

Case Number:	CM15-0186006		
Date Assigned:	09/28/2015	Date of Injury:	08/07/2013
Decision Date:	11/23/2015	UR Denial Date:	09/03/2015
Priority:	Standard	Application Received:	09/21/2015

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 60 year old female who sustained an industrial injury on 8-7-2013. A review of medical records indicates the injured worker is being treated for cervical muscle spasm, cervical radiculopathy, cervical stenosis, left rotator cuff tear, left shoulder adhesive tendinitis, left shoulder myospasm, status post-surgery, left shoulder, and chronic pain. Medical records dated 7-21-2015 noted neck pain radiating the left shoulder and left shoulder pain. Pain scale was not available. Medical records dated 7-16-2015 noted pain a 3-4 out of 10. The pain was aggravated by gripping, grasping, reaching, pulling, lifting, and doing work at or above the shoulder level. Medical records dated 6-18-2015 noted pain was a 4 out 10. She explains medications offer her temporary relief of pain and improve her ability to have restful sleep. Physical examination 7-16-2015 noted tenderness to palpation of the occiputs, trapezius, and sternocleidomastoid and levator scapula muscles. Cervical range of motion was reduced. There was tenderness to palpation of the shoulders. Treatment has included medications including Ketoprofen 20% cream, Cyclobenzaprine 5% cream, Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex since at least 5-21-2015. Utilization review noncertified Ketoprofen 20% cream, Cyclobenzaprine 5% cream, Synapryn 10mg-1ml, Tabradol 1mg, Deprizine 15 mg, Dicopanol 5 mg, and Fanatrex 25mg.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed, Ketoprofen is also not FDA approved for topical use due to high incidence of photocontact dermatitis, therefore the request for Ketoprofen 20% cream is not medically necessary.

Cyclobenzaprine 5% cream: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Topical Analgesics.

Decision rationale: Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed and per the MTUS, cyclobenzaprine is a muscle relaxant and there is no evidence for use of any muscle relaxant as a topical product therefore the request for cyclobenzaprine 5% cream is not medically necessary.

Synapryn 10 mg/1 ml oral suspension: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids, specific drug list.

Decision rationale: The MTUS states that tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. Opioids are recommended for chronic pain, especially neuropathic pain that has not responded to first line recommendations like antidepressants and anticonvulsants. Long term users should be reassessed per specific guideline recommendations and the dose should not be lowered if it is working. Per the MTUS, Tramadol is indicated for moderate to severe pain. Synapryn contains tramadol. A review of the injured workers medical records do not show that she has difficulty swallowing or is unable to tolerate other recommended non liquid oral medications, there is also no documentation of pain and functional improvement according to guideline recommendations for ongoing opioid use and without this information Synapryn 10mg/1ml oral suspension is not medically necessary.

Tabradol 1 mg/ml oral suspension: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril).

Decision rationale: Per the MTUS, Cyclobenzaprine is recommended as an option in the treatment of chronic pain using a short course of therapy. It is more effective than placebo in the management of back pain, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment suggesting that shorter courses may be better. Treatment should be brief, it is not recommended for use for longer than 2-3 weeks. Tabradol contains cyclobenzaprine, however a review of the injured workers medical records do not show that she has difficulty swallowing or is unable to tolerate other recommended non liquid oral medications and without this information Tabradol oral suspension is not medically necessary.

Deprizine 15 mg/ml oral suspension: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Proton Pump Inhibitors (PPIs).

Decision rationale: Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Per the ODG, PPIs are recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects

compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective (AHRQ, 2011). A review of the injured workers medical records that are available to me do not justify the use of Deprizine over the use of other first line recommended agents, there is no indication that the injured worker has difficulty swallowing or is at increased risk for a gastrointestinal event, therefore Deprizine 15mg/ml oral suspension is not medically necessary.

Dicopanol 5 mg/ml oral suspension: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph - Diphenhydramine (Benadryl).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) / Insomnia, Insomnia treatment.

Decision rationale: The MTUS did not specifically address the treatment of insomnia in chronic pain therefore other guidelines were consulted. Per the ODG, correcting sleep deficits is recommended as non restorative sleep is one of the strongest predictors of pain. Sedating antihistamines have been suggested for sleep aids, for example diphenhydramine, tolerance develops within a few days and next day sedation, impaired psychomotor and cognitive functions have been noted, side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. Dicopanol is diphenhydramine and a review of the injured workers medical records did not reveal any difficulty swallowing or tolerating non liquid oral medications, there is also no quantifiable improvement in sleep noted, without this information the request for Dicopanol 5mg/ml oral suspension is not medically necessary.

Fanatrex 25 mg/ml oral suspension: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Per the MTUS, antiepilepsy drugs are recommended for neuropathic pain. Gabapentin is considered first line treatment for neuropathic pain. Fanatrex contains gabapentin. The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. However a review of the injured workers medical records does not reveal difficulty swallowing or tolerating non liquid oral medications neither was there documentation of improvement in pain and function as required by the guidelines and without this information the request is not medically necessary and is not established.