

<b>Case Number:</b>	CM13-0033910		
<b>Date Assigned:</b>	12/06/2013	<b>Date of Injury:</b>	05/09/2002
<b>Decision Date:</b>	06/03/2014	<b>UR Denial Date:</b>	10/04/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/11/2013

### 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 Internal Medicine and is licensed to practice in the District of Columbia and Virginia. 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 is a 52 year old male who suffered an injury on May 9, 2002 after stocking merchandise. He developed pain in his neck and shoulders. ██████ saw the patient on Nov 20, 2012 for neck pain and right arm pain and numbness. The patient had had an MRI of the C spine in May 2, 2011 which showed interval progression of the disc disease above C5-6 fusion and an MRI of the L spine on Jan 12, 2010 which showed mild to moderate left greater than right lateral recess stenosis. He was prescribed: baclofen 10mg bid, diclofenac patch, limbrel 250mg bid, nucynta 1 tab tid, oxycontin 20mg every 12 hours, percocet 1 tab 4 x d as needed for pain, relpax 40mg daily prn, senokot, soma 350mg tid prn, xanax 0.25mg bid prn. ██████ saw the patient on Dec 19 2013 for ongoing pain complaints and thought the patient's symptoms were out of proportion to his imaging. The patient was then suggested to make lifestyle modification changes. ██████ saw patient on Dec 12 2012 and instructed to start sancuso and sennokot but stop nucynta. ██████ saw patient on Feb 12 2013 for follow up and noted there was not much improvement in the pain levels and an increase in neck pain. ██████ saw patient on June 4 2013 for follow up and noted there was not much improvement in the pain levels and increase in sleep disturbance. He was prescribed amiben 12.5mg at bedtime, baclofen,lyrica, oxycontin, percocet , senokot, soma, xanax, zofran. ██████ saw patient on July 2 and 9 , Aug 27 2013, for follow up with no improvement in pain levels.His medications were continued.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**OXYCONTIN 30MG, #90 EVERY 8 HOURS: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 74,75,92,96.

**Decision rationale:** This patient had ongoing pain in his neck following an an injury on May 9, 2002. He was prescribed a few medications, which included Oxycodone. Oxycodone, being an opiate, has habit-forming properties and the duration of therapy should be outlined. Also patient's response to therapy did not demonstrate improvement. From the clinical documentation provided, the patient continued to have ongoing pain despite being on this medication. Therefore, the request for Oxycontin 30mg #90 every 8 hours is not medically necessary and appropriate.

**PERCOCET 10/325MG, #120, 1 BY MOUTH 4 TIMES A DAY:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 75, 92, 131.

**Decision rationale:** This patient had ongoing pain in his neck following an injury that required multiple medications. He was prescribed a few medications, which included Percocet. It contains Oxycodone and Acetaminophen. Oxycodone, being an opiate, has habit-forming properties and the duration of therapy should be outlined, as well as the response to therapy. From the clinical documentation provided, none of this information can be found. Therefore, the request for Percocet 10/325mg, #120 1 by mouth 4 times a day is not medically necessary and appropriate.

**BACLOFEN 20MG TWO TIMES A DAY (BID), #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 Treatment Guidelines Page(s): 40, 53, 55, 63-64, 113.

**Decision rationale:** The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved) Side Effects: Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation. This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). Use with caution in patients with renal and liver impairment. Dosing: Oral: 5 m g three times a day. Upward titration can be made every 3 d ays up to a maximum dose of 80 mg a day. (See, 2008) Per MTUS, this medication has no indication to treat

muscle spasm that is not related to multiple sclerosis or spinal cord injuries. Therefore, the request for Baclofen 20mg two times a day (BID) #60 is not medically necessary and appropriate.

**LIMBREL 500MG TWO TIMES A DAY (BID): Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Orphan Drug Act and <http://www.ncbi.nlm.nih.gov/pubmed/22711078>.

**Decision rationale:** Limbrel is a medical food and contains flavocoxid, which has been linked to cause clinically significant liver injury. Per ODG guidelines, as a 'food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which are established by medical evaluation'. To be considered the product must, at a minimum, meet the following criteria: 1. The product must be a food for oral or tube feeding; 2. The product must be labeled for dietary management of a nutritional requirements; 3. The product must be used under medical supervision'. In addition, some adverse effects have been noted with limbrel. Therefore, the request for Limbrel 500mg two times a day (BID) is not medically necessary and appropriate.

**XANAX 0.25MG DAILY, #45: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23.

**Decision rationale:** 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. (Baillargeon, 2003) (Ashton, 2005). Long term usage of xanax is not medically indicated. Therefore, the request for Xanax 0.25mg daily, #45 is not medically necessary and appropriate.

**SOMA TWO TIMES A DAY, #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 Treatment Guidelines Page(s): 29.

**Decision rationale:** This medication is not recommended. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a "Las Vegas Cocktail"); & (5) as a combination with codeine (referred to as "Soma Coma"). (Reeves, 1999) (Reeves, 2001) (Reeves, 2008) (Schears, 2004). Therefore, the request for Soma two times a day #60 is not medically necessary and appropriate.

**ZOFRAN ODT 8MG, #30 EVERY MORNING:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) ZOFRAN.

**Decision rationale:** Per ODG guidelines, Zofran is not recommended for nausea and vomiting secondary to chronic opioid use. Additionally, this drug is a serotonin 5-HT<sub>3</sub> receptor antagonist. It is FDA approved for nausea and vomiting post operative use. Acute use is FDA approved for gastroenteritis'. For this patient and with the clinical documentation provided, there is no medical indication for this medication. Therefore, the request for Zofran ODT 8mg #30 every morning is not medically necessary and appropriate.

**SANCUSO 1 PATCH EVERY WEEK, #4:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/19948469>.

**Decision rationale:** Granisetron transdermal system (Sancuso(R), ProStrakan, Inc.) is the first transdermal medication patch indicated for the prevention of nausea and vomiting in patients receiving moderately or highly emetogenic chemotherapy. As with all transdermal medications, safety considerations exist with respect to storing, handling, applying, and disposing of the

Granisetron transdermal system. There is no medical indication for usage of this drug for this particular patient. Therefore, the request for Sancuso 1 patch every week, #4 is not medically necessary and appropriate.

**SENOKOT 1-2 BY MOUTH TWO TIMES A DAY, #100: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**Decision rationale:** Per ODG, 'when prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and motility. Other over the counter medications can help loosen otherwise hard stools , add bulk and increase water content of the stool'. This patient was no longer taking opioids, therefore, the request for Senokot 1-2 by mouth 2 times a day #100 is not medically necessary and appropriate.

**AMBIEN 12.5MG, 1 BY MOUTH A BEDTIME, #30: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) ZOLPIDEM.

**Decision rationale:** Ambien is a short acting nonbenzodiazepine hypnotic which is approved for short term(usually 2-6 weeks) treatment of insomnia, per ODG. Ambien has ben linked to an increase in motor vehicle accidents and increased ER visits. It is not indicated for long term usage as in the case of this patient. Therefore, the request for Ambien 12.5 1 by mouth at bedtime, #30 is not medically necessary and appropriate.

**REPLAX 40MG, 1 BY MOUTH DAILY, WITH 9 REFILLS FOR CHRONIC NECK, LOW BACK AND BILATERAL SHOULDER PAIN: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) TRIPTANS FOR HEADACHE.

**Decision rationale:** Per ODG, triptans are recommended for migrain sufferers. At marketed doses, all oral triptans are effective and well tolerated, such as sumatriptan. The patient did not appear to have migraine headaches so it is not clear what the medical indication of this drug was for this patient. Therefore, the request for Replax 40mg 1 by mouth daily, with 9 refills for chonic neck, low back and bilateral shoulder pain is not medically necessary and appropriate.