

Case Number:	CM15-0191516		
Date Assigned:	10/05/2015	Date of Injury:	08/23/2012
Decision Date:	12/10/2015	UR Denial Date:	09/10/2015
Priority:	Standard	Application Received:	09/29/2015

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: Emergency 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 51 year old female who sustained an industrial injury August 23, 2012. According to a primary treating physician's progress report dated August 6, 2015, the injured worker presented for a follow-up visit with complaints of sharp radicular neck pain and muscle spasm, greater on the left side, rated 6-7 out of 10 and associated with numbness and tingling of the bilateral upper extremities. She also complains of burning left shoulder pain, rated 6 out of 10, radiating down the arm to the fingers and associated with muscle spasms; constant right forearm and elbow pain, rated 3-4 out of 10 associated with numbness and tingling of the right elbow, wrist and fingers; burning right wrist pain, rated 5-6 out of 10, and muscle spasms with weakness numbness, and tingling of the hand and fingers. She reports her thumb fall asleep and the pain in her right hand wakes her at night. She also complains of anxiety, stress, and insomnia, brought on by chronic pain. Objective findings included; cervical spine-anterior head carriage, 2+ tenderness at suboccipital region; left shoulder-tenderness to palpation at the rotator cuff tendon as well as the AC joint and subacromial space; right forearm-elbow- wearing a tennis elbow brace, decreased grip strength on the right compared to the unaffected left; right wrist- tenderness at the carpal tunnel and the first dorsal extensor muscle compartment, Tinel's wrist positive right, Phalen's negative right, Finkelstein's positive right; sensory intact bilateral upper extremities. The treating physician's notes (04-13-2015) revealed the injured worker had been taking Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex. Diagnoses are cervical spine multilevel herniated nucleus pulposus per MRI 08-20-2014; cervical spine multi-level degenerative disc disease; cervical radiculopathy; left shoulder tendinitis; right elbow lateral

epicondylitis; triangular fibrocartilage tear, per MRI 08-20-2014; mood and sleep disorder. At issue, is a request for authorization for Compound medications; HMPC2 240gms and HNPC1 240gms, Ketoprofen, Cyclobenzaprine, Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex. An MRI of the left forearm dated August 30, 2015, (report present in the medical record) impression; negative MRI of the forearm. An MRI multi-position of the left shoulder dated August 30, 2015 (report present in the medical record) impression as; supraspinatus, infraspinatus, subcapularis tendinosis; subacromial-subdeltoid bursitis; glenohumeral joint effusion; no new abnormalities. A report of an MRI of the cervical spine with flexion and extension dated August 30, 2015, is present in the medical record. According to utilization review dated September 10, 2015, the requests for Compound medications; HMPC2 240gms and HNPC1 240gms are non-certified. The requests for Ketoprofen 20% cream 167gms, Cyclobenzaprine 5% cream 110gms, Synapryn 10mg-ml 500 ml, Tabradol 1 mg-ml 250 ml, Deprizine 15mg-ml 250 ml, Dicopanol 5mg-ml 150 ml, and Fanatrex 25mg-ml 420 ml are non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound medication: HMPC2 240 gms.: 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: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the use of this product is not indicated. This is secondary to poor scientific evidence of efficacy for the patient's condition when applied topically. As such, the request is not medically necessary.

Compound medication: HNPC1 240 gms.: 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: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not

recommended." In this case, the use of this product is not indicated. This is secondary to poor scientific evidence of efficacy for the patient's condition when applied topically. As such, the request is not medically necessary.

Ketoprofen 20% cream 167 gms: 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: The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states that the efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. It is indicated for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the treatment duration. As such, the request is not medically necessary.

Cyclobenzaprine 5% cream 110 gms: 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: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, the use of the topical muscle relaxant is not indicated for use for the patient's condition. As indicated above, due to inadequate clinical evidence of efficacy, the request is not medically necessary.

Synapryn 10mg/ml 500 ml.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Meds.com.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

Decision rationale: Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. As such, the request is not medically necessary.

Tabradol 1mg/ml 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Meds.com.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

Deprizine 15mg/ml 250 ml.: 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), Chronic Pain, Medical FoodMeds.com.

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)/Compounded drugs.

Decision rationale: The request is for the use of a compounded medication. The official disability guidelines state the following regarding this topic: Not recommended as a first-line

therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. (Wynn, 2011) See specific entries for each ingredient. See also Topical analgesics, compounded. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. Unlike commercially available drugs, these products are not approved by the FDA but rather are regulated by the state pharmacy board and state law governing the practice of pharmacy. The FDA does not regulate pharmacy-compounded products in recognition of the important public health function performed by traditional compounding. Recently, some pharmacies have been making and marketing stock compound drugs for the WC patient population. Among the FDA Red Flags for Enforcement Action on Compounded Drugs is: "Compounding drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to amounts compounded after receiving valid prescriptions." (FDA, 2011) Compound topical analgesics may provide relief by acting locally over the painful site with lower risk of systemic adverse effects on the gastrointestinal system and drug interactions than oral NSAIDs. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate and whether payments are reasonable, with the latter issue possibly also involving who dispenses the drug. Medical necessity should be based on the patient's needs combined with the medical and scientific evidence presented in ODG. ODG does not address pricing and fee schedules, but in general there should be consistency within a pharmacy fee schedule for products containing the same active ingredients, so that there is not an inappropriate incentive to use compounding. (Wynn, 2011) See also Co-pack drugs; Medical foods; Physician-dispensed drugs; Repackaged drugs; & Topical analgesics, compounded. Criteria for Compound drugs:(1) Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs.(2) Include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code.(3) Is not a drug that was withdrawn or removed from the market for safety reasons.(4) Is not a copy of a commercially available FDA-approved drug product.(5) Include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence. See specific entries for each ingredient in ODG for the medical and scientific evidence.(6) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. See also Topical analgesics, compounded. (Wynn, 2011)As stated above the use of this medication is not indicated. This is secondary to no documentation which states that there has been a failure of first-line FDA approved drug therapy or any explanation as to why this compounded formula is superior in efficacy. As such, the request is not medically necessary.

Dicopanol 5mg/ml 150 ml.: 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), Chronic Pain, Medical FoodMeds.com.

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

Decision rationale: The request is for the use of Diphenhydramine which is in the category of an antihistamine. The MTUS guidelines are silent regarding this topic. The ODG states the following regarding its use: Not recommended. See Insomnia treatment, where sedating antihistamines are not recommended for long-term insomnia treatment. The AGS updated Beers criteria for inappropriate medication use includes diphenhydramine. (AGS, 2012) Anticholinergic drugs, including diphenhydramine, may increase the risk for dementia by 50% in older adults. There is an obvious dose-response relationship between anticholinergic drug use and risk of developing dementia, but chronic use, even at low doses, would be in the highest risk category. While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition, and generally awareness of this issue is very low, and both the public and doctors need to be encouraged to use alternative treatments where possible. (Gray, 2015) As stated above, the use of this medication is not indicated for use in this patient for insomnia. There is inadequate documentation of the reasoning for its use for other indications. As such, the request is not medically necessary.

Fanatrex 25mg/ml 420 ml.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Meds.com.

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)/Compounded drugs.

Decision rationale: The request is for the use of a compounded medication. The official disability guidelines state the following regarding this topic: Not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. (Wynn, 2011) See specific entries for each ingredient. See also Topical analgesics, compounded. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. Unlike commercially available drugs, these products are not approved by the FDA but rather are regulated by the state pharmacy board and state law governing the practice of pharmacy. The FDA does not regulate pharmacy-compounded products in recognition of the important public

health function performed by traditional compounding. Recently, some pharmacies have been making and marketing stock compound drugs for the WC patient population. Among the FDA Red Flags for Enforcement Action on Compounded Drugs is: "Compounding drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to amounts compounded after receiving valid prescriptions." (FDA, 2011) Compound topical analgesics may provide relief by acting locally over the painful site with lower risk of systemic adverse effects on the gastrointestinal system and drug interactions than oral NSAIDs. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate and whether payments are reasonable, with the latter issue possibly also involving who dispenses the drug. Medical necessity should be based on the patient's needs combined with the medical and scientific evidence presented in ODG. ODG does not address pricing and fee schedules, but in general there should be consistency within a pharmacy fee schedule for products containing the same active ingredients, so that there is not an inappropriate incentive to use compounding. (Wynn, 2011) See also Co-pack drugs; Medical foods; Physician-dispensed drugs; Repackaged drugs; & Topical analgesics, compounded. Criteria for Compound drugs: (1) Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. (2) Include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code. (3) Is not a drug that was withdrawn or removed from the market for safety reasons. (4) Is not a copy of a commercially available FDA-approved drug product. (5) Include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence. See specific entries for each ingredient in ODG for the medical and scientific evidence. (6) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. See also Topical analgesics, compounded. (Wynn, 2011)As stated above the use of this medication is not indicated. This is secondary to no documentation which states that there has been a failure of first-line FDA approved drug therapy or any explanation as to why this compounded formula is superior in efficacy. As such, the request is not medically necessary.