

<b>Case Number:</b>	CM15-0083130		
<b>Date Assigned:</b>	05/05/2015	<b>Date of Injury:</b>	06/06/2014
<b>Decision Date:</b>	06/09/2015	<b>UR Denial Date:</b>	04/03/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/30/2015

### 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: New York, Tennessee  
 Certification(s)/Specialty: Emergency Medicine

### 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 male who sustained an industrial injury on June 6, 2014. Previous treatment includes home exercise, aqua therapy, physical therapy, epidural steroid injection, and massage therapy. Currently the injured worker complains of low back pain with radiation of pain to the left leg. He rates the pain as a 5 on a 10-point scale and reports the pain as constant pain with a shooting sensation. His pain score of 5 was unchanged from his previous evaluation. He reports that his pain is much improved with the initiation of Hysingla and because the medication has been so helpful, he was able to discontinue all of his other oral medications. He reports that the topical anti-inflammatory cream is helpful with his low back pain. The documentation provided did not provide evidence of specific functional improvement related to the use of Hysingla or the Flurbiprofen 20% Lidocaine 5% topical cream. Diagnoses associated with the request include degeneration of lumbar or lumbosacral intervertebral disc, thoracic or lumbosacral neuritis or radiculitis, lumbago and sciatica. The treatment plan includes transforaminal epidural steroid injection, Hysingla and Flurbiprofen 20% Lidocaine 5%.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**2 Flurbiprofen 20% Lidocaine 5% 300 grams: quantity not given refills not listen: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112.

**Decision rationale:** This medication is a compounded topical analgesic containing flurbiprofen and lidocaine. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Flurbiprofen is recommended as an oral agent for the treatment of osteoarthritis and the treatment of mild to moderate pain. It is not recommended as a topical preparation.

Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy, such as an antidepressant or antiepileptic drug. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. In this case documentation in the medical record does not support the diagnosis of postherpetic neuralgia. Lidocaine is not indicated. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request is not medically necessary.

**Hysingla ER 30 mg oral tablet #30 refills unlisted:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM, Low back disorders. Official Disability Guidelines Drug Formulary.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain, Hysingla.

**Decision rationale:** Hysingla ER is an extended release preparation of the opioid hydrocodone. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain or function. It is recommended for short-term use if first-line options, such as acetaminophen or NSAIDs have failed. Hysingla is 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. 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. In this case there is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. Criteria for long-term opioid use have not been met. The request is not medically

necessary.