

Case Number:	CM13-0048224		
Date Assigned:	12/27/2013	Date of Injury:	08/14/2008
Decision Date:	06/16/2014	UR Denial Date:	10/24/2013
Priority:	Standard	Application Received:	11/05/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesiology, Pain Medicine and is licensed to practice in Florida. 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 physician 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 53-year-old male who reported injury on 08/14/2008. The injured worker's medication history included Fanatrex, Tabradol, Synapryn, Deprizine, and Dicopanol as of 2010. The mechanism of injury was not provided for review. The injured worker was utilizing Cyclophene and Ketoprofen since 03/2013. The documentation of 10/02/2013 revealed the injured worker had burning radicular low back pain that was moderate to severe rated a 7/10 and burning pain in the right foot at 6/10 that was moderate to severe. The injured worker indicated the medications offered temporary relief of the pain and improved the injured worker's ability to have a restful sleep. The injured worker denied problems with medications. The diagnoses included lumbar spine pain, lumbar radiculopathy and right foot pain. The treatment plan included a refill of medications and a return appointment.

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUND MEDICATION: KETOPROFEN 20% GEL 120 GRAMS: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), and Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, Section Ketoprofen Page(s): 111-112.

Decision rationale: The California MTUS Guidelines indicate that Ketoprofen is a non-approved topical non-steroidal anti-inflammatory drugs (NSAIDs). Topical analgesics are largely experimental in use with few randomized control studies to determine safety or efficacy. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug or drug class that is not recommended, is not recommended. The clinical documentation indicated the injured worker had been utilizing the medication since 03/2013. There was a lack of documentation of efficacy for the requested medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for compounded ketoprofen 20% gel 120 grams is not medically necessary.

ORAL SUSPENSION: SYNAPRYN 10MG/ML 500ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), and Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines GLUCOSAMINE SULFATE; ONGOING MANAGEMENT; TRAMADOL Page(s): 50,78,82,93,94.

Decision rationale: The California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been Food and Drug Administration (FDA) approved. The approved form of Tramadol is for oral consumption. The California MTUS guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included tramadol and glucosamine sulfate. The clinical documentation submitted for review failed to provide the necessity for an oral suspension which included tramadol and glucosamine sulfate. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient was being monitored for aberrant drug behavior and side effects. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since 2010. There was a lack of documentation of objective functional benefit. There was a lack of documentation indicating the injured worker had moderate arthritis. There was a lack of documentation of objective decrease in pain. There was documentation the injured worker was being monitored for aberrant drug behavior and side effects. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Synapryn 10 mg 1 per mL oral suspension 500 mL is not medically necessary.

ORAL SUSPENSION: TABRADOL 1MG/ML 250ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), and Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CYCLOBENZAPRINE Page(s): 41.

Decision rationale: The California MTUS indicate that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. They do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California MTUS guidelines and Official Disability Guidelines (ODG), along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence based literature for the oral compounding of cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications. The clinical documentation submitted for review indicated the injured worker had been taking the medication since 2010. There was a lack of documented efficacy for the requested medication. The frequency for use of the medication was not submitted. Given the above, the request for Tabradol 1 mg per mL oral suspension 250 mL is not medically necessary.

ORAL SUSPENSION: DEPRIZINE 15MG/ML 250 ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), and Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69.

Decision rationale: The California MTUS Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to non-steroidal anti-inflammatory drugs (NSAIDs) therapy. The clinical documentation submitted for review indicated the medication Deprizine includes ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since 2010. There was a lack of documentation indicating the efficacy for the requested medication. There was a lack of documentation of exceptional factors to support the use of this medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Deprizine 15 mg per mL oral suspension 250 mL is not medically necessary.

ORAL SUSPENSION: DICOPANOL (DIPHENHYDRAMINE) 5MG/ML 150 ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), and 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, Insomnia Treatments.

Decision rationale: The Official Disability Guidelines (ODG) indicates that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine) and that tolerance seems to develop within a few days. Per Drugs.com, Dicopanол is diphenhydramine hydrochloride and it was noted this drug has not been found by the Food and Drug Administration (FDA) to be safe and effective and the labeling was not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to FDA regulations. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since 2010. It indicated the medication improved the injured worker's ability to have a restful sleep. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Dicopanол (diphenhydramine) 5 mg per mL oral suspension 150 mL is not medically necessary.

ORAL SUSPENSION: FANATREX 25MG/ML 420 ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), and Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Gabapentin Page(s): 16. Decision based on Non-MTUS Citation Non-MTUS: <http://www.drugs.com/search.php?searchterm=Fanatrex>.

Decision rationale: The California MTUS guidelines indicate that Gabapentin is used in the treatment of neuropathic pain. Per drugs.com, Fanatrex is noted to be an oral suspension of Gabapentin and has not approved by the Food and Drug Administration (FDA). The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since 2010. There was a lack of documented efficacy. There is a lack of documentation of exceptional factors to warrant nonadherence to FDA Guidelines. The request as submitted failed to indicate the frequency for the requested medication. Given the

above, the request for Fanatrex (gabapentin) 25 mg per mL oral suspension 420 mL is not medically necessary.

COMPOUND MEDICATION: CYCLOPHENE 5% GEL 120 GRAMS: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Food and Drug Administration (FDA), and Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS; TOPICAL MUSCLE RELAXANTS; CYCLOBENZAPRINE Page(s): 111-113,41.

Decision rationale: The California MTUS Guidelines indicate that Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug or drug class that is not recommended, is not recommended. They do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant and there is no evidence for the use of any other muscle relaxant as a topical product. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since 03/2013. There was a lack of documentation of objective functional benefit that was received. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Cyclophene 5% gel 120 grams is not medically necessary.