MAXIMUS Federal Services

Case Number:	CM14-0012242		
Date Assigned:	02/21/2014	Date of Injury:	10/26/2009
Decision Date:	09/08/2014	UR Denial Date:	01/17/2014
Priority:	Standard	Application Received:	01/30/2014

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 & Rehabilitation and is licensed to practice in Texas and Ohio. 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 57-year-old female who reported an injury on 10/26/2009 due to an industrial injury. The injured worker had a history of neck pain radiating to the bilateral upper extremities and lower back pain radiating to the lower extremities. The injured worker had diagnoses of cervical spine radiculitis, lumbar spine radiculitis, and internal derangement to bilateral shoulders. The MRI of the lumbar spine dated 08/05/2012 revealed a disc herniation at the T11-12, mild spinal canal narrowing at the L1-2, moderate spinal canal narrowing at the L2-3, and diffuse disc bulge with facet arthropathy at the L3-4 and a diffuse disc bulge at the L4-5. The MRI dated 11/27/2013 revealed that the cystic lesion to the left lateral aspect of the spinal canal at L3-4 was not visualized. There was persistent narrowing of the spinal canal at the disc bulge and ligamentum flavum hypertrophy and moderate spinal canal narrowing at L4-5 with disc herniation. The past treatments included multiple lumbar epidural spinal injections. The objective findings dated 12/12/2013 of the lumbar spine revealed tenderness to the cervical and lumbar spine paravertebral muscles, mild difficulty standing from a sitting position, and ambulation with a guarded gait. The medications included Ambien 10 mg, Norco 10/325 mg, Tizanidine 4 mg, Theramine, Trazadone, Sentra, Gabadone, Terocin patch, compounded topical creams, Genecin, Somnicin, and Trepadone. The injured worker reported her pain at 10/10 using the VAS. The treatment plan included recommended surgery, medication regimen, chiropractic therapy, and massage therapy. The request for authorization was not submitted with documentation. The rationale for the multiple medications was not provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

THERAMINE #120 COUNT: 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, MEDICAL FOODS.

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

Decision rationale: The Official Disability Guidelines do not recommend Theramine. Theramine is a medical food from physician therapeutics that is a posterity blend of gamma aminobutyric acid and choline bitartrate. It is intended for the use and management of pain syndrome that include acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. There was no indication for the use of this product. In a manufacture study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing significant side effects, however until there is higher quality study of the ingredients in Theramine, it is not recommended. The documentation provided did not indicate if the Theramine had been effective for pain control. There was no frequency given. The guidelines do not recommend Theramine. Therefore, the request for Theramine #120 count is not medically necessary.

TREPADONE #120 COUNT: 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, MEDICAL FOODS.

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

Decision rationale: The Official Disability Guidelines Recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) 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 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 criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Per the clinical notes the injured worker's report pain was 10/10 using the VAS which had increased from 08/14/2013, showing no efficacy. Per the guidelines Trepradone should be administered enterally. The request did not address the frequency or dosage. Therefore, the request for Trepadone #20 is not medically necessary.

SENTRA AM #60 COUNT: 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, MEDICAL FOODS.

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

Decision rationale: The Official Disability Guidelines recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) 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 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 criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Per the clinical notes the injured worker's reported pain was 10/10 using the VAS which had increased from 08/14/2013, showing no efficacy. Per the guidelines Sentra should be administered enterally. The request did not address the frequency or dosage. Therefore, the request for Sentra AM #60 count is not medically necessary.

SENTRA PM #60 COUNT: 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, MEDICAL FOODS.

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

Decision rationale: The Official Disability Guidelines recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) 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 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 criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Per the clinical notes the injured worker's report pain was 10/10 using the VAS which had increased from 08/14/2013, showing no efficacy. Per the guidelines Sentra should be

administered enterally. The request did not address the frequency or dosage. As such, the request for Sentra PM #60 count is not medically necessary.

GABADONE #60 COUNT: 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, MEDICAL FOODS.

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

Decision rationale: The Official Disability Guidelines Recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) 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 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 criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Per the clinical notes the injured worker's reported pain was 10/10 using the VAS which had increased from 08/14/2013, showing no efficacy. Per the guidelines Gabadone should be administered enterally. The request did not address the frequency or dosage. As such, the request for Gabadone #60 is not medically necessary.

TEROCIN PAIN PATCH 2 BOXES: 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 California MTUS Guidelines on topical analgesics state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Topical Lidocaine, in the formulation of a Lidoderm patch, has been designated as an orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine, whether creams, lotions, or gels, are indicated for neuropathic pain. A Terocin patch is a topical analgesic with active ingredients of Lidocaine 4% and Methodyl 4%. The combination of Lidocaine with any other topical medication is not recommended per Guidelines. Per the clinical notes, the injured worker's pain had been at 6/10 at the 08/14/2014 office visit then increased to a 10/10 at the 12/12/2014 office visit. The injured worker had showed no improvement with current medication

regimen. The request did not address the frequency. Therefore, the request for Terocin pain patch 2 boxes is not medically necessary.

COMPOUNDED TOPICAL CREAMS: 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 California MTUS Guidelines on topical analgesics state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Topical Lidocaine, in the formulation of a Lidoderm patch, has been designated as an orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine, whether creams, lotions, or gels, are indicated for neuropathic pain. A Terocin patch is a topical analgesic with active ingredients of Lidocaine 4% and Methodyl 4%. The combination of Lidocaine with any other topical medication is not recommended per Guidelines. Per the clinical notes the injured worker's pain had been at 6/10 at the 08/14/2014 office visit then increased to a 10/10 at the 12/12/2014 office visit. The injured worker had showed no improvement with current medication regimen. The request did not address the frequency, duration or dosage. Therefore, the request for compounded topical creams is not medically necessary.

FLURIBIPROFEN/LIDOCAINE/AMITRIPTYLLINE 180 GRAM TUBE: 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 California MTUS Guidelines on topical analgesics state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Topical Lidocaine, in the formulation of a Lidoderm patch, has been designated as an orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine, whether creams, lotions, or gels, are indicated for neuropathic pain. A Terocin patch is a topical analgesic with active ingredients of Lidocaine 4% and Methodyl 4%. The combination of Lidocaine with any other topical medication is not recommended per Guidelines. Per the clinical notes, the injured worker's pain had been at 6/10 at the 08/14/2014 office visit then increased to a 10/10 at the 12/12/2014 office visit. The injured worker had showed no improvement with current medication regimen. The request did not address the frequency. Therefore, the request for Flurbiprofen/ Lidocaine/ Amitriptylline is not medically necessary.

Retrospective request for Gabapentin/Cyclobenzaprine/Tramadol cream 180 gm tube, DOS: 11/20/13: 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 California MTUS Guidelines on topical analgesics state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. Topical Lidocaine, in the formulation of a Lidoderm patch, has been designated as an orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine, whether creams, lotions, or gels, are indicated for neuropathic pain. Gabapentin is not recommended. There is no peer-reviewed literature to support use. The combination of Gabapentin with any other topical medication is not recommended per Guidelines. Per the clinical notes the injured worker's pain had been at 6/10 at the 08/14/2014 office visit then increased to a 10/10 at the 12/12/2014 office visit. The injured worker had showed no improvement with current medication regimen. The request did not address the frequency of dosage. Therefore, the retrospective request for Gabapentin/Cyclobenzaprine/Tramadol cream 180gm tube DOS: 11/20/13 is not medically necessary.

GENECIN #90: 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 Glucosamine (and Chondroitin Sulfate) Page(s): 50.

Decision rationale: The California/ MTUS recommends Glucosamine as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Per the clinical notes there is no indication the injured worker had a diagnosis of arthritis. The request did not address the frequency, dosage or route. As such, the request is not medically necessary.

Retrospective request for Somnicin #30 DOS: 11/20/13: 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, MEDICAL FOODS.

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

Decision rationale: The Official Disability Guidelines criteria for medical food indicate 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 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 criteria. The product must be a food for oral or tube feeding. This drug/medical food is not medically necessary. The clinical notes provided do not support the use of this request. The request did not address the frequency, dosage or route. As such, the request is not medically necessary.