

<b>Case Number:</b>	CM15-0165130		
<b>Date Assigned:</b>	09/02/2015	<b>Date of Injury:</b>	04/04/2005
<b>Decision Date:</b>	10/19/2015	<b>UR Denial Date:</b>	08/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/24/2015

### 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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational 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 32 year old female who sustained an industrial injury on 04-04-2005. The initial diagnosis was low back contusion status post fall, 2nd trimester pregnancy. On 06-22-2015, the injured worker underwent a lumbar epidural injection. According to the most recent progress report submitted for review and dated 07-31-2015, current diagnoses included lumbago multilevel with bilateral radiculopathy, facet arthropathy left greater than right, sacroiliac joint arthropathy left greater than right, myofascial syndrome, reactive insomnia and reactive depression and anxiety. She had been previously seen on 07-20-2015. Her current VAS score was elevated at 7 on a scale of 1-10. She continued to experience the elevated levels of pain down the legs, particularly in the right lower extremity, as well as the relatively new symptoms in the ankle, heel and foot. This had left the injured worker unable to ambulate without crutches. A new MRI was requested due to the new symptoms. Her current functional status was somewhat diminished, due to the higher pain levels and new symptoms. Current medications helped with her pain. Medications included Norco 10-325 mg 1-2 tablets by mouth every 3-4 hours as needed maximum 8 every day for general and breakthrough pain #240, Restoril 15 mg 2 tablets by mouth every bedtime for sleep issues and Duexis 800-26.6 mg 1 tablet four times a day #90 for general pain. The injured worker had been unable to fill Zohydro because the pharmacy did not carry this medication. The provider noted that a previous attempt was made to prescribe Hysingla but insurance did not cover it. The treatment plan included a request for an MRI and current medications. The injured worker was not maximally medically improved at this time. She was temporarily partially disabled. She had significant pain with disability and remained in need of further medical care. Urine toxicology was obtained. On 08-14-2015, the provider requested authorization for Norco 10-325 mg #240, Restoril 15 mg #60, Duexis 800-26.6 #90 and Hysingla ER 30 mg #30. Currently under review is the request for Norco 10-325 mg #240, Restoril 15 mg #60, Duexis 800-26.6 #90 and Hysingla ER 30 mg #30.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #240:** 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, Opioids for chronic pain.

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines state that all therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. Chronic Pain Medical Treatment Guidelines state that on-going management of opioid therapy should include ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain, the least reported pain over the period since the last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. Information from family members or other caregivers should be considered in determining the patient's response to treatment. In addition to pain relief, the practitioner should monitor side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. MTUS Guidelines state that pain and functional improvement should be documented and compared to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. Pain should be assessed at each visit and functioning should be measured at 6 month intervals using a numerical scale or validated instrument. In this case, documentation shows long term use of Norco. The treating provider did not document the least reported pain over the period since the last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. Pain level remained elevated. Functioning was not measured using a numerical scale or validated instrument. In addition, there is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.

**Restoril 15mg #60:** 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): Benzodiazepines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress Chapter-Insomnia Treatment and Other Medical Treatment Guidelines [www.pdr.net](http://www.pdr.net).

**Decision rationale:** Literature states that Restoril (temazepam) is a benzodiazepine indicated for short-term treatment of insomnia (7-10 days). CA MTUS Guidelines state that benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes

sedative, hypnotic, anxiolytic, anticonvulsant and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Official Disability Guidelines (ODG) recommend that treatment of insomnia be based on the etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed and include sleep onset, sleep maintenance, sleep quality and next-day functioning. ODG recommend non-benzodiazepine sedative-hypnotics as first-line medications for treatment of insomnia. In this case, documentation shows, long-term use of Restoril which is not recommended by guidelines. In the most recent progress report, the treating provider did not discuss sleep onset, sleep maintenance, sleep quality and next day functioning. Medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.

**Duexis 800/26.6 #90:** 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): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-Duexis (Ibuprofen & Famotidine).

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines state that all therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. CA MTUS Chronic Pain Medical Treatment Guidelines state that NSAIDs (non-steroidal anti-inflammatory drugs) are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. MTUS specific recommendations for NSAIDs include treatment of osteoarthritis for the shortest time possible and short term treatment of back pain. It may be useful for breakthrough and mixed pain conditions in patients with neuropathic pain. Other chronic pain conditions are not discussed. Guidelines recommend NSAIDs for acute exacerbations of chronic back pain as a second-line treatment after acetaminophen. According to the CA MTUS, Proton Pump Inhibitors, such as Omeprazole (Prilosec), are recommended for patients taking NSAIDs with documented GI distress symptoms or specific GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose and/or multiple NSAIDs. Official Disability Guidelines state that Duexis (Ibuprofen & Famotidine) is not recommended as a first-line drug. [REDACTED] recently announced the launch of Duexis, a combination of ibuprofen 800 mg and famotidine 26.6 mg, indicated for rheumatoid arthritis and osteoarthritis. Ibuprofen (e.g., Motrin, Advil) and famotidine (e.g., Pepcid) are also available in multiple strengths over the counter and other strategies are recommended to prevent stomach ulcers in patients taking non-steroidal anti-inflammatory drugs. With less benefit and higher cost, using Duexis as a first-line therapy is not justified. On 05-01-2015, the provider noted that the injured worker had gastrointestinal issues with previous anti-inflammatories in the past including Aleve and Ibuprofen and that Duexis allowed both

pain control and avoidance of the gastrointestinal issue. In this case, there is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.

**Hysingla ER 30mg #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, Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-Hysingla (Hydrocodone).

**Decision rationale:** ODG Official Disability Guidelines state that 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. 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 Official Disability Guidelines. In this case, documentation shows that the injured worker had been utilizing Norco, a short acting opioid, (hydrocodone and acetaminophen) and continued to experience high pain levels without evidence of objective functional improvement. There is no discussion in the progress reports as to why Hysingla was being requested. Medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.