

Case Number:	CM15-0054681		
Date Assigned:	03/30/2015	Date of Injury:	02/07/2014
Decision Date:	05/15/2015	UR Denial Date:	03/11/2015
Priority:	Standard	Application Received:	03/23/2015

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: Preventive Medicine, Occupational Medicine, Public Health & General Preventive Medicine

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 63-year-old female who reported an injury on 02/07/2014. The mechanism of injury was the injured worker was assisting a resident and lifting the leg and felt pain in her left shoulder. The diagnosis included left shoulder sprain and strain, rule out internal derangement; left shoulder acromioclavicular arthrosis; left shoulder bicipital tenosynovitis; left elbow sprain and strain, rule out internal derangement; left wrist sprain and strain, rule out internal derangement; left wrist effusion. The documentation of 02/05/2015 revealed the injured worker had persistent complaints of pain in the left shoulder. The left shoulder pain was rated 8/10 to 9/10 and the left elbow pain was 6/10 to 7/10. The left wrist pain was 5/10 to 6/10. The documentation indicated the injured worker had utilized the medications since 09/2014. Prior therapies included physical therapy. The injured worker underwent urine drug screens. There was a Request for Authorization submitted for review dated 02/05/2015. The treatment plan from 02/05/2015 revealed a refill of the medications; acupuncture for the left shoulder, left elbow, and left wrist; periodic urine toxicology evaluations; PRP therapy for the left shoulder and left elbow; shockwave therapy; as well as a referral to an orthopedic surgeon and the use of Terocin patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream 167 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Topical Analgesics, Muscle relaxants (for pain), Antiepilepsy drugs (AEDs) Page(s): 111-113, 68, 63-64, 75, 18. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter - Insomnia, Compound Drugs.

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

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicates that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Ketoprofen is not currently FDA approved for a topical application. The clinical documentation submitted for review failed to provide documentation the injured worker had a trial of an antidepressant and anticonvulsant. The documentation indicated the injured worker had utilized the medication since late 2014. There was a lack of documentation of objective functional improvement and an objective decrease in pain. The request as submitted failed to indicate the body part to be treated with the requested medication. Additionally, the frequency was not provided. Given the above, the request for ketoprofen 20% cream 167 grams is not medically necessary.

Deprizine 15mg/ml, 250ml (Ranitidine): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Muscle relaxants (for pain), Antiepilepsy drugs (AEDs), Topical Analgesics Page(s): 111-113, 68, 63-64, 75, 18. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter - Insomnia, Compound Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, does not specifically address Deprizine, however it does address H-2 Blockers Page(s): 69. Decision based on Non-MTUS Citation www.drugs.com/search.php?searchterm=Deprizine.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine: Generic Name: ranitidine hydrochloride has not been found by FDA to be safe and effective, and this labeling has not been approved by 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 utilized the medication for an extended duration of time. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency and specific

quantity of the medication per dose. Given the above, the request for Deprizine 15mg/ml, 250ml (Ranitidine) is not medically necessary.

Tabradol 1mg/ml, 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Topical Analgesics, Muscle relaxants (for pain), Antiepilepsy drugs (AEDs) Page(s): 111-113, 68, 63-64, 75, 18. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter - Insomnia, Compound Drugs.

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

Decision rationale: Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California Medical Treatment Utilization Schedule 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 provide documentation of exceptional factors. There was a lack of documentation indicating the injured worker had an inability to swallow a pill. There was a lack of documentation indicating a necessity for both an oral and topical form of muscle relaxant. Additionally, the request as submitted failed to indicate the frequency and the specific dosage. Given the above, the request for Tabradol 1 mg/1 mL 250 mL is not medically necessary.

Cyclobenzaprine 5% 110 gms: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Topical Analgesics, Muscle relaxants (for pain), Antiepilepsy drugs (AEDs) Page(s): 111-113, 68, 63-64, 75, 18. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter - Insomnia, Compound Drugs.

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

Decision rationale: The California Medical Treatment Utilization Schedule indicates topical analgesics 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. 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. The clinical documentation submitted for review failed to provide documentation that an antidepressant and anticonvulsant have failed. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. There was a lack of documentation indicating a necessity for both an oral and topical form of muscle relaxant. The request as submitted failed to indicate the body part and frequency to be treated. Given the above, the request for cyclobenzaprine 5% 110 grams is not medically necessary.

Fanatrex 25mg/ml, 420ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Topical Analgesics, Muscle relaxants (for pain), Antiepilepsy drugs (AEDs) Page(s): 111-113, 68, 63-64, 75, 18. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter - Insomnia, Compound Drugs.

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

Decision rationale: The California Medical Treatment Utilization Schedule guidelines indicate that Gabapentin is used in the treatment of neuropathic pain. Per drugs.com, Fanatrex is an oral suspension of Gabapentin that 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. The clinical documentation submitted for review failed to indicate the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation of exceptional factors as the medication Fanatrex is not FDA approved. The request as submitted failed to indicate the specific frequency and dosage for the requested medication. There was a lack of documentation of exceptional factors. Given the above, the request for Fanatrex 25 mg/mL 420 mL is not medically necessary.

Synapryn 10mg/1ml, 500ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Topical Analgesics, Muscle relaxants (for pain), Antiepilepsy drugs (AEDs) Page(s): 111-113, 68, 63-64, 75, 18. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter - Insomnia, Compound Drugs.

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 Medical Treatment Utilization Schedule Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic and they 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 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. As

Tramadol is a form of an opiate, the California Medical Treatment Utilization Schedule chronic pain guidelines recommend opiates for chronic pain. 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 clinical documentation submitted for review failed to provide documentation of exceptional factors. There was a lack of documentation indicating the injured worker had an inability to swallow tablets or pills. There was a lack of documentation of objective functional improvement and an objective decrease in pain. There was a lack of documentation of side effects. The request as submitted failed to indicate the frequency and specific dosage. Given the above and the lack of documentation, the request for Synapryn 10 mg/1 mL 500 mL is not medically necessary.

Dicopanol 5 mg/ml, 150 ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Topical Analgesics, Muscle relaxants (for pain), Antiepilepsy drugs (AEDs) Page(s): 111-113, 68, 63-64, 75, 18. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter - Insomnia, Compound Drugs.

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 and Other Medical Treatment Guidelines www.drugs.com/search.php?searchterm=Dicopanol.

Decision rationale: The Official Disability Guidelines indicate 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, 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 documentation of exceptional factors to warrant non-adherence to guideline recommendations. Additionally, as this medication is not approved by the Federal Drug Administration, this medication would not be supported. The request as submitted failed to indicate the frequency and the specific dosage being requested. Given the above, the request for Dicopanol 5 mg/mL 150 mL is not medically necessary.