extended release formulation of oxymorphone. The MTUS notes that Opana ER is not intended for PRN use. Patients are to avoid alcohol while on Opana ER due to increased (possibly fatal) plasma levels. The ODG guidelines note that oxymorphone (Opana) is not recommended. Due to issues of abuse and Black Box FDA warnings, oxymorphone is recommended as second line therapy for long acting opioids. Oxymorphone products do not appear to have any clear benefit over other agents and have disadvantages related to dose timing (taking the IR formulation with food can lead to overdose), and potential for serious adverse events (when the ER formulation is combined with alcohol use a potentially fatal overdose may result). (Opana FDA labeling) Ongoing review requires documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug- taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. In this case the treating provider does document improved ability to function with use of medications however, there is no pain assessment and documentation of objective functional improvement. The records indicate that overall pain is worsening with activity decreasing. Utilization review on 12/16/18 modified the request for all opioid medications to allow for weaning or appropriate documentation supporting continued use within the guidelines.The MTUS states that for chronic low back pain, opioids appear to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassement and consideration of alternative therapy. The request for Opana ER 20 mg, 1 tablet every 12 hours, #60 is not medically necessary.