

Case Number:	CM14-0127084		
Date Assigned:	08/13/2014	Date of Injury:	12/07/2005
Decision Date:	10/14/2014	UR Denial Date:	07/15/2014
Priority:	Standard	Application Received:	08/11/2014

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 Occupational Medicine 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 claimant was injured on 12/07/05 and her mechanism of injury was described as cumulative trauma. However, she also fell off a step ladder. A urine drug screen, theramine, gabadone, trepadone, and FluriFlex ointment are under review. She saw [REDACTED], an orthopedic surgeon, for an AME on 12/05/06. She complained of neck and low back pain radiating into the right leg. She had tried rest, medications, PT, and exercises and had imaging studies of her neck and back. She had 2 subsequent falls after the injury. She continued to be symptomatic. Her medications included Skelaxin, tramadol, Ultram [sic], and Lyrica and she was taking vitamins. On 12/19/07, she had a reevaluation with [REDACTED]. She was having trouble with her right knee and was using a hinged knee brace. She still needed anti-inflammatories and pain medications. On 03/13/08, another supplemental report was done. She had been advised to have a knee replacement. On 04/17/13, she saw [REDACTED] and was prescribed gabapentin at bedtime, theramine for neuropathic pain, trepadone for inflammation, Lyrica, Norco, Nucynta, and Zanaflex. She saw [REDACTED] on 05/13/13 and complained of bilateral knee, left hand, neck, left shoulder, and hand pain. There were no new symptoms. She needed her medications refilled. She had elevated pain levels. She was diagnosed with myofascial syndrome and neuropathic pain and was given refills of gabapentin, theramine, trepadone, Lyrica, Norco, and FluriFlex ointment. She was to discontinue Nucynta and Zanaflex. On 06/03/13, gabapentin, theramine, and trepadone were continued and she received Norco and Fluriflex ointment. She is status post right knee arthroplasty on 11/05/13 and still had a high pain levels. On 12/10/13, she was seen again and received refills of the medications but not the supplements. She was given Ketoflex cream. On 01/24/14, she was seen again and her medications were refilled including the Ketoflex cream. There is no mention of supplements. The Nucynta and Zanaflex were discontinued. On 06/03/14, she continued gabapentin, theramine, trepadone, Norco, and Fluriflex and Lyrica was

discontinued. On 06/24/14, she continued theramine and was given Percura and trepadone and was to resume Lyrica and continue Norco. Fluriflex ointment was prescribed. On 07/24/14, gabapentin was continued with Percura and trepadone and Lyrica was resumed. She received Norco and Fluriflex was discontinued.

IMR ISSUES, DECISIONS AND RATIONALES

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

Urine Drug Screen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Urine Drug Testing.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines DRUG TESTING Page(s): 77.

Decision rationale: The history and documentation do not objectively support the request for a urine drug screen. The MTUS state "drug testing is recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs." There is no evidence of noncompliance with her prescribed medications, either because she is escalating her dose or has been running out early. There is also no indication that there is any suspicion by the provider of illegal drug or medication use by this claimant. The medical necessity of a urine drug screen has not been clearly demonstrated. 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, 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): Official Disability Guidelines (ODG), Treatment Index, 8th Edition (web), 2010, Chronic Pain-Medical food.

Decision rationale: The history and documentation do not objectively support the request for theramine #120. The MTUS do not address medical food supplements. The ODG, Pain - Medical foods state theramine is a medical food/supplement that is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. ODG quoting the FDA specifically states "to be considered the product must, at a minimum, meet the following criteria:... (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements;..." Theramine is a medical food comprised of a number of amino acids, neurotransmitter metabolites and herbals. While ODG does recognize the possible efficacy for some of these components, there is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications such as NSAIDs, opioid narcotics, muscle relaxants, or proton pump inhibitors. A search of US NIH NLM

PubMed 2010 did not result in any high-quality research studies supporting the use of theramine under these clinical conditions. Therefore, theramine is not certified as medically necessary drugs and there is no medical necessity for any medication containing this food supplement.

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, Gabadone

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Official Disability Guidelines (ODG), Treatment Index, 8th Edition (web), 2010, Chronic Pain-Medical food.

Decision rationale: The history and documentation do not objectively support the request for gabadone #60. The MTUS do not address medical food supplements. The ODG, Pain - Medical foods state gabadone is a medical food/supplement that is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. ODG quoting the FDA specifically states "to be considered the product must, at a minimum, meet the following criteria:... (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements;...." Gabadone is a medical food comprised of a number of amino acids, neurotransmitter metabolites and herbals. While ODG does recognize the possible efficacy for some of these components, there is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications such as NSAIDs, opioid narcotics, muscle relaxants, or proton pump inhibitors. A search of US NIH NLM PubMed 2010 did not result in any high-quality research studies supporting the use of gabadone under these clinical conditions. Therefore, gabadone is not certified as medically necessary drug and there is no medical necessity for any medication containing this food supplement.

Trepadone #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, Pain (Chronic), 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): Official Disability Guidelines (ODG), Treatment Index, 8th Edition (web), 2010, Chronic Pain-Medical food.

Decision rationale: The history and documentation do not objectively support the request for trepadone #120. The MTUS do not address medical food supplements. The ODG, Pain - Medical foods state trepadone is a medical food/supplement that is intended for specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. ODG quoting the FDA specifically states "to be considered

the product must, at a minimum, meet the following criteria:... (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements;...." Trepadone is a medical food comprised of a number of amino acids, neurotransmitter metabolites and herbals. While ODG does recognize the possible efficacy for some of these components, there is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications such as NSAIDs, opioid narcotics, muscle relaxants, or proton pump inhibitors. A search of US NIH NLM PubMed 2010 did not result in any high-quality research studies supporting the use of trepadone under these clinical conditions. Therefore, trepadone is not certified as medically necessary drug and there is no medical necessity for any medication containing this food supplement.

Fluriflex Ointment 240 gm #1: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic) Fluriflex: Topical Analgesics, Compounded

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 143.

Decision rationale: The history and documentation do not objectively support the request for Fluriflex ointment. The MTUS state "topical agents may be recommended as an option [but are] largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004)." There is no evidence of failure of all other first line drugs. The claimant received refills of many other oral medications and food supplements for her symptoms but there is no documentation of significant side effects or lack of effect of the medications such that topical medications are indicated. The medical necessity of this request for Fluriflex ointment 240 gm #1 has not been clearly demonstrated. The request is not medically necessary.