

<b>Case Number:</b>	CM15-0160196		
<b>Date Assigned:</b>	08/26/2015	<b>Date of Injury:</b>	12/03/2008
<b>Decision Date:</b>	10/13/2015	<b>UR Denial Date:</b>	07/17/2015
<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: New York, California  
 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 54 year old female, who sustained an industrial injury on 12-3-2008. She reported low back and neck pain. The mechanism of injury is not indicated. The injured worker was diagnosed as having low back pain, lumbago, cervicgia, lumbar radiculopathy, pain in thoracic spine, lumbosacral spondylosis without myelopathy, extremity pain, neuralgia, neuritis, radiculitis, chronic pain syndrome, primary localized osteoarthritis of hip, and hip pain. Treatment to date has included medications, psychological treatment, physical therapy, and home exercise program. The request is for Duexis, Alprazolam, Norco, and a bilateral lumbar facet joint injection at L3-4. Several pages of the medical records have handwritten information which is difficult to decipher. On 4-14-2015, she reported low back pain. Her pain is rated 7 out of 10 currently, worst pain 10 out of 10, least pain 5 out of 10 and average 7 out of 10. Her pain is reported to remain the same since her previous visit. She reported constipation, drowsiness and nausea with her medications, and that her medications helped to improve her functioning. The treatment plan included: Xanax, Soma, Norco, lumbar medial branch block bilateral at L3, L4, L5 and Toradol injection of the right hip per routine. On 6-9-2015, she reported pain to the low back with radiation down the legs, and neck pain. She indicated the pain to decrease her function and interfere with sleep and walking. Her pain is reported to be the same since her last visit, and she is doing well with her current medications, which she indicated to help her functioning and quality of life. She rated her pain at its worst 10 out of 10, least at 4 out of 10, average 7 out of 10, and current 7 out of 10. The provider noted her pain to be relieved by zero

percent by taking medications. There is notation of an opioid contract. The treatment plan included: Norco, Alprazolam, Duexis, drug screen, and follow up.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Duexis 800mg #90:** Upheld

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

**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, Proton pump inhibitors, duexis.

**Decision rationale:** Per the ODG guidelines, Duexis is a combination of Ibuprofen and Famotidine. It 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 (eg, Motrin, Advil) and famotidine (eg, Pepcid) are also available in multiple strengths over the counter (OTC), and other strategies are recommended to prevent stomach ulcers in patients taking NSAIDs. With less benefit and higher cost, using Duexis as a first-line therapy is not justified. Per the CA MTUS guidelines, Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID), are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The CA MTUS does not recommend chronic NSAIDs for low back pain; NSAIDs should be used for the short term only. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. Package inserts for NSAIDs recommend periodic monitoring of a complete blood count (CBC) and chemistry profile (including liver and renal function tests). Famotidine is not directly addressed in the CA MTUS and ODG. Per Drugs.com, Famotidine is a histamine-2 blocker used to treat and prevent ulcers in the stomach and intestines. The MTUS recommends co-therapy of non-steroidal anti-inflammatory agents (NSAIDs) with a proton pump inhibitor (PPI) in patients who are determined to be at intermediate or high risk of a gastrointestinal (GI) event. The gastrointestinal event risk factors include: age over 65 years, history of peptic ulcer, GI (gastrointestinal) bleeding or perforation, concurrent use of ASA (aspirin), corticosteroids, and/or an anticoagulant, or high dose or multiple oral NSAID (non-steroidal anti-inflammatory drug) use. There is no recommendation for H2 receptor antagonists for gastric protection from NSAID use. An H2-receptor antagonist may be considered for treatment of dyspepsia secondary to NSAID therapy. In this case, there is no discussion of periodic blood work. She is 54 years old. There is no discussion of a history of peptic ulcer, GI (gastrointestinal) bleeding or perforation, concurrent use of ASA (aspirin), corticosteroids, and/or an anticoagulant, or high

dose or multiple oral NSAID (non-steroidal anti-inflammatory drug) use. Therefore, the request for Duexis 800mg #90 is not medically necessary.

**Alprazolam 1mg #30 with 1 refill:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Benzodiazepines, Xanax (alprazolam).

**Decision rationale:** The CA MTUS does not directly address Xanax. The ODG guidelines, state that Xanax (alprazolam) is a benzodiazepine used to treat anxiety disorders, panic disorders, and anxiety caused by depression. The CA MTUS and ODG guidelines state 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, anti-convulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions, as tolerance to hypnotic effects develops rapidly. The tolerance to the anxiolytic effects occurs within months and long term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an anti-depressant. The tolerance to anti-convulsant and muscle relaxant effects occurs within weeks. According to the CA MTUS, all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit,; and a reduction in the dependency on continued medical treatment. In this case, she has been utilizing Xanax (Alprazolam) for greater than 4 weeks without noted benefit. 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. Therefore, the request for Alprazolam 1mg #30 with 1 refill is not medically necessary.

**Norco 7.5-325mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids for chronic pain, Opioids, specific drug list.

**Decision rationale:** Per the CA MTUS, Norco is a combination of Hydrocodone & Acetaminophen. Hydrocodone is considered a semi-synthetic opioid which is considered the most potent oral opioid that does not require special documentation in some states (not

including California). The CA MTUS Chronic Pain Medical Treatment Guidelines state that Hydrocodone/Acetaminophen (Norco) is indicated for moderate to moderately severe pain. The guidelines note that there are no FDA-approved hydrocodone products for pain unless formulated as a combination. The guidelines state that the usual dose of 5-500mg is 1 or 2 tablets by mouth every four to six hours as needed for pain (Max 8 tablets per day). For higher doses of hydrocodone (>5mg per tab) and acetaminophen (>500mg per tab) the recommended dose is usually 1 tablet every four to six hours as needed for pain. The guidelines state that Hydrocodone has a recommended maximum dose of 60mg per 24 hours and that the dose is limited by the dosage of acetaminophen, which should not exceed 4g per 24 hours. The CA MTUS indicates the 4 A's for ongoing monitoring of opioids should be documented for analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. The CA MTUS Chronic Pain Medical Treatment Guidelines indicates that 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 level; the least reported pain over the period since last assessment; average pain level; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts with the use of Norco. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. According to the CA MTUS all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit; and a reduction in the dependency on continued medical treatment. In this case, there is no discussion of: the least reported pain over the period since last assessment, intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts with the use of Norco. There is discussion of an opioid contract; however there is no discussion of appropriate medication use, clinically significant improvement in activities of daily living or a reduction in work restrictions, and a reduction in the dependency on continued medical treatment. 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. Therefore, the request for Norco 7.5-325mg #60 is not medically necessary.

**Bilateral lumbar facet joint injection L3/4, L4/5: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Diagnostc Criteria, Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low back chapter, Facet injections, Facet joint diagnostic blocks (injections), Facet joint intra-articular injections (therapeutic blocks).

**Decision rationale:** Per the ACOEM guidelines, invasive techniques (e.g., local injections and facet-joint injections of cortisone and lidocaine) are of questionable merit. Although epidural steroid injections may afford short-term improvement in leg pain and sensory deficits in patients with nerve root compression due to a herniated nucleus pulposus, this treatment offers no significant long term functional benefit, nor does it reduce the need for surgery. Despite the fact that proof is still lacking, many pain physicians believe that diagnostic and/or therapeutic injections may have benefit in patients presenting in the transitional phase between acute and chronic pain. The ODG guidelines have specific criteria for use of diagnostic blocks for facet "mediated" pain: The criteria is: Clinical presentation should be consistent with facet joint pain, signs & symptoms. 1) one set of diagnostic medial branch blocks is required with a response of greater than or equal to 70%. The pain response should be approximately 2 hours for Lidocaine. 2) Limited to patients with cervical pain that is non-radicular and at no more than 2 levels bilaterally. 3) There is documentation of failure of conservative treatment (including home exercise, physical therapy and non-steroidal anti-inflammatory drugs) prior to the procedure for at least 4-6 weeks. 4) No more than 2 joint levels are injected in one session. 5) Recommended volume of no more than 0.5 cc of injectate is given to each joint, with recent literature suggesting a volume of 0.25 cc to improve diagnostic accuracy. 6) No pain medication from home should be taken for at least 4 hours prior to the diagnostic block and for 4-6 hours afterward. 7) Opioids should not be given as a "sedative" during the procedure. 8) The use of IV sedation may be grounds to negate the results of a diagnostic block, and should only be given in cases of extreme anxiety. 9) The patient should document pain relief with an instrument such as a VAS (visual analog scale), emphasizing the importance of recording the maximum pain relief and maximum duration of pain. The patient should also keep medication use and activity logs to support subjective reports of better pain control. 10) Diagnostic facet blocks should not be performed in patients whom a surgical procedure is anticipated. 11) Diagnostic facet blocks should not be performed in patients who have had a previous fusion procedure at the planned injection level. In this case, the injured worker has a radiculopathy diagnosis. Additionally, the request for a joint injection does not include the medication that would be injected such as analgesic or a steroid. Without the specifics, the request cannot be properly evaluated. Therefore, the request for Bilateral lumbar facet joint injection L3/4, L4/5 is not medically necessary.