

Case Number:	CM15-0169668		
Date Assigned:	10/02/2015	Date of Injury:	07/17/2002
Decision Date:	11/13/2015	UR Denial Date:	08/18/2015
Priority:	Standard	Application Received:	08/28/2015

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 73 year old male, who sustained an industrial injury on 07-17-2002. He has reported injury to the low back. The diagnoses have included low back pain, history of radicular symptoms, right leg, with neuropathic pain; degenerative disc disease, multilevel, with facet arthrosis, disc herniations at L4-L5 and L5-S1 causing bilateral compromise of the exiting nerve roots, per MRI; and right knee pain, history of prior arthroscopy. Treatment to date has included medications, diagnostics, TENS (transcutaneous electrical nerve stimulation) unit, and lumbar epidural steroid injections. Medications have included Norco, Dilaudid, Zanaflex, Lyrica, Lodine, Celebrex, Hysingla, and Gralise. A progress report from the treating provider, dated 07-29-2015, documented an evaluation with the injured worker. The injured worker reported intractable back pain that continues to shoot down his right leg, with ongoing knee pain and instability; the orthopedic surgeon "wants to hold off on further surgery on his knee at this time"; Naprosyn and Omeprazole help somewhat, but he still requires pain medication to keep himself functional; he has been using Norco for pain and Hysingla at night as a long-acting analgesic; he is using Zanaflex for severe cramps in his back; he is using Gralise at nighttime to offset neuropathic burning pain in his leg; and he reports 50% reduction in pain and functional improvement with activities of daily living with the medications versus not taking them at all. Objective findings included the back exam reveals limited range; right and left straight leg raising tests are both 80 degrees and causing right-sided back pain; there is sensory loss to light touch and pinprick in the right lateral calf and bottom of his foot; the right Achilles reflex is absent; there is 4 out of 5 weakness in the right thigh flexion and knee extension; and palpation reveals muscle spasm in the lumbar trunk. The treatment plan has included the request for Hysingla 60mg #30. The original utilization review, dated 08-18-2015, non-certified the request for Hysingla 60mg #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hysingla 60mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Medications for chronic pain, Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) chapter, under Hysingla.

Decision rationale: The patient was injured on 07/17/02 and presents with back pain that shoots down his right leg with ongoing right knee pain and instability. The request is for Hysingla 60 MG #30 as a long-acting analgesic. The RFA is dated 08/03/15 and the patient's current work status is not provided. The patient has been taking this medication as early as 05/06/15 and treatment reports are provided from 03/11/15 to 07/29/15. MTUS, criteria for use of opioids section, pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS, criteria for use of opioids section, page 78 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. MTUS, criteria for use of opioids section, p77, states that "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS, medications for chronic pain section, page 60 states that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." MTUS, opioids for chronic pain section, pages 80 and 81 states "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Official Disability Guidelines, Pain (Chronic) chapter, under Hysingla states the following: Not recommended for first-line use for treatment of acute or chronic non-malignant pain. Short-acting opioids are recommended prior to use of long-acting opioids. See Opioids, long-acting. The FDA approved the extended-release (ER) single-entity opioid analgesic hydrocodone bitartrate (Hysingla ER, ██████████) with abuse-deterrent properties. Hysingla ER has properties that are expected to reduce, but not totally prevent, abuse of the drug when chewed and then taken orally, or crushed and snorted or injected. The product is indicated for treatment of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Opioids are not recommended as a first-line treatment for chronic non-malignant pain in ODG. See Opioids for chronic pain. The FDA also approved another extended-release single-entity hydrocodone drug, Zohydro in October 2013. The 07/01/15 report indicates that he rates his pain as a 4/10 with medications and a 10/10 without them. The 07/29/15 report states that medications keep the patient functional. He reports 50% reduction in pain and functional improvement with activities of daily living with the medications versus not taking them at all. He is under a narcotic contract with our office. Urine drug screens have been appropriate. Prior to the request of Hysingla, the patient was on Morphine. In this case, not all of the 4 A's are addressed as required by MTUS Guidelines. There

are no examples of specific ADLs which demonstrates medication efficacy nor are there any discussions provided on adverse behavior/side effects. No validated instruments are used either. No outcome measures are provided as required by MTUS Guidelines. The treating physician does not provide adequate documentation that is required by MTUS Guidelines for continued opiate use. The requested Hysingla is not medically necessary.