MAXIMUS Federal Services

Case Number:	CM15-0039233		
Date Assigned:	04/02/2015	Date of Injury:	05/07/2013
Decision Date:	05/13/2015	UR Denial Date:	02/17/2015
Priority:	Standard	Application Received:	03/02/2015

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: California Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 41-year-old male who reported injury on 05/07/2013. The mechanism of injury was not provided. The documentation of 03/11/2015 revealed the injured worker had cervical spine and lumbar spine decreased range of motion. The injured worker had difficulty sleeping. The office note was handwritten and difficult to read. The diagnoses included cervical spine strain, lumbar spine strain, and insomnia. The other diagnoses were illegible. The request was made for a continuation of medications and the use of topical compound creams. The medications included Theramine, Gabadone, Sentra AM and PM, and the request was made for acupuncture, and for physical therapy as well as a sleep study. The injured worker was noted to undergo urine drug screens. The mechanism of injury was not provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine #90: 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).

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, Theramine.

Decision rationale: The Official Disability Guidelines do not recommend Theramine for the treatment of chronic pain. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the frequency for the requested medical food. Given the above, the request for Theramine #90 is not medically necessary.

Sentra PM #50: 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).

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, Sentra PM.

Decision rationale: The Official Disability Guidelines indicates that Sentra PM and is intended for use in management of sleep disorders associated with depression. It is a blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Glutamic Acid is used in complementary medicine for digestive disorders. 5-hydroxytryptophan is possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. The clinical documentation submitted for review failed to provide the efficacy for the requested medical food. The request as submitted failed to indicate the frequency for the requested medical food. Given the above, the request for Sentra PM #50 is not medically necessary.

Sentra AM #60: 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).

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: The Official Disability Guidelines indicate that medical foods are not recommended for chronic pain. However, to be considered a medical food, the product must be a food for oral or tube feeding, must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements and the product must be used under medical supervision. Per Marvista health center.com Sentra AM is a blend of Choline bitartrate and glutamate, acetyl-L-carnitine, cocoa powder, ginko biloba and grape seed extract and is utilized in the treatment of chronic and generalized fatigue, fibromyalgia, post-traumatic stress disorder. The clinical documentation submitted for review failed to provide documentation of exceptional factors. There was a lack of documentation of efficacy for the requested medical food. The request as submitted failed to indicate the frequency. Given the above, the request for Sentra AM #60 is not medically necessary.

Gabadone #60: 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).

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, Gabadone.

Decision rationale: The Official Disability Guidelines do not recommend the use of Gabadone. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The efficacy was not provided. The request as submitted failed to indicate the frequency for the requested medical food. Given the above, the request for Gabadone #60 is not medically necessary.

Tramadol 150mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain, ongoing management Page(s): 60, 78.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend opiates for the treatment of chronic pain. There should be documentation of objective functional improvement, an objective decrease in pain and documentation the injured worker is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review indicated the injured worker was being monitored for aberrant drug behavior. There was, however, a lack of documentation of objective functional improvement and an objective decrease in pain. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for tramadol 150 mg #60 is not medically necessary.

Topical compound cream: Flurbiprofen/Capsaicin/Camphor10/0.25%/2%/1%(120gm): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Topical Capsaicin, Salicylates topicals Page(s): 72, 111, 28, 105.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or

topical administration. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. The guidelines recommend Topical Salicylates. The clinical documentation submitted for review failed to provide documentation the injured worker had a trial and failure of antidepressants and anticonvulsants. Additionally, there was a lack of documentation indicating the injured worker was intolerant to other treatments. There was a lack of documentation of exceptional factors as flurbiprofen is not currently FDA approved for topical application. The request as submitted failed to indicate the frequency and body part to be treated. Given the above, the request for Topical compound cream: Flurbiprofen/Capsaicin/Camphor10/0.25%/2%/1% (120gm) is not medically necessary.

Topical cream: Ketoprofen/Cyclobenzaprine/Lidocaine 10%/3%/5% (120gm): 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, Lidocaine, Ketoprofen, Cyclobenzaprine Page(s): 111, 112, 113, 41.

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. Ketoprofen is not currently FDA approved for a topical application. The guidelines indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation of exceptional factors. Additionally, there was a lack of documentation indicating a necessity for 2 topical NSAIDs. The request as submitted failed to indicate the frequency and the body part to be treated. Given the above, the request for Topical cream: Ketoprofen/Cyclobenzaprine/Lidocaine 10%/3%/5% (120gm) is not medically necessary.