

Case Number:	CM13-0059408		
Date Assigned:	12/30/2013	Date of Injury:	04/22/2013
Decision Date:	05/15/2014	UR Denial Date:	11/07/2013
Priority:	Standard	Application Received:	12/02/2013

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 Illinois. 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 49-year-old female who reported an injury on 04/22/2013. The mechanism of injury was the injured worker was giving a patient a shower and the patient became mad and kicked the injured worker in the right inner knee and the injured worker ended up with pain and swelling in the knee. The diagnosis for the injured worker included abdominal pain, lumbar spine herniated nucleus pulposus, lumbar spine degenerative disc disease, lumbar radiculopathy, bilateral knee osteoarthritis, left knee chondromalacia patella, left knee Baker's cyst, right knee medial meniscus tear, and anxiety, mood, and sleep disorders, and stress. The injured worker had been treated with oral ibuprofen. The documentation of 10/06/2013 revealed the injured worker had cumulative injuries from 04/22/2012 to 04/22/2013. Physical examination revealed decreased range of motion of the lumbar spine and a positive leg raise bilaterally. The physical examination of the bilateral knees included +1 effusion and tenderness to palpation over the medial and lateral joint lines bilaterally. The injured worker had a positive McMurray's test on the right.

IMR ISSUES, DECISIONS AND RATIONALES

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

COMPOUND KETOPROFEN 20% IN PLO GEL, 120 GRAMS (AS OF 10/4/13): 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).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics and Ketoprofen Page(s): 111-112.

Decision rationale: California Medical Treatment Utilization Schedule (MTUS) indicates 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. Regarding the use of ketoprofen: This agent is not currently FDA approved for a topical application. The compound also included topical ketamine which is under study and is only recommended in treatment of neuropathic pain which is refractory to all primary and secondary treatment. The guidelines do not recommend ketoprofen and as such the use of the compound would not be supported. The clinical documentation submitted for review failed to indicate the injured worker had neuropathic pain and that trials of antidepressants and anticonvulsants have failed. There was lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. This was an initial trial for the medication. The request as submitted failed to indicate the frequency. Given the above, the request for ketoprofen 20% in PLO gel 120 grams as of 10/04/2013 is not medically necessary.

COMPOUND CYCLOPHENE 5% in PLO GEL, 120 GRAMS (AS OF 10/4/13): 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).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Topical Muscle Relaxants and Cyclobenzaprine Page(s): 111,113,41.

Decision rationale: California Medical Treatment Utilization Schedule (MTUS) indicates topical analgesics are 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 one drug (or drug class) that is not recommended is not recommended. California MTUS Guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review failed to indicate the injured worker had neuropathic pain and that the injured worker trialed and failed antidepressants and anticonvulsants. The request as submitted failed to provide the frequency for the requested medication. There was lack of documentation indicating necessity for both a topical and oral form of cyclobenzaprine. This was an initial trial for the medication. Given the above, the request for compound Cyclophene 5% in PLO gel 120 grams as of 10/04/2013 is not medically necessary.

SYNAPRYN 10 MG/ML ORAL SUSPENSION 500 ML (AS OF 10/4/13): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing Management and Tramadol Page(s): 50,78,82,93-94.

Decision rationale: California Medical Treatment Utilization Schedule (MTUS) Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. A thorough search of Food and Drug Administration (FDA).gov did not indicate there was a formulation of topical tramadol that had been FDA approved. The approved form of tramadol is for oral consumption. 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 on-line package insert included tramadol and glucosamine sulfate. 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 is 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. Clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guideline recommendations. The clinical documentation submitted for review failed to indicate the necessity for a liquid form of this medication. There was lack of documentation indicating the injured worker had inability to swallow a tablet or capsule. The request as submitted failed to indicate the frequency for the medication. This was an initial trial for the medication. Given the above, the request for Synapryn 10 mg/mL oral suspension 500 mL as of 10/04/2013 is not medically necessary.

TABRADOL 1 MG/ML ORAL SUSPENSION 250 ML (AS OF 10/4/13): Upheld

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

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

Decision rationale: California Medical Treatment Utilization Schedule (MTUS) indicates that cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2 to 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 the American College of Occupational and Environmental Medicine (ACOEM), California MTUS Guidelines and Official Disability Guidelines, 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 failed to indicate the necessity for both a topical and oral form of a muscle relaxant. There was lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. There is lack of documentation indicating the injured worker had necessity for a liquid form of the medication. The request as submitted failed to indicate the frequency for the medication. This was an initial trial for the medication. Given the above, the request for Tabradol 1 mg/mL oral suspension 250 mL as of 10/04/2013 is not medically necessary.

DEPRIZINE 15 MG/ML ORAL SUSPENSION 250 ML (AS OF 10/4/13): Upheld

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

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

Decision rationale: California Medical Treatment Utilization Schedule (MTUS) Guidelines recommends histamine 2 blockers for treatment of dyspepsia secondary to Non-steroidal anti-inflammatory drugs (NSAID) 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 failed to indicate the injured worker had signs and symptoms of dyspepsia secondary to NSAID therapy. There was lack of documentation indicating the injured worker had necessity for a liquid form of the medication. The request as submitted failed to indicate the frequency for the medication. This was an initial trial for the medication. Given the above, the request for Deprizine 15 mg/mL oral suspension 250 mL as of 10/04/2013 is not medically necessary.

DICOPANOL (DIPHENHYDRAMINE) 5MG/ML ORAL SUSPENSION 150 MG (AS OF 10/4/13): 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=Dicopanol>.

Decision rationale: Per Drugs.com, Dicopanol is diphenhydramine hydrochloride and it was noted this drug has not been found by the 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 failed to indicate necessity for a liquid form of diphenhydramine. This medication was for a trial basis. The request as submitted failed to indicate the frequency for the medication. This was an initial trial for the medication. Given the above, the request for Dicopanol (diphenhydramine) 5 mg/mL oral suspension 150 mg as of 10/04/2013 is not medically necessary.

FANATREX (GABAPENTIN) 25 MG/ML ORAL SUSPENSION 420 ML (AS OF 10/4/13): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16.

Decision rationale: California Medical Treatment Utilization Schedule (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 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. Given the above, and the lack of documentation of exceptional factors to warrant non-adherence to FDA guidelines, the request for prescription for Fanatrex is not medically necessary. The clinical documentation submitted for review failed to indicate the injured worker had necessity for an oral solution versus a pill. The request as submitted failed to indicate the frequency for the medication. This was an initial trial for the medication. Given the above, the request for Fanatrex (gabapentin) 25 mg/mL oral suspension 420 mL as of 10/04/2013 is not medically necessary.