

<b>Case Number:</b>	CM15-0047666		
<b>Date Assigned:</b>	03/19/2015	<b>Date of Injury:</b>	03/21/2012
<b>Decision Date:</b>	05/01/2015	<b>UR Denial Date:</b>	03/02/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/12/2015

### 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 44 year old female injured worker suffered an industrial injury on 3/21/2012. The diagnoses were left ankle fracture, complex regional pain syndrome and tarsal tunnel syndrome. The diagnostic studies were left ankle x-rays and left ankle magnetic resonance imaging. The injured worker had been treated with medications, physical therapy, left ankle arthroscopy, steroid injections, ankle brace and casting. On 1/21/2015, the treating provider reported constant pain in the left foot and ankle with swelling and discoloration of the lower leg when she's on her feet. She reports that over time she has begun to notice the pain and numbness creeping up the leg from the ankle/foot region. On exam, there was a mild impairment of gait and deformity of the left ankle. The left ankle/foot is slightly swollen with the left foot cooler than the right foot. After manipulating the left foot and ankle there was significant mottling turning dark purple. The treatment plan included Hysingla.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Hysingla ER Tab 40mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 91. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain chapter.

**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 (Chronic) chapter under Hysingla.

**Decision rationale:** The patient was injured on 03/21/12 and presents with left foot pain and left ankle pain. The request is for Hysingla ER TAB 40 MG. There is no RFA provided and the patient is not currently working. The report with the request is not provided. ODG Guidelines regarding the 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." MTUS Guidelines 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 page 78 also requires documentation of the 4A's (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 page 98 also continues to state that the maximum dose for hydrocodone is 60 mg per day. There is no indication of when the patient began taking this medication, nor is there any discussion provided regarding Hysingla. In this case, none of the 4As are addressed as required by MTUS Guidelines. The treater does not provide any pain scales. There are no examples of ADLs which demonstrate medication efficacy, nor are there any discussions provided on adverse behavior/side effects. There are no pain management issues discussed such as CURES reports, pain contract, et cetera. No outcome measures are provided either as required by MTUS Guidelines. No urine drug screens are provided to indicate if the patient is compliant with his prescribed medications. The treating physician does not provide proper documentation that is required by MTUS Guidelines for continued opiate use. Therefore, the requested Hysingla IS NOT medically necessary.