MAXIMUS Federal Services

Case Number:	CM15-0104204		
Date Assigned:	06/11/2015	Date of Injury:	08/01/2005
Decision Date:	07/14/2015	UR Denial Date:	05/18/2015
Priority:	Standard	Application Received:	06/01/2015

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 51 year old female, who sustained an industrial injury on 08/01/2005. Initial complaints and diagnosis were not clearly documented. On provider visit dated 03/23/2015 the injured worker has reported headache, posterior neck pain, and bilateral arm pain. On examination of the cervical spine was noted to have tenderness to palpation with decreased range of motion. She was noted to have continued dysesthesia and hypoesthesia diffusely the lateral upper extremities to the index fingers. The diagnoses have included chronic neck pain, cervical degenerative disc disease and cervical radiculopathy. Treatment to date has included stretching, ice, heat, acupuncture and medication Zohydro, Cymbalta, Valium and Belsomra. The provider requested Zohydro ER 15MG #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zohydro ER 15MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone, Opioids, criteria for use, Weaning of Medications Page(s): 51, 78-80, 124. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Online Version, Zohydro (Hydrocodone).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria For Use of Opioids Page(s): 76-78, 88-89. Decision based on Non-MTUS Citation Official disability guidelines Pain chapter, under Zohydro.

Decision rationale: The patient presents on 05/28/15 with neck and bilateral upper extremity pain rated 7-8/10 with medications, 8/10 without medications. The patient's date of injury is 08/01/05. Patient is status post anterior cervical fusion at C4 through C7 levels in 2006. The request is for Zohydro ER 15mg #60. The RFA is dated 05/28/15. Physical examination dated 05/28/15 reveals tenderness to palpation of the posterior cervical paraspinal region and bilateral trapezius, levator scapulae, interscalene and sternocleidomastoid muscles. Cervical range of motion is decreased by 50 percent in all planes, and the provider also notes positive Spurling's maneuver, tenderness in the bilateral wrists, and continued dysesthesia and hypoesthesia diffusely in the bilateral upper extremities to the index fingers. The patient is currently prescribed Zohydro. Diagnostic imaging included MRI of the cervical spine dated 07/17/06, significant findings include: "C3-4 small central focal disc protrusion... C4-5, C5-6, C6-7 disc bulging and osteophytic ridging causing central canal compromise." Patient's current work status is not provided. MTUS Guidelines pages 88 and 89 under Criteria for use of Opioids (Long-Term Users of Opioids): "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 under Criteria For Use of Opioids, Therapeutic Trial of Opioids, also requires documentation of the 4As, analgesia, ADLs, adverse side effects, and adverse behavior, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. ODG Pain chapter, under Zohydro has the following: "Not recommended. See Hydrocodone. Zohydro ER ([redacted] is the first single-entity extended-release (ER) formulation of hydrocodone approved by the FDA; unlike Vicodin, Lortab and Norco, it is not buffered with acetaminophen or some other OTC medication. Each pill will be very potent, but Zohydro initially did not have abuse-deterrent technology. According to the FDA, Zohydro ER should be reserved for use in patients for whom alternative treatment options are ineffective. FDA's Drug Advisory Committee of independent experts voted 11 to 2 to recommended against approval of Zohydro for the treatment of moderate to severe chronic pain. Zohydro is not recommended as a first line drug in ODG." In regard to Zohydro for this patient's chronic neck pain, the provider has not documented adequate analgesia attributed to medications and has not established that Zohydro is necessary for this patient. Progress note dated 05/28/15 notes that this patient's pain is 7-8/10 with medications, and 8/10 without medications; failing to establish efficacy in regard to analgesia. The same note does provide some evidence of functional improvements; such as the ability to perform household chores. No consistent urine drug screenings or discussion of consistency is provided either, and there is no stated lack of aberrant behavior. MTUS guidelines require documentation of analgesia via a validated scale (with a 20% reduction in pain being considered effective analgesia), activity-specific functional improvements, consistent urine drug screening, and a stated lack of aberrant behavior. In this case, only limited evidence of functional improvement has been provided. In addition, ODG does not support the use of Zohydro in patients for whom alternative treatments have been ineffective, no such discussion as to why Zohydro is necessary was provided. Owing to a lack of guideline support for first-line use of this medication, and a lack of complete 4A's documentation as required by MTUS, the request is not medically necessary.