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| Case Number: | CM15-0013799 | | |
| Date Assigned: | 04/16/2015 | Date of Injury: | 07/22/2014 |
| Decision Date: | 06/09/2015 | UR Denial Date: | 01/12/2015 |
| Priority: | Standard | Application Received: | 01/23/2015 |

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, Arizona
 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 20-year-old, who reported an injury of 07/22/2014. The mechanism of injury was the injured worker was pushing and pulling on a large trash dumpster trying to pull the dumpster out. The diagnoses include bilateral wrist sprain/strain, carpal tunnel syndrome, lumbar spine sprain/strain, rule out herniated nucleus pulposus, lumbar radiculopathy, and right knee sprain/strain rule out internal derangement. Treatments to date have included braces, home therapy units, oral medications, topical pain medications, manual therapy, an MRI of the bilateral wrists, an MRI of the right knee, and an MRI of the low back. The progress report dated 12/17/2014 indicates that the injured worker complained of burning bilateral wrist pain, rated 5-7 out of 10; burning , radicular low back pain, rated 5-7 out of 10; and burning right knee pain, rated 5-6 out of 10. It was noted that the medications offered him temporary relief of pain and improved his ability to have restful sleep. The injured worker denied any problems with the medications. The objective findings include tenderness of the carpal tunnel and the first dorsal extensor muscle compartment; decreased bilateral wrist range of motion; tenderness to palpation at the lumbar paraspinal muscles and over the lumbosacral junction; trigger point; sciatic notch tenderness; decreased lumbar range of motion; tenderness to palpation over the right medial and lateral joint line and to the patella-femoral joint; and decreased range of motion of the right knee. The treating physician requested Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine cream, and Ketoprofen cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

(1) Prescription of Deprizine 15mg/ml 250ml: 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 based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://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 failed to provide the efficacy for the requested medication. 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 dosage of medication being requested. Given the above, the request for (1) Prescription of Deprizine 15mg/ml 250ml is not medically necessary.

(1) Prescription of Dicopanol 5mg/ml 150ml: Upheld

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

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 Other Medical Treatment Guideline or Medical Evidence: <http://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 nonadherence to the FDA recommendations. 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 dosage of medication being requested. Given the above, the request for (1) Prescription of Dicopanol 5mg/ml 150ml is not medically necessary.

(1) Prescription of Fanatrex 25mg/ml 420ml: 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 based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Fanatrex>.

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 provide documentation of exceptional factors to warrant nonadherence to guideline recommendations. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The efficacy was not provided. The request as submitted failed to indicate the frequency and specific dosage of medication being requested. Given the above, the request for (1) Prescription of Fanatrex 25mg/ml 420ml is not medically necessary.

(1) Prescription of Synapryn 10mg/1ml 500ml: 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, Tramadol Page(s): 50, 78, 82, 93, 94. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Synapryn online drug insert.

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 the injured worker had an inability to

swallow or tolerate a pill. There was a lack of documentation indicating objective functional improvement, an objective decrease in pain, and evidence the injured worker was being monitored for aberrant drug behavior. The request as submitted failed to indicate the frequency and specific dosing. Given the above, the request for (1) Prescription of Synapryn 10mg/1ml 500ml is not medically necessary.

(1) Prescription of Tabradol 1mg/ml 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 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 to support a necessity for an oral suspension. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation to support the necessity for both an oral and topical form of muscle relaxant. The request as submitted failed to indicate the frequency and specific dosage being requested. Given the above, the request for (1) Prescription of Tabradol 1mg/ml 250ml is not medically necessary.

(1) Prescription of Cyclobenzaprine 5% cream, 100 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxant, topical.

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

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 of topical analgesics 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 a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review failed to provide documentation that trials of

antidepressants and anticonvulsants had failed. There was a lack of documentation indicating a necessity and rationale for both the topical and oral form of muscle relaxants. The request as submitted failed to indicate the frequency and body part to be treated. Given the above, the request for (1) Prescription of Cyclobenzaprine 5% cream, 100 grams is not medically necessary.

(1) Prescription of Ketoprofen 20% cream, 165 grams: Upheld

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

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

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. Ketoprofen is not currently FDA approved for a topical application. The clinical documentation submitted for review failed to provide documentation of a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The request as submitted failed to indicate the body part to be treated and the frequency. Given the above, the request for (1) Prescription of Ketoprofen 20% cream, 165 grams is not medically necessary.