

Case Number:	CM14-0029287		
Date Assigned:	06/20/2014	Date of Injury:	02/08/2011
Decision Date:	09/10/2014	UR Denial Date:	02/14/2014
Priority:	Standard	Application Received:	03/07/2014

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 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:

The injured worker is a 28-year-old female who reported an injury on 02/08/2011, due to a fall. The injured worker complained of right sided low back and shoulder pain. The injured worker also reports that the pain is associated with weakness, numbness, and tingling. The pain radiates to her wrist and right leg. On physical examination of the lumbar spine there was tenderness to palpation, guarding, and spasms noted in the paravertebral region bilaterally. There were trigger points noticeable in the lumbar paraspinal muscles bilaterally. Manual muscle testing revealed 4/5 strength with flexion, extension, and lateral bend. Range of motion was restricted due to pain and spasm. Range of motion of the lumbar spine, flexion 50/60 degrees, extension 15/25 degrees, right and left lateral bending 15/15 degrees and the normal is 25 degrees for both. The injured worker's diagnoses were lumbar disc protrusion and lumbago. That was on the physical examination dated 01/03/2014. The injured worker's treatments, diagnostic testing was an open sided MRI of the lumbar spine dated 12/02/2013. Impression was at the L5-S1 disc space; there was evidence of a 3 mm right lateral protrusion/subligamentous extrusion which abuts the right S1 root sleeve without displacement. There was no foraminal stenosis or central canal stenosis. The injured worker's treatment plan was for Terocin Patch, Cyclobenzaprine Hydrochloride 7.5 mg, Xanax 1 mg, Theramine, Trepadone, Sentra AM, Sentra PM, GABAdone in combination with 60 mg of Toradol, and vitamin B12 injection. The Request for Authorization Form was not provided with documentation for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin pain patch #20: 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): 111-112.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines state that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compound product that contains at least 1 drug or drug class that is not recommended is not recommended. According to guidelines, Lidocaine is for neuropathic pain recommended for localized peripheral pain after there has been evidence of a trial of first line therapy (tri-cyclics or SNRI antidepressants or an AED such as Gabapentin or Lyrica). Topical Lidocaine, in the formulation of dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulation of Lidocaine, whether creams, lotions, or gels, are indicated for neuropathic pain. The injured worker complained of constant low back pain that radiates to the right lower extremity with numbness and tingling despite medication. However, Terocin (Note in file states Terocin) Patch has a compound of Lidocaine and menthol, which is not recommended per guidelines. Furthermore, the request does not include the frequency of the proposed medication. Given the above, the request is not medically necessary.

Cyclobenzaprine Hydrochloride 7.5mg # 60: Upheld

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

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

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommends no sedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbation in patients with chronic low back pain. The documentation submitted for review indicates that the injured worker was complaining of right sided low back and shoulder pain. Guidelines indicate muscle relaxants are not recommended for long term use. Furthermore, there is no mention of frequency on the request. As such, the request for Cyclobenzaprine Hydrochloride 7.5 mg # 60 is not medically necessary.

Xanax 1.0 mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: The injured worker reported that she had pain that is associated with weakness, numbness, giving away, and tingling. The California Medical Treatment Utilization Schedule Guidelines state that 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. The range of reactions includes sedative/hypnotic, anxiolytic, anticonvulsants, and muscle relaxant. Many benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effect develops rapidly. Tolerance to anxiolytic effects occurs within months and long term use may usually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsants and muscle relaxant effects occurs within weeks. In addition, there was no mention of frequency for this request. As such, the request is not medically necessary.

Theramine #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Food.

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

Decision rationale: According to the Official Disability Guidelines the request is considered a medical food preparation, a food which is formulated to be consumed or administered internally under the supervision of a physician, which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. To be a food for oral or tube feeding, the product must be labeled for dietary management of a specific medical disorder, disease, and condition for which there are distinctive nutritional requirements. The product must be used under medical supervision. The injured worker has diagnoses of lumbar disc protrusion and lumbago and has been complaining of low back pain on the right. However, as guidelines indicate, it does not mention the specific medical disorder or disease for which it is requested for. Furthermore, the request does not include the frequency for the proposed medication. Given the above, the request is not medically necessary.

Trepadone: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Food.

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

Decision rationale: According to the Official Disability Guidelines medical food preparations are formulated to be consumed or administered internally under the supervision of a physician, which is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles are established by medical evaluation. To be considered the product must, at a minimum, meet the following requirements. The product must be a food for oral or tube feeding. The product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The product must be used under medical supervision. The physical examination dated 01/03/2014; the injured worker had tenderness to palpation of the lumbar spine. There is no supporting documentation subjectively or objectively to establish medical necessity for this request. In addition, there is no mention of frequency for the proposed request. Therefore, the request for Trepadone is not medically necessary.

Sentra AM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Food.

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

Decision rationale: According to the Official Disability Guidelines medical food preparations are formulated to be consumed or administered internally under the supervision of a physician, which is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles are established by medical evaluation. To be considered the product must, at a minimum, meet the following requirements. The product must be a food for oral or tube feeding. The product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The product must be used under medical supervision. Therefore, the request is not medically necessary.

Sentra PM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Food.

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

Decision rationale: According to the Official Disability Guidelines medical food preparations are formulated to be consumed or administered internally under the supervision of a physician, which is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles are established by medical evaluation. To be considered the product must, at a minimum, meet the following requirements. The product must be a food for oral or tube feeding. The product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The product must be used under medical supervision. Therefore, the request is not medically necessary.

Gabadone in combination with 60mg Toradol: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Food - Gamma-aminobutyric acid (GABA).

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

Decision rationale: GABAdone is considered a medical food product. According to the Official Disability Guidelines medical food preparations are formulated to be consumed or administered internally under the supervision of a physician, which is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles are established by medical evaluation. To be considered the product must, at a minimum, meet the following requirements. The product must be a food for oral or tube feeding. The product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. The product must be used under medical supervision. There is no documentation of acute exacerbation of pain, acute myospasm or sprain. Therefore, the combination of GABAdone and Toradol 60 mg is not medically necessary. As such, the request is not medically necessary.

Vitamin B12 injection: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Food.

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

Decision rationale: According to Official Disability Guidelines vitamin B is not recommended. Vitamin B is frequently used for treating peripheral neuropathy, but its efficacy is not clear. There is only limited data in randomized trials testing the efficacy of vitamin B for treatment of

peripheral neuropathy and the evidence is insufficient to determine whether vitamin B is beneficial or harmful. In addition, there was no mention of frequency for this request. As such, the request for vitamin B12 is not medically necessary.