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| <b>Case Number:</b>   | CM14-0109373 |                              |            |
| <b>Date Assigned:</b> | 08/01/2014   | <b>Date of Injury:</b>       | 03/11/2008 |
| <b>Decision Date:</b> | 10/09/2014   | <b>UR Denial Date:</b>       | 06/17/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 07/14/2014 |

### 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 Physical Medicine and Rehabilitation and is licensed to practice in Illinois. 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:

The injured worker is a 52 year old female who reported an injury on 03/11/2008. The mechanism of injury was not indicated in the clinical notes. Her diagnoses included GERD, hypertension, hyperlipidemia secondary to hypertension, obstructive sleep apnea, status post laminectomy, status post shoulder surgery, and constipation secondary to pain medications. Her past treatments consisted of medications, surgery, and topical creams. The injured worker's diagnostic exams included a 2D echocardiogram, urine drug screens, a Carotid ultrasound on 05/06/2014, an EKG, and abdominal ultrasound on 05/06/2014. Her surgical history comprised of a shoulder surgery on 10/2011, a hernia repair, and a laminectomy on an unspecified date. On 06/02/2014, the injured worker complained of worsening GERD with bloating, decreased sleep quality, neck pain, and constipation/diarrhea. The physical exam revealed the injured worker had 2+ epigastric tenderness to palpation, with diffused abdominal pain on palpation. Her medications consisted of Lansoprazole, Simethicone, Amtiza, Probiotics, Colace, and Gaviscon. The treatment plan encompassed the use of Probiotics #60 with 2 refills, Topical Cream Flurbiprofen 20%, Tramadol 20% 210 grams, and increase fluid intake for regular bowel movements. The rationale for the request was not clearly indicated in the clinical notes. The Request for Authorization form was not signed or dated.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Probiotics #60, Refills x2:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/181732>

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation [Rxlist.com/Probiotics](http://Rxlist.com/Probiotics)

**Decision rationale:** Rxlist.com states that probiotics are used to improve digestion and restore normal flora. Probiotics have been used to treat bowel problems such as diarrhea and irritable bowel syndrome. Probiotics are available in foods such as yogurt, milk, juices, and soy beverages. The FDA has not reviewed this product for safety or effectiveness. The clinical notes indicate the injured worker reported gastrointestinal discomfort. She complained of diarrhea/constipation and was prescribed medications for irritable bowel syndrome and constipation. Subsequently, Rxlist.com indicated that the FDA has not reviewed this product for safety or effectiveness. Additionally, the injured worker can obtain probiotics from food sources such as yogurt, milk, juices, and soy beverages. Thus, the lack of evidence to support the use of probiotics, lack of frequency of dosage and the lack of clinical studies to show efficacy and safety does not support the use of probiotics. Therefore, due to lack of support the request for Probiotics #60 with two refills is not medically necessary.

**Topical Cream Flurbiprofen 20%, Tramadol 20% 210 grams:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The MTUS Chronic Pain Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical Analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. In regard to the use of topical NSAIDs, the guidelines state that this treatment may be recommended for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment; however, there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The clinical notes show no indication of neuropathic pain or a diagnosis that indicates such etiology. The injured worker complained of neck pain but the clinical notes do not clearly show that a thorough exam was performed to the neck to determine the causation of her pain. In addition, the injured worker is being treated for pain in her neck, which the guidelines state that use of topical NSAIDs is not recommended in treatment of these areas. Therefore, this component is not supported. In the absence of documentation showing that the injured worker has a diagnosis of neuropathic pain, and as the requested compound contains one or more ingredients that are not recommended, the compound is also not recommended. Additionally, the request, as submitted, did not specify a frequency of use. Subsequently, the

request for Topical Cream Flurbiprofen 20%, Tramadol 20% 210 grams is not medically necessary.