

<b>Case Number:</b>	CM15-0160331		
<b>Date Assigned:</b>	08/26/2015	<b>Date of Injury:</b>	04/20/1978
<b>Decision Date:</b>	10/02/2015	<b>UR Denial Date:</b>	08/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/17/2015

### 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 is a 55 year old male/female who sustained an industrial-work injury on 4-20-78. He reported an initial complaint of back and hip pain. The injured worker was diagnosed as having lumbago. Treatment to date includes medication. Currently, the injured worker complained of ongoing back and hip pain along with depression. Per the primary physician's report (PR-2) on 7-17-15, exam noted antalgic gait, muscles are tense, tenderness to palpation. Lumbar range of motion noted forward flexion at 50 degrees, extension to 10 degrees, side bending of 20 degrees with pain. The requested treatments include Hyslinga ER 60mg x 7 tablets for seven day supply and Hyslinga ER 80mg x 30 tablets for 30 day supply.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Hyslinga ER 60mg x 7 tablets for seven-day supply:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Hyslinga.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 91. 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, [REDACTED]) 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 p 78 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 no 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. The medical records contain UDS report dated 12/22/14 which was consistent with prescribed medications. It is noted per the documentation that the injured worker is already using norco and Methadone, with an apparent desire to switch off norco and onto Hysingla. However, as MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed. Therefore, the request is not medically necessary.

**Hysingla ER 80mg x 30-tablets for 30 day supply:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Hysingla.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 91. 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, [REDACTED]) 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 p 78 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 no 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. The medical records contain UDS report dated 12/22/14 which was consistent with prescribed medications. It is noted per the documentation that the injured worker is already using norco and Methadone, with an apparent desire to switch off norco and onto Hysingla. However, as MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed. Therefore, the request is not medically necessary.