

<b>Case Number:</b>	CM14-0139158		
<b>Date Assigned:</b>	09/05/2014	<b>Date of Injury:</b>	07/28/2005
<b>Decision Date:</b>	10/03/2014	<b>UR Denial Date:</b>	08/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/28/2014

### 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 37-year old roofer reported a back injury due to lifting a heavy roll of roofing paper on 7/28/05. He has not worked since his injury. Treatment has included medications, chiropractic manipulation, a two-level global spinal fusion with instrumentation, physical therapy, epidural steroid injections, a failed attempt to complete a functional restoration program, removal of hardware, and a failed trial of a spinal cord stimulator. Current diagnoses include S/P lumbar hardware removal, prior global fusions at L4-5 and L5-S1, MRI showing solid fusions and are otherwise normal, Normal EMG B/L lower extremity 9/30/09, depression, trial of functional restoration program, S/P spinal cord stimulator trial with negative response. There are five progress notes from the primary provider's office in the available records, ranging from 12/10/13 to 7/25/14. All of them were written by PAs. They all document essentially the same level of pain (10/10 which decreases to 4-5/10 with medications) and function level (walks up to 15 minutes twice per day, cares for 2 young children, does light household chores, cooks, cleans, and performs self hygiene). Physical exam documentation is limited and often states simply that it is unchanged. When a physical exam is documented, it includes decreased back range of motion and sometimes a nonfocal neurological exam of the lower extremities. The patient is documented as taking Norco, Neurontin, Cymbalta and Prilosec at each visit. Due to a slight increase in pain level, tizanidine (Zanaflex) was added on 5/30/14 and carried forward. The medications are mostly dispensed from the provider's office. Tizanidine was modified from #240 to #60 in UR on 6/25/14, and discontinuation was recommended. The 7/25/14 progress note continues to note that the patient is taking tizanidine four times a day. The patient's symptoms and objective findings are documented as unchanged, except that he is having a lot of dry mouth. The patient's average pain level has been 6-7/10 for the past two months. There are statements that Neurontin continues to significantly help with lower extremity pain, and that tizanidine has

significantly helped with myofascial and low back pain. The documentation of the patient's activities are exactly the same as in previous notes, and do not include documentation of improvement in any specific activity. His Cymbalta dose was decreased, and 2-month supplies of Norco, Neurontin and tizanidine were dispensed. A request for authorization of Norco, Neurontin and tizanidine was made and reviewed in UR on 8/14/14. The Norco was certified, the Neurontin modified from #540 to 480, and the tizanidine non-certified. A request for IMR regarding these decisions was generated on 8/27/14.

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

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

**Neurontin 600mg #540:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16 and 18.

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

**Decision rationale:** Neurontin (gabapentin) is an anti-epilepsy drug, or AED. 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 do not support the continued use of gabapentin. There is no documented evidence that this patient has neuropathic pain. He has had a negative lower extremity EMG, and does not have documented symptoms or physical findings compatible with radiculopathy. There is no documentation of any functional goal with improvement as a result of taking gabapentin. The patient's functional level remains minimal, and apparently has been so for years. In addition, the patient is complaining of dry mouth, which was presumed by him and by his treater to be due to Cymbalta for reasons that are unclear, since dry mouth is a common side effect of gabapentin. Based on the evidence-based references cited above and on the clinical findings in the case, Neurontin is not medically indicated. Neurontin 600 mg #540 is not medically necessary because the patient does not have clear indications for it (i.e. it is not clear that he has neuropathic pain), because no functional outcomes are being monitored that have improved with its use.

**Zanaflex 4mg #240:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Muscle relaxants Page(s): 60; 63-66.

**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. Per the second reference, non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In most low back pain patients, they show no benefit. There is no additional benefit if they are used in combination with NSAIDs. Efficacy appears to diminish over time. Tizanidine is a centrally acting antispasmodic drug. Its side effects include somnolence, dizziness and dry mouth. The clinical findings in this case do not support the continued use of Zanaflex (tizanidine). It was apparently started as a result of a slight increase in pain. The subsequent progress note states that his pain level is unchanged, and that he is complaining of dry mouth. Again, it is inexplicable that the patient and provider assumed that the patient's dry mouth was due to Cymbalta. No improvement in physical findings or functional level is noted. Based on the evidence-based references cited above and the clinical findings in the case, Zanaflex 4 mg #240 is not medically necessary because it is a sedating muscle relaxant, it is not recommended for long-term use, it has produced no improvement in the patient's pain level or function.