

<b>Case Number:</b>	CM15-0232177		
<b>Date Assigned:</b>	12/07/2015	<b>Date of Injury:</b>	01/01/1980
<b>Decision Date:</b>	01/15/2016	<b>UR Denial Date:</b>	11/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/25/2015

### 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  
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 70 year old, male who sustained a work related injury on 1-1-80. A review of the medical records shows he is being treated for low back pain. In the progress notes dated 9-15-15 and 10-13-15, the injured worker reports increasing low back pain. He describes the pain as sharp, dull-aching, pins and needles, stabbing, numbness and electrical-shooting. He rates his pain level a 6-7 out of 10 on a "good day." He rates his pain level a 9 out of 10 on a "bad day." Upon physical exam dated 10-13-15, he has diffuse tenderness over lumbar area. He has right sciatic notch tenderness. She has positive straight leg raise in right leg. Left leg raise causes back pain. He has bilateral lumbar spasms. Treatments have included medications, home exercises and heat therapy. Current medications include Norco, Cyclobenzaprine, Duexis, Omeprazole, Terazosin, Verapamil, Pravastatin, and Fluoxetine. He has been taking the Norco and Duexis since at least March, 2015. No notation of working status. The treatment plan includes requests for medication refills. In the Utilization Review dated 11-16-15, the requested treatment of Norco 10-325mg. #150 was modified to Norco 10-325mg. #75. The requested treatment of Duexis 800-26.6mg, #90 with 2 refills is not medically necessary.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10-325 mg #150: 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): Medications for chronic pain, Opioids, criteria for use, Opioids for chronic pain.

**Decision rationale:** Based on progress report dated 12/08/15, the patient presents with ongoing and increasing pain in low back. The request is for NORCO 10-325 MG #150. The request for authorization form is dated 12/08/15. The patient is status post L4, L5 lumbar fusion. Physical examination of the lumbar/sacral reveals a well healed midline incision. Diffuse tenderness to palpation. Sciatic notch tenderness present on right. Sensory exam reveals sensation to light touch decreased in right lower extremity. Patient is to continue with conservative treatment to include home exercise program, moist heat, and stretches. The patient was counseled as to the benefits of the medication and the potential side effects. Patient's medications include Norco, Cyclobenzaprine, Duexis, and Gabapentin. The patient is permanent and stationary. MTUS, CRITERIA FOR USE OF OPIOIDS Section, pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS, CRITERIA FOR USE OF OPIOIDS Section, page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS, CRITERIA FOR USE OF OPIOIDS Section, p77, states that "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS, MEDICATIONS FOR CHRONIC PAIN Section, page 60 states that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." MTUS, p90 states, "Hydrocodone has a recommended maximum dose of 60mg/24hrs." Treater does not specifically discuss this medication. Review of provided medical records show the patient was prescribed Norco on 03/24/15. MTUS requires appropriate discussion of the 4A's, however; treater does not discuss how Norco significantly improves patient's activities of daily living with specific examples. Analgesia is not discussed, specifically showing pain reduction with use of Norco. There is discussion regarding adverse effects but not aberrant drug behavior. A UDS dated 06/16/15 was provided for review. In this case, the treater has not adequately discussed the 4A's as required by MTUS. Therefore, given the lack of documentation, the request IS NOT medically necessary.

**Duexis 80026.6 mg #90 times 2 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Pain: Duexis (Ibuprofen and Famotidine).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications, NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Based on progress report dated 12/08/15, the patient presents with ongoing and increasing pain in low back. The request is for DUEXIS 800-26.6 MG #90 TIMES 2 REFILLS. The request for authorization form is dated 12/08/15. The patient is status post L4, L5 lumbar fusion. Physical examination of the lumbar/sacral reveals a well healed midline incision. Diffuse tenderness to palpation. Sciatic notch tenderness present on right. Sensory exam reveals sensation to light touch decreased in right lower extremity. Patient is to continue with conservative treatment to include home exercise program, moist heat, and stretches. The patient was counseled as to the benefits of the medication and the potential side effects. Patient's medications include Norco, Cyclobenzaprine, Duexis, and Gabapentin. The patient is permanent and stationary. Per FDA label indication, Duexis is a combination of the NSAID Ibuprofen and the histamine H2-receptor antagonist famotidine indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. MTUS, pg 22 Anti-inflammatory medications section states: "Anti-inflammatories 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. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP." MTUS, NSAIDs, GI symptoms & cardiovascular risk Section, pages 68 and 69 regarding Famotidine states: "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors." MTUS recommends determining risk for GI events before prescribing prophylactic PPI or omeprazole. GI risk factors include: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High dose/multiple NSAID. Treater does not specifically discuss this medication. Review of provided medical records show the patient was prescribed Duexis on 03/24/15. MTUS does not recommend routine use of PPI's for prophylactic use without a proper GI risk assessment. Review of medical records do not show GI risk assessment, or documentation of GI issues such as GERD, gastritis or peptic ulcer, for which histamine H2-receptor antagonist such as Duexis would be indicated. Treater does not discuss why a combination medication is required, either. Therefore, the request IS NOT medically necessary.