

Case Number:	CM15-0184871		
Date Assigned:	10/16/2015	Date of Injury:	02/26/2015
Decision Date:	12/18/2015	UR Denial Date:	09/10/2015
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: 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 33 year old male, who sustained an industrial injury on 2-26-2015. Diagnoses include cervical, thoracic, and lumbar spine sprain-strain, bilateral shoulder sprain-strain, and bilateral hand sprain-strain. Treatments to date include activity modification, physical therapy, chiropractic therapy, shockwave treatments, localized intense neurostimulation therapy, acupuncture treatments, and medication therapy. On 8-28-15, he complained of ongoing pain in the neck, bilateral shoulder, bilateral wrists and hands, mid pain and low back. There was associated numbness and tingling noted to bilateral upper and bilateral lower extremities. Medications prescribed for greater than six months included Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex, and topical creams including HMPC2, HMPC2, Ketoprofen, and Cyclobenzaprine. The records documented medication offer temporary relief of pain and improve ability to have a restful sleep. Oral suspensions and topical creams were prescribed at the initial evaluation in March 2015, with no documentation of intolerance or failed treatment with tablets or capsules, or condition documented requiring suspension medications. The physical examination documented tenderness, decreased range of motion, and multiple positive musculoskeletal test findings. The plan of care included additional testing, therapy, and continuation of previously prescribed medications. The appeal requested authorization for one orthopedic surgeon consultation regarding the right shoulder, electromyogram and nerve conduction studies (EMG-NCS), six (6) shockwave therapy sessions, one pain management consultation regarding a lumbar epidural steroid injection, one platelet-rich plasma, and prescriptions for Synapryn 10mg-ml oral suspension 500ml, Tabradol 1mg-ml oral suspension

250ml, Deprizine 15mg-ml oral suspension 250ml, Dicopanol 5mg-ml oral suspension 150ml, Fanatrex 25mg-ml oral suspension 420ml, HMPC2 (Flurbiprofen 20%, Baclofen 10%, Dexamethasone Micro 0.2%, Hyaluronic Acid 0.2% in cream base) 40 grams, HMPC2 (Amitriptyline HCL 10%, Gabapentin 10%, Bupivacaine HCL 5%, Hyaluronic Acid 0.2% in cream base) 240 grams, Ketoprofen 20% cream 167 grams, and Cyclobenzaprine 5% cream 167 grams. The Utilization Review dated 9-10-15, denied this request.

IMR ISSUES, DECISIONS AND RATIONALES

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

HMPC2-Flurbiprofen 20%, Baclofen 10%, Dexamethasone Micro 0.2%, Hyaluronic acid 0.2% in cream base 240gm: 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 compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: 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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: 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 stated above, the patient would not qualify for the use of a topical NSAID. This is based on the treatment duration with the patient's injury being far greater than 12 weeks. As such, the request is not medically necessary.

HNPC1-Amitriptyline HCL 10%, Gabapentin 10%, Bupivacaine HCL 5%, Hyaluronic acid 0.2% in cream base 240gm: Upheld

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

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)/topical analgesics.

Decision rationale: The request is for the use of a compounded topical medication to aid in pain relief. The official disability guidelines state the following regarding this topic: "Recommended as an option as indicated below. 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor)." As stated above, the use of any topical compounded medication with an antidepressant included is not evidence based. As such, it is not medically necessary.

Ketoprofen 20% cream 167gm: Upheld

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

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)/Ketoprofen, topical.

Decision rationale: The request is for the use of Ketoprofen topically. The official disability guidelines state the following regarding this topic: Not recommended in the U.S., as there are currently no FDA approved versions of this product, but it is a first-line drug in Europe. See Topical analgesics, Non-steroidal anti-inflammatory agents (NSAIDs), and the ketoprofen topical listing, for more information and references. Topical NSAIDs are generally recommended for short-term use for acute sprain/strains and longer term for osteoarthritis of the knee and hand, particularly in individuals with risk for GI ulceration, but they are not indicated for treatment of the low back or neuropathic pain. At this time, the only available FDA-approved topical NSAID is diclofenac, but recent high quality studies have identified a dangerous increased risk profile with diclofenac, including topical formulations, making it a second-line recommended treatment in ODG. Topical ketoprofen has been approved by the European FDA (the European Medicines Agency), and the European EULAR and NICE guidelines state these approved formulations of topical ketoprofen should be a first-line treatment, and should be considered before oral NSAIDs because they have shown efficacy significantly superior to placebo and similar to oral NSAIDs, without the same risks of adverse effects. While there are no FDA approved formulations of topical ketoprofen available in the U.S., the product is available from compounding pharmacies. Compound medications are not FDA approved, but they are allowed under state pharmacy regulations. See Compound drugs. Because each compounding pharmacy may create their own version, FDA cannot be a source of information on safety and effectiveness of each version, or on generic equivalency. At this time, there are no

high quality studies of any of the various pharmacy compounded formulations of topical ketoprofen available in the U.S. Also, while topical ketoprofen has been used extensively in Europe, in 2009 France removed this product from the market due to photosensitivity reactions. The drug has been reinstated, but this may be a serious problem. See the ketoprofen topical listing in Topical analgesics, Non-steroidal anti-inflammatory agents. Note: Topical ketoprofen is not listed on the ODG Drug Formulary because the scope of the ODG Drug Formulary only includes FDA approved drugs. (Formulary Scope). In this case, the use of this medication is not guideline-supported. This is secondary to no FDA approved versions of this product. As such, the request is not medically necessary.

Cyclobenzaprine 5% cream 110gm: 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 the topical muscle relaxant is not indicated for use for the patient's condition. The MTUS states the following regarding muscle relaxants used topically: "Baclofen: Not recommended. There is currently one Phase III study of Baclofen Amitriptyline Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." As indicated above, due to inadequate clinical evidence of efficacy, the request is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml: Upheld

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

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 supported by the guidelines. 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 the patient is intolerant to tablets or capsules. As such, the request is not medically necessary.

Tabradol 1mg/ml oral suspension 250ml: Upheld

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

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 supported by the guidelines. 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 the patient is intolerant to tablets or capsules. As such, the request is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: Upheld

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

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 supported by the guidelines. 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 the patient is intolerant to tablets or capsules. As such, the request is not medically necessary.

Dicopanol 5mg/ml oral suspension 150ml: Upheld

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

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 supported by the guidelines. 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 the patient is intolerant to tablets or capsules. As such, the request is not medically necessary.

Fanatrex 25mg/ml oral suspension 420ml: Upheld

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

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 supported by the guidelines. 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 the patient is intolerant to tablets or capsules. As such, the request is not medically necessary.

1 orthopedic surgeon consultation regarding right shoulder: Upheld

Claims Administrator guideline: Decision based on MTUS Shoulder Complaints 2004.

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)/Office visits.

Decision rationale: The request is for an orthopedic surgery consultation to address the right shoulder. The MTUS guidelines are silent regarding this issue. The ODG state the following: Recommended as determined to be medically necessary. Evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical role in the proper diagnosis and return to function of an injured worker, and they should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved

with eventual patient independence from the health care system through self care as soon as clinically feasible. The ODG Codes for Automated Approval (CAA), designed to automate claims management decision-making, indicates the number of E&M office visits (codes 99201-99285) reflecting the typical number of E&M encounters for a diagnosis, but this is not intended to limit or cap the number of E&M encounters that are medically necessary for a particular patient. Office visits that exceed the number of office visits listed in the CAA may serve as a "flag" to payers for possible evaluation, however, payers should not automatically deny payment for these if preauthorization has not been obtained. Note: The high quality medical studies required for treatment guidelines such as ODG provides guidance about specific treatments and diagnostic procedures, but not about the recommended number of E&M office visits. Studies have and are being conducted as to the value of "virtual visits" compared with inpatient visits, however the value of patient/doctor interventions has not been questioned. (Dixon, 2008) (Wallace, 2004) Further, ODG does provide guidance for therapeutic office visits not included among the E&M codes, for example Chiropractic manipulation and Physical/Occupational therapy. See also Telehealth. In this case, the request is not medically necessary. This is secondary to poor documentation as to the reasoning for the visit and consultation. There is inadequate discussion of the specific issue requiring further evaluation and assessment. The patient is also receiving conservative therapy, which has not been exhausted.

EMG/NCV of the bilateral upper extremities: Upheld

Claims Administrator guideline: Decision based on MTUS Elbow Complaints 2007, Section(s): Diagnostic Criteria, and Forearm, Wrist, and Hand Complaints 2004, Section(s): Diagnostic Criteria.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and upper back/EMGs (electromyography).

Decision rationale: The request is for an EMG. The ODG state the following regarding this topic: Recommended (needle, not surface) as an option in selected cases. The American Association of Electrodiagnostic Medicine conducted a review on electrodiagnosis in relation to cervical radiculopathy and concluded that the test was moderately sensitive (50%-71%) and highly specific (65%-85%). (AAEM, 1999) EMG findings may not be predictive of surgical outcome in cervical surgery, and patients may still benefit from surgery even in the absence of EMG findings of nerve root impingement. This is in stark contrast to the lumbar spine where EMG findings have been shown to be highly correlative with symptoms. Indications when particularly helpful: EMG may be helpful for patients with double crush phenomenon, in particular, when there is evidence of possible metabolic pathology such as neuropathy secondary to diabetes or thyroid disease, or evidence of peripheral compression such as carpal tunnel syndrome. In this case, the patient does not meet criteria for the study requested. This is secondary to poor physical exam findings suggestive of peripheral nerve compression. Pending receipt of information further clarifying how this study would change the management rendered, the study is not medically necessary.

6 sessions of shockwave therapy for the lumbar spine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back (Acute and Chronic), Shock wave therapy.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Lumbar & Thoracic (Acute & Chronic)/ Extracorporeal shock wave therapy (ESWT).

Decision rationale: The request is for Extracorporeal shock wave therapy (ESWT). The MTUS guidelines has limited information regarding this topic for back pain. The Official Disability Guidelines state the following: Not recommended. The available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. (Seco, 2011) In this case, the use of this treatment modality is not supported by the guidelines. This is secondary to poor clinical evidence regarding effectiveness of use. As such, the request is not medically necessary.

1 pain management consultation regarding a lumbar epidural steroid injection: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Office Visits.

Decision rationale: The request is for a pain management consult for an epidural steroid injection to aid in pain relief. There are certain qualifying criteria regarding the use of this treatment modality. The MTUS guidelines state the following on this topic: Criteria for the use of Epidural steroid injections: Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007)8) Current research does

not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections. In this case, the patient does not meet the criteria set above. This is secondary to inadequate documentation of physical exam and radiographic findings of radiculopathy. As such, the request is not medically necessary.

1 Platelet-rich plasma: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Ankle and Foot (Acute and Chronic), Platelet-rich plasma.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg/Platelet-rich plasma (PRP).

Decision rationale: The request is for the use of platelet-rich plasma to aid in pain relief. The official disability guidelines state the following regarding this topic:ODG Criteria for Platelet-rich plasma (PRP) intra-articular injection:(1) Significantly symptomatic osteoarthritis: (a) Not responded adequately to recommended conservative non-pharmacologic (e.g., exercise) and pharmacologic treatments or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications), after at least 6 months; (b) Documented symptomatic mild-moderate (not advanced) osteoarthritis of the knee; (c) Under 50 years of age; (d) Pain interferes with functional activities (e.g., ambulation, prolonged standing) and not attributed to other forms of joint disease; (e) Failure to adequately respond to aspiration and injection of intra-articular steroids; (f) Generally performed without fluoroscopic or ultrasound guidance; (g) Single injection highly concentrated WBC-poor (filtered); (h) Maximum once yearly if previous injection documented significant relief for over 6 months; OR (2) Refractory patella tendinosis: (a) Not responded adequately to recommended conservative non-pharmacologic (e.g., exercise) and pharmacologic treatments or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications), after at least 12 months; (b) Single injection, not multiple. In this case, this treatment is not advised for the patient's condition based the guidelines. This is secondary to a lack of a diagnosis documented, which would support its use, such as significantly symptomatic osteoarthritis with failure to respond to intra-articular steroids or refractory patella tendinosis. As such, the request is not medically necessary.