

<b>Case Number:</b>	CM15-0116186		
<b>Date Assigned:</b>	06/24/2015	<b>Date of Injury:</b>	07/20/2008
<b>Decision Date:</b>	07/29/2015	<b>UR Denial Date:</b>	06/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/16/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: Internal 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 59-year-old female injured worker suffered an industrial injury on 07/20/2008. The diagnoses included lumbosacral spondylosis with radiculopathy, cervical radiculopathy, post-laminectomy syndrome, insomnia, depression, arachnoiditis, and constipation. The diagnostics included lumbar magnetic resonance imaging, cervical magnetic resonance imaging, thoracic magnetic resonance imaging, electromyographic studies and computerized tomography myelogram. The injured worker had been treated with multiple spinal surgeries and medications. An Agreed Medical Examination in January 2015 notes that the injured worker was not working. Klonopin and zanaflex have been prescribed since September 2014. On 6/3/2015, the treating provider noted the injured worker reported chronic low back pain with left lower extremity pain with numbness and intermittent weakness. On exam, the lumbar spine had tenderness over the incision with some decrease in sensation. The right shoulder had tenderness and reduced range of motion. The provider reported the pain was chronic and intractable. The physician noted that the injured worker's pain and ability to function are significantly improved with the medication regime. The treatment plan included Klonopin, Zanaflex and Floranex. Floranex was noted to be prescribed for constipation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Klonopin 1mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines benzodiazepines Page(s): 24.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24, 66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter: benzodiazepines, anxiety medications in chronic pain.

**Decision rationale:** This injured worker has chronic back pain. Klonopin has been prescribed for at least nine months. The treating physician has not specified the reason for use of klonopin. Per the MTUS, 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. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. The MTUS states that a more appropriate treatment for anxiety disorder is an antidepressant. The MTUS does not recommend benzodiazepines for long-term use for any condition. The MTUS does not recommend benzodiazepines as muscle relaxants. The Official Disability Guidelines recommend against prescribing benzodiazepines with opioids and other sedatives. This injured worker has also been prescribed dilaudid, kadian, and Oxycodone. Due to length of use in excess of the guideline recommendations and prescribing not consistent with the guideline recommendations, the request for klonopin is not medically necessary.

**Zanaflex 4mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63, 64, 66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-66.

**Decision rationale:** This injured worker has chronic back pain. Zanaflex has been prescribed for at least nine months. The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long-term use, not for a short period of use for acute pain. No reports show any specific and significant improvement in pain or function because of prescribing muscle relaxants. Return to work was not documented, and the documentation suggests that the injured worker was not working. There was no documentation of improvements in specific activities of daily living because of use of zanaflex. Tizanidine (Zanaflex) is FDA approved for management of spasticity and unlabeled for use for low back pain. Side effects include somnolence, dizziness, dry mouth, hypotension, weakness, and hepatotoxicity. Liver function tests should be monitored. It should be used with caution in renal impairment and avoided in hepatic impairment. There was no documentation of monitoring of liver function tests for this injured worker. Due to length of

use in excess of the guideline recommendations, lack of functional improvement and potential for toxicity, the request for zanaflex is not medically necessary.

**Floranex #30:** 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 opioids: Initiating Therapy [with opioids] Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: opioid induced constipation treatment.

**Decision rationale:** Floranex is a probiotic containing lactobacillus acidophilus and bulgarius. Probiotics are microorganisms that have beneficial properties for the host. Most commercial products have been derived from food sources. Mechanisms for the benefits of probiotics are incompletely understood, but may be related to suppression of growth or invasion by pathogenic bacteria, improvement in intestinal barrier function, modulation of the immune system, and modulation of pain perception. Probiotics have been used in the treatment of certain gastrointestinal disorders, including inflammatory bowel disease, diarrheal illnesses, constipation, irritable bowel syndrome, and others. Many brands of probiotics containing different microorganisms are available. The MTUS notes that when initiating therapy with opioids, prophylactic treatment of constipation should be initiated. Per the ODG, constipation occurs commonly in patients receiving opioids. If prescribing opioids has been determined to be appropriate, prophylactic treatment of constipation should be initiated. First line treatment includes increasing physical activity, maintaining appropriate hydration, and diet rich in fiber. In this case, floranex was noted to be prescribed for constipation. There was no documentation of use of first line measures for the treatment of constipation. As such, the request for floranex is not medically necessary.