

Case Number:	CM15-0190846		
Date Assigned:	10/05/2015	Date of Injury:	09/11/2007
Decision Date:	11/16/2015	UR Denial Date:	08/27/2015
Priority:	Standard	Application Received:	09/28/2015

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 52 year old male, who sustained an industrial-work injury on 9-11-07. He reported initial complaints of low back pain. The injured worker was diagnosed as having lumbar radiculopathy, insomnia, myalgia, and lumbar degenerative disc disease. Treatment to date has included medication, two ESI (epidural steroid injection), transcutaneous electrical nerve stimulation (TENS) unit, and H-wave unit. Currently, the injured worker complains of worsening aching, burning pain in low back, right buttock, and right leg. The right leg is getting weaker and gives out. Meds include Flexeril, Naproxen, Norco, Omeprazole, trazodone and Gabapentin. He is able to walk more, sleep better, and do ADL's (activities of daily living) with medication. Pain is 9 out of 10 without meds and 6 out of 10 with medication. Per the primary physician's progress report (PR-2) on 8-19-15, exam noted 4+ out of 5 strength in his right lower extremity, sensation decreased over the right lower extremity, bladder control problems, DTR (deep tendon reflexes) are 1+ on the right, tenderness over the paraspinals on the right at L5-S1, increased pain with flexion and extension, and positive straight leg raise on the right. Current plan of care includes medication. The Request for Authorization requested service to include Hysingla ER mg every 24 hours #30. The Utilization Review on 8-27-15 denied the request for Hysingla ER mg every 24 hours #30, per CA MTUS (California Medical Treatment Utilization Schedule), Chronic Pain Medical Treatment Guidelines 2009.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hysingla ER mg every 24 hours #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

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 rationale: The patient presents on 08/19/15 with lower back pain which radiates into the right lower extremity rated 6/10 with medications, 7/10 without. The patient's date of injury is 09/11/07. Patient has no documented surgical history directed at this complaint. The request is for Hysingla ER MG every 24 hours #30. The RFA is dated 09/01/15 and there is an identical request on RFA dated 08/20/15. Physical examination dated 08/19/15 reveals tenderness to palpation of the lumbar paraspinals at L5-S1 level, positive straight leg raise test on the right, and decreased sensation in the right lower extremity. The patient is currently prescribed Trazodone, Omeprazole, Anaprox, Neurontin, Flexeril, Norco, and Lidoderm. Patient is currently classified as temporarily totally disabled. 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, Purdue Pharma) 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. In regard to the requested Hysingla for the management of this patient's chronic pain, the request is not supported per MTUS. Progress note dated 08/19/15 states that this patient's pain is rated 6/10 with medications, 9/10 without medications. Addressing function, the provider states: "He is

able to walk longer and help out more along the house and he can sleep better. He is able to be more social with the help of his medications." MTUS guidelines require analgesia via a validated scale (with before and after ratings), activity-specific functional improvements, consistent urine drug screening, and a stated lack of aberrant behavior. In this case, the requesting physician has satisfied 4As documentation requirements. However, more importantly, MTUS pg 80, 81 also states the following regarding narcotics for chronic pain: "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Long-term use of opiates may in some cases be indicated for nociceptive pain per MTUS, which states, "Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer)." This patient has been prescribed narcotic medications long term, and is not presumed to be suffering from nociceptive pain. Addressing the need for Hysingla, progress note dated 8/19/15, has the following: "We hope that by starting him on this medication he will be able to take less Norco." MTUS guidelines do not support the use of Hysingla as a first line medication for patients not suffering from pain secondary to cancer. While this patient presents with significant chronic complaints, without evidence of an existing condition which could cause nociceptive pain (such as cancer), continuation of this medication is not appropriate and the patient should be weaned. The request is not medically necessary.