

<b>Case Number:</b>	CM15-0183127		
<b>Date Assigned:</b>	09/24/2015	<b>Date of Injury:</b>	07/27/2011
<b>Decision Date:</b>	11/06/2015	<b>UR Denial Date:</b>	09/02/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/17/2015

### 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, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 (IW) is a 65-year-old female who sustained an industrial injury on 07-27- 2011. Medical records indicate the worker is treated for postlaminectomy syndrome status post L5-S1 fusion (1985) and hardware removal (2010) with subsequent decompression (2011); pain in joint lower leg status post bilateral knee arthroscopies (right- in the early 2000's) with severe chondromalacia, and a left knee arthroscopic meniscetomy and chondroplasty (04-23-2013). In the provider notes of 08/24/2015, the injured worker is seen for a chronic neck and left knee pain (date of injury 07-27-2011). Her current medications include Lidoderm patch, Hysingla ER 30 mg 1 tablet per day, Motrin (from another provider), Potassium, and Levothyroxine. The Hysingla was first trialed 07-2015 at 40 mg but reduced due to her complaint of dizziness. She reports a complaint of headaches. She does have high blood pressure. She complains of itching of the skin but denies rash and yellowing of the skin. She complains of urinary incontinence but denies blood in urine, urinary hesitancy and painful urination, she complains of balance problems, poor concentration and weakness but denies memory loss, numbness seizures and tremors. She complains of constipation, nausea and abdominal pain but denies heartburn, black tarry stools and bloody emesis. Her medical history includes arthritis, asthma, bowel irregularity, depression, diabetes, liver disease, and history of pyelonephritis. Objectively, she has an antalgic gait, she is tearful, and she has suicidal ideation but denies a plan or intent. There are no ratings of the intensity or frequency of her pain or her response to medications. She does report a benefit of pain without sedation with the Hysingla 30 mg. The worker is currently not working. A request for authorization was submitted for Hysingla extended release 30mg quantity 30. A utilization review decision 09-02-2015 modified the request to approve quantity 20, non-approving 10.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Hysingla extended release 30mg quantity 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. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Hysingla.

**Decision rationale:** Per the ODG guidelines regarding Hysingla, "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." Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "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 non-adherent) drug related behaviors. These domains have been summarized as the "4 A's" (Analgesia, activities of daily living, adverse side effects, and any 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." Review of the available medical records reveals neither documentation to support the medical necessity of Hysingla nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS dated 6/16/15 was positive for opiates. CURES report was not available for review. As MTUS recommends discontinuing opioids if there is no overall improvement in function, medical necessity is not medically necessary.