

<b>Case Number:</b>	CM14-0118888		
<b>Date Assigned:</b>	09/24/2014	<b>Date of Injury:</b>	09/17/2001
<b>Decision Date:</b>	12/19/2014	<b>UR Denial Date:</b>	07/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/29/2014

### 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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 44-year old site support specialist reported injuries to the neck and bilateral shoulders after a motor vehicle accident on 9/7/2001. Treatment has included medications, physical therapy, chiropractic manipulation, epidural steroid injections and cervical facet blocks. The patient has seen a neurosurgeon several times, and surgery has been requested. She is apparently waiting for authorization for a second opinion. Current diagnoses include shoulder pain, cervical radiculopathy, cervical pain, muscle spasm, cervical facet syndrome and mood disorder. The available records contain multiple notes from the primary treater from 1/29/14 through 10/8/14. All document lower levels of pain with medications than without. All notes document less than normal cervical range of motion, which has increased slightly over the documented time period. All notes document decreased shoulder range of motion bilaterally, which has not improved. The patient has continued to work full time throughout the documented period, except for the period from 6/19/14 to 7/9/14 due to "unbearable pain", which the provider states was due to denial of her medications. However, the notes from this time period document that she was taking her medications as usual. A reportedly successful cervical facet block procedure was performed on 6/30/14, which may also account for the patient's ability to return to work on 7/9/14. The patient has been prescribed Percocet "for breakthrough pain" during the period documented, without any change in dose. Lidoderm, Intermezzo, and Soma have also been prescribed for most of the period without dose change. The gabapentin was started on 5/21/14 and its dose gradually increased. The patient was originally taking Celebrex and Nexium, which were changed to Duexis on 6/18/14 when Nexium was denied in UR. Duexis, gabapentin, Soma, Percocet, Intermezzo and Lidoderm patches were non-certified in UR on 7/21/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Duexis 200/26.6 MG #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC formulary

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Duexis

**Decision rationale:** Duexis is a brand-name combination of two generically available drugs: ibuprofen and famotidine. Ibuprofen is an NSAID (non-steroidal anti-inflammatory drug) and famotidine is an H2 blocker used for peptic acid related disorders. The first guideline cited above states that clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. They should determine if the patient is at risk for GI events. Risk factors include age over 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of aspirin, corticosteroids, or an anticoagulant; or high-dose or multiple NSAIDs, or an NSAID combined with aspirin. Patients with no GI risk factors and no cardiovascular disease may be prescribed a non-selective NSAID. Those at intermediate risk for GI disease should receive a non-selective NSAID plus a proton pump inhibitor (PPI) or misoprostol; or a Cox-2 selective NSAID. Patients at high GI risk should receive a Cox-2 selective NSAID and a PPI if an NSAID is absolutely necessary. According to the ODG citation above, Duexis is not recommended as a first-line drug. It was launched by Horizon Pharma with the indications of rheumatoid and osteoarthritis. Ibuprofen and famotidine are available in multiple strengths over the counter, and other strategies are recommended to prevent stomach ulcers in patients taking NSAIDs, specifically proton pump inhibitors. Duexis is not recommended as first-line therapy because it has less benefit and higher cost than other available therapies. The clinical documentation in this case does not support the use of Duexis. The provider states that it controls the patient's inflammatory pain and prevents acid reflux. There is no actual documentation of reflux symptoms or of a diagnosis of reflux in the available records. There is no documentation of an assessment of the patient's risk for GI events. If she were at risk for GI events, a PPI would be indicated rather than famotidine. There is no documentation that the patient has arthritis, and therefore Duexis would not be indicated according to its manufacturer. Finally, according to the ODG there are cheaper and better ways to prescribe ibuprofen and a drug for acid symptoms. According to the evidence-based citations above and the clinical documentation provided for my review, Duexis is not medically necessary for this patient. It is not medically necessary because there is no clear documentation of a diagnosis of symptoms of reflux; because there is no documentation of an assessment of the patient's risk for GI events; because it would not be an appropriate drug if the patient actually were at risk for GI events; because it is not recommended by the ODG; and because better and cheaper medications are available for the indications recorded by the physician requesting this drug.

**Gabapentin 300 mg #90: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines AEDs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Antiepilepsy drugs (AEDs) Page(s): 16-19, 60.

**Decision rationale:** Per the first reference cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. The next reference states that AEDs are recommended for neuropathic pain. The choice of specific agents depends on the balance between effectiveness and adverse reactions. A good response to an AED has been defined as a 50% reduction in pain, and a moderate response as a 30% reduction in pain. A reduction in pain below 30% may trigger a switch to a different agent or combination therapy if a single drug fails. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects. The continued use of AEDs depends on improved outcomes versus tolerability of side effects. Common side effects of gabapentin include dizziness, somnolence, confusion, ataxia, peripheral edema and dry mouth. The clinical findings in this case support the use of gabapentin. Gabapentin was started on 5/21/14. Its dosage was gradually increased over the following months to the point where the patient reports that her neuropathic pain levels are nearly 0 while taking it, and increases to 9-10/10 pain while not taking it. The patient has been able to continue full-time work. Intolerable side effects from the gabapentin are not recorded. Based on the MTUS citation above and on the clinical documentation made available to me, gabapentin 300 mg # 90 is medically necessary because it has resulted in excellent pain relief, has not caused intolerable side effects, and has assisted this patient in remaining at regular work.

**Soma 250 mg 330:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxant. Decision based on Non-MTUS Citation ODG formulary

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol Page(s): 29.

**Decision rationale:** Soma is brand-name carisoprodol, a centrally-acting skeletal muscle relaxant. The MTUS guideline above states that carisoprodol is not recommended, and is not indicated for long-term use. Its primary metabolite, meprobamate, is a controlled substance. Carisoprodol has substantial abuse potential. It also may augment the effects of other drugs including benzodiazepines and hydrocodone, resulting in increased sedation. Some abusers claim that the combination of carisoprodol and hydrocodone produces effects that are similar to those of heroin. The clinical findings in this case do not support the use of Soma. The provider states it is being used to allow the patient to sleep. However, she has been on Soma since at least 1/29/14, and the quality of her sleep recorded over the time she has been taking it is almost always recorded as "fair". Doxepin was started as an adjunctive sleep aide while she was taking Soma, but was discontinued because it was ineffective. Soma is an addictive medication with substantial abuse potential and sedation, particularly in combination with Percocet and zolpidem,

which the patient is also taking. A previous UR modified a request for Soma to allow for tapering and discontinuation of this medication, which the primary treater apparently ignored. Based on the MTUS citations above and on the clinical documentation in this case, Soma 250 mg #30 is not medically necessary because it is not recommended by MTUS, because it is addictive, because it is sedating in combination with the other medications the patient is taking, and because it does not appear to have been effective in improving the provider's stated indication of insomnia.

**Percocet 10/325 mg #75: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of Opioids Page(s): 76-89.

**Decision rationale:** Percocet is brand-name oxycodone with acetaminophen. Oxycodone is an opioid analgesic. The MTUS citations above state that opioids should not be started without an evaluation of the patient's current status in terms of pain control and function. An attempt should be made to determine if the patient's pain is nociceptive or neuropathic. Red flags indicating that opioid use may not be helpful should be identified, as should risk factors for abuse. Specific goals should be set, and continued use of opioids should be contingent on meeting these goals. Opioids should be discontinued if there is no improvement in function or if there is a decrease in function. Opioids should be continued if the patient has returned to work, or if the patient has improved pain and function. For patients on long-term use of opioids, the dose should not be lowered if it is working. The clinical documentation in this case supports the use of Percocet for this patient. Although the patient's initial evaluation for opioid use is not contained in the available records, there is enough information to determine that Percocet is working for this patient. She states that it lowers her pain level from 8/10 to 2/10, and that the effect lasts 6-8 hours. With Percocet she can sit 3-4 hours, without it 15-30 minutes. She has remained at full time work from 1/29/14 to 10/8/14 except for one brief hiatus. She does not complain of side effects related to Percocet use. Her dose of Percocet has not changed at all during that 8-month period. The primary treater reports occasional urine drug tests which are consistent with her medications, and CURES reports which do not reveal aberrant drug behavior. Based on the MTUS criteria above and the clinical findings in this case, Percocet 10/325 #75 is medically necessary, because it allows the patient to remain at full-time work, because it decreases her level of pain and increases her ability to function, because it has not caused significant side effects, because its dose has not escalated over an 8-month period, and because the patient has exhibited no signs of aberrant drug behavior.

**Intermezzo 1.75 mg #20: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Mosby drug Consult.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), insomnia chapter American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004), Medications for Chronic Pain, page 60.

**Decision rationale:** Intermezzo is brand-name zolpidem, in a sub-lingual short acting form. Per the first guideline cited above, medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. Per the ODG reference above, treatment of insomnia should be based on its 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 components of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Short-acting zolpidem is indicated for the short-term treatment of insomnia. Side effects include daytime drowsiness, headache, dizziness, and blurred vision. Abnormal thinking and bizarre behavior have occurred. Sleep driving and other activities for which the patient has no recollection may occur. The medication should be discontinued if the latter occurs. Abrupt discontinuation may lead to withdrawal. Adults who use zolpidem have a greater than 3-fold increased risk for early death, according to results of a large matched cohort analysis. The clinical documentation in this case does not support the use of Intermezzo. Apparently Intermezzo was started in April of 2014, but there is no progress note available which documents why it was started. There is no documentation of a careful evaluation of the patient's sleep difficulties and their potential causes. The patient's sleep did not improve significantly after it started, since her sleep quality continued to be documented as "fair". There was no obvious improvement in function due to taking it, since she was already working full time. Its use has continued over 6 months, and is obviously well past the period where its use could be called short term. According to the evidence-based citations above and to the clinical findings in this case, Intermezzo 1.75 mg #20 is not medically necessary. It is not medically necessary because no appropriate evaluation was documented prior to its use, because the patient's sleep quality and level of function do not appear to have improved with its use, and because short-acting zolpidem is indicated for short term use only.

**Lidoderm patch %5 # 30:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain -topical analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Medications for Chronic Pain, Lidoderm (lidocaine p.

**Decision rationale:** The first reference cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. According to the other MTUS citations above, Lidoderm is indicated for localized neuropathic pain if there is

evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Only FDA-approved products are indicated, and no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Topical lidocaine is not indicated for non-neuropathic pain. The clinical findings support the use of Lidocaine patches in this case. The patient is taking gabapentin, which is a first-line treatment for neuropathic pain. She is documented as stating that Lidoderm patches decrease her shoulder pain from 8-9/10 to a 2/10 level, and that they allow her to continue working through the day. Based on the MTUS citation above and on the clinical documentation provided for my review, Lidoderm patches 5% #30 are medically necessary. They are medically necessary because they are being used as an adjunct to a first-line therapy for neuropathic pain, because they afford significant pain relief to the patient and because they assist her in staying at full time work.