

Case Number:	CM15-0149886		
Date Assigned:	08/13/2015	Date of Injury:	05/07/2013
Decision Date:	10/02/2015	UR Denial Date:	07/21/2015
Priority:	Standard	Application Received:	08/03/2015

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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational 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 33 year old female, who sustained an industrial injury on May 7, 2013. She reported cumulative trauma injuries of her neck, right shoulder, midback, and low back. The injured worker was diagnosed as having cervical spine herniated nucleus pulposus, cervical spine degenerative disc disease, cervical radiculopathy, right shoulder acromioclavicular arthrosis and tendonitis, thoracic spine herniated nucleus pulposus, lumbar spine herniated nucleus pulposus, and lumbar radiculopathy. Diagnostic studies to date have included: On May 29, 2015, an MRI of the cervical spine revealed the beginning of disc desiccation at cervical 2-cervical 3 down through cervical 5-cervical 6 and endplate changes at the inferior endplate of cervical 2 and cervical 3. At cervical 3-4, there was 1.1 millimeter broad-based disc herniation which abuts the thecal sac, concurrent right uncovertebral joint degenerative change. There was right neural foraminal narrowing with contact on the right cervical 4 exiting nerve root caused by disc material and uncovertebral joint degenerative change. At cervical 4-cervical 5 and cervical 5-cervical 6, there was 1.1 millimeter broad-based disc herniation which abuts the thecal sac with disc material causing bilateral neural foraminal narrowing. At cervical 6-cervical 7, there was a 2.3 millimeter broad-based disc herniation which abuts the thecal sac with disc material causing left neural foraminal narrowing. On May 29, 2015, an MRI of the thoracic spine revealed disc desiccation at thoracic 1-2 down to thoracic 3-4. There were 2.9 millimeter focal central disc herniations which abut the thecal sac at thoracic 4-thoracic 5, thoracic 6-thoracic 7, and thoracic 8-thoracic 9. On May 29, 2015, an MRI of the lumbar spine revealed 1.3 millimeter broad-based disc herniations which abut the thecal sac at lumbar 2-lumbar 3, lumbar 3-lumbar 4, and lumbar 5-sacral 1. There was a 2.7 millimeter broad-based disc herniation which abutted the

thecal sac at L4-lumbar 5. On May 30, 2015, an MRI of the right shoulder revealed a flat, lateral downsloping acromium, acromioclavicular joint osteoarthritis, and supraspinatus and infraspinatus tendinosis. Treatment to date has included physical therapy, chiropractic therapy, acupuncture, shockwave therapy, work modifications, a non-steroidal anti-inflammatory injection, and medications including opioid analgesic, topical analgesics, muscle relaxant, histamine 2 antagonist, sleep-inducing, opioid analgesic-glucosamine supplement, and non-steroidal anti-inflammatory. There were no noted previous injuries or dates of injury, and no noted comorbidities. Work status is return to modified work with limitations and restrictions including no repetitive movement of the head and neck. No sustained posturing of the head and neck. No overhead lifting 10 pounds. No repetitive work at or above shoulder level. No pushing or pulling greater than 5 pounds. No repetitive bending, stooping, twisting, or turning. No prolonged standing, sitting, or walking. No prolonged standing or sitting longer than 20 minutes with the ability to sit or stand at will. No participation in physical exercises or sports activities. She should wear the recommended braces at work and home. She should be allowed a 5 minute break for each hour worked. The restrictions also apply to at home and off-work hours. If unable to accommodate, then she is to be temporarily totally disabled. On June 12, 2015, the injured worker reported constant burning, radicular neck pain, rated 6-7 out of 10. Associated symptoms include numbness and tingling of the bilateral upper extremities. She reported constant burning, right shoulder pain radiating down the arms to the fingers with associated muscle spasms. The pain was rated 6 out of 10. She reported constant burning, midback pain and muscle spasms, rated 6-7 out of 10. She reported constant burning, radicular low back pain and muscle spasms. Associated symptoms include numbness and tingling of the bilateral lower extremities. The pain was rated 6-7 out of 10. She reported her medications help her pain and improve her restful sleep ability. The physical exam revealed tenderness to palpation of the cervical paraspinal muscles with decreased cervical range of motion. There was tenderness of the delto-pectoral groove and on the insertion of the supraspinatus muscle and decreased range of motion of the right shoulder. There was slightly decreased sensation over the cervical 5 through thoracic 1 dermatomes, decreased motor strength due to pain, and normal deep tendon reflexes of the right upper extremity. There was tenderness to palpation and muscle spasms of the bilateral thoracic paraspinals, decreased range of motion, and normal dermatomes of the thoracic spine. There was tenderness to palpation of the paraspinal muscles and decreased range of motion of the lumbar spine. There was decreased sensation at the lumbar 4 through sacral 1 dermatomes, decreased motor strength due to pain, and normal deep tendon reflexes of the bilateral lower extremities. The treatment plan includes Topical Ketoprofen 20% cream, Tabradol (Cyclobenzaprine), Deprizine (rantidine), Dicopanol (diphenhydramine), Fanatrex (gabapentin), Topical Cyclobenzaprine 5% cream, and Synapryn.

IMR ISSUES, DECISIONS AND RATIONALES

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

Topical Ketoprofen 20% cream 165g: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: The California Medical Treatment Utilization Schedule (CMTUS) guidelines primarily recommended topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Per the CMTUS, topical Ketoprofen, a non-steroidal anti-inflammatory drug, is not approved by the Food and Drug Administration (FDA) for topical use. There was lack of documentation of the injured worker having failed trials of antidepressants and anticonvulsants. The guidelines do not support the topical use of Ketoprofen. Therefore, the Ketoprofen 20% topical cream is not medically necessary.

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 Official Disability Guidelines, Medications-compounded.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 299, 308, Chronic Pain Treatment Guidelines Chronic Pain: Cyclobenzaprine (Flexeril); Muscle Relaxants (for pain) Page(s): 41; 63-66.

Decision rationale: The requested treatment is Tabradol, which is an oral suspension of Cyclobenzaprine. Per the California Medical Treatment Utilization Schedule (CMTUS) guidelines, non-sedating muscle relaxants are recommended with caution for short-term treatment of acute exacerbations of chronic low back pain as a second-line option. The efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. The CMTUS guidelines recommend Cyclobenzaprine for short-term treatment (no longer than 2-3 weeks) to decrease muscle spasms in the lower back. The ACOEM (American College of Occupational and Environmental Medicine) guidelines recommend muscle relaxants for the short-term treatment of acute spasms of the low back. There was lack of documentation of a recent acute exacerbation of chronic low back pain. The medical records show that the injured worker has been taking cyclobenzaprine as needed since at least May 2015, which exceeds the short-term treatment recommended by the guidelines. This patient has chronic pain with no evidence of prescribing for flare-ups of low back pain. In this case, cyclobenzaprine is added to other agents, and the oral suspension form plus topical is experimental and unproven. Prescribing was not for a short term exacerbation. Topical Cyclobenzaprine in addition to the Tabradol (Cyclobenzaprine has been prescribed for this injured worker, which is redundant. Therefore, the Tabradol (Cyclobenzaprine) is not medically necessary.

Deprizine 15mg/ml 250ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Medications-compounded.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

Decision rationale: The requested treatment is for Deprizine, which the medical records show

contains ranitidine (a H2-receptor antagonist) and other unnamed ingredients. Per the California Medical Treatment Utilization Schedule (CMTUS) guidelines, recommends stopping the NSAID, switch to a different NSAID, or considering a H2-receptor antagonists or a proton pump inhibitor functional improvement for the treatment of non-steroidal anti-inflammatory drug (NSAID)-induced dyspepsia. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. Deprizine is not medically necessary on this basis alone. In addition, there is lack of evidence of the injured worker experiencing gastrointestinal symptoms related to NSAID use. The injured worker's current medications do not include non-steroidal anti-inflammatory medication. There is lack of objective evidence of gastrointestinal issues on the physical exam. Therefore, the Deprizine is not medically necessary.

Dicopanol (diphenhydramine) 5mg/ml 150ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Medications-compounded.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Stress & Illness: Diphenhydramine (Benadryl); Insomnia treatment.

Decision rationale: The requested treatment is for Dicopanol, which the medical records show is Dicopanol is used for the treatment of insomnia and contains diphenhydramine and other unnamed ingredients. The California Medical Treatment Utilization Schedule (CMTUS), Chronic Pain Medical Treatment Guidelines are silent with regard to non-benzodiazepine hypnotics. Per the Official Disability Guidelines (ODG), Diphenhydramine, a sedating antihistamine, is not recommended for long-term insomnia treatment as tolerance develops quickly, and that there are many, significant side effects. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. The medical record shows the injured worker has been taking Dicopanol (diphenhydramine) since at least May 2015. The requested treatment is for Dicopanol, which the medical records show is Dicopanol is used for the treatment of insomnia and contains diphenhydramine and other unnamed ingredients. The California Medical Treatment Utilization Schedule (CMTUS), Chronic Pain Medical Treatment Guidelines are silent with regard to non-benzodiazepine hypnotics. Per the Official Disability Guidelines (ODG), Diphenhydramine, a sedating antihistamine, is not recommended for long-term insomnia treatment as tolerance develops quickly, and that there are many, significant side effects. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. Dicopanol is not medically necessary on this basis alone. In addition, there is lack of physician documentation describing the specific criteria for a sleep disorder. There is lack of evidence initiating hypnotic treatment following the careful diagnosis of a sleep disorder. Therefore, the request for Dicopanol (diphenhydramine) is not medically necessary.

Fanatrex (gabapentin) 25mg/ml 420ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Medications-compounded.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs); Gabapentin (Neurontin) Page(s): 16-21; 49.

Decision rationale: The requested treatment is for Fanatrex, which the medical records show is a formulation of gabapentin stated that it is for neuropathic pain. The California Medical Treatment Utilization Schedule (CMTUS) guidelines recommend anti-epilepsy drugs (also referred to as anti-convulsants) as a first-line treatment for neuropathic pain. A 50% reduction in pain is defined as a good response to the use of anti-epilepsy drugs and a 30% reduction in pain is defined as a moderate response. A less than 30% response to the use of anti-epilepsy drugs may prompt a switch to a different first-line agent or combination therapy if treatment with a single drug agent fails. Per the CMTUS, Gabapentin is recommended as a first-line treatment for neuropathic pain. There is a lack of documentation of a 30% or reduction in pain and a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. In addition, the CMTUS notes that anti-epilepsy drugs have a significant risk of teratogenicity and alterations in contraceptives, and this must be discussed with the patient. There is lack of evidence that this reproductive-age woman has been counseled regarding this significant issue. The medical records show the injured worker has been taking Gabapentin since at least May 2015. Therefore, the request for Gabapentin is not medically necessary.

Topical Cyclobenzaprine 5% cream 100g: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: The California Medical Treatment Utilization Schedule (CMTUS) guidelines primarily recommended topical analgesics for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Per the CMTUS, topical muscle relaxants are not recommended for use. There was lack of documentation of the injured worker having failed trials of antidepressants and anticonvulsants. Cyclobenzaprine, a muscle relaxant, is not recommended by the guidelines for topical use. In addition, the injured worker has been prescribed topical Cyclobenzaprine in addition to oral Cyclobenzaprine (Tabradol), which is redundant. Therefore, the cyclobenzaprine 10% tramadol 10% topical cream is not medically necessary.

Synapryn 10mg/1ml 500ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Medications-compounded.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate); Opioids; Tramadol (Ultram) Page(s): 50; 74-96; 113.

Decision rationale: The requested treatment is Synapryn, which the medical records show is contains Tramadol, glucosamine, and other unspecified agents. The California Medical Treatment Utilization Schedule (CMTUS) guidelines recommend the synthetic opioid Tramadol as a second-line treatment for moderate to severe pain. Per the CMTUS, Glucosamine Sulfate is recommended treating moderate arthritis pain, particularly knee osteoarthritis. Other forms of glucosamine are not supported by good medical evidence. The treating physician in this case has not provided evidence of the form of glucosamine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. There is lack of physician documentation of the rationale for the combining of Tramadol and glucosamine. The combination product is illogical and not indicated, as tramadol is generally a prn medication to be used as little as possible, and that glucosamine (assuming a valid indication) is to be taken regularly regardless of acute symptoms. In addition, the long term usage of opioid therapy is discouraged by the CMTUS guidelines unless there is evidence of "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment, average pain, intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." There was lack of physician documentation of the least reported pain over the period since last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief, how long pain relief lasts, improvement in pain, and improvement in function. Therefore, the Synapryn is not medically necessary.