

Case Number:	CM15-0082501		
Date Assigned:	05/04/2015	Date of Injury:	10/09/2013
Decision Date:	06/12/2015	UR Denial Date:	04/20/2015
Priority:	Standard	Application Received:	04/29/2015

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: Internal 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 49-year-old female, with a reported date of injury of 10/09/2013. The diagnoses include status post anterior cervical disc fusion; rule out reflex sympathetic dystrophy syndrome of the right upper extremity; airbag injury to the neck; severe degenerative disc disease at C5-6 and C6-7, rule out stenosis; myoligamentous sprain/strain of the lumbosacral spine; degenerative disc disease at L5-S1, rule out stenosis; cervical spine myoligamentous sprain/strain; right elbow myoligamentous sprain/strain; right wrist myoligamentous sprain/strain; right shoulder rule out rotator cuff tear; and cervical stenosis. Treatments to date have included cervical spine fusion on 03/26/2015, oral medications, a neck brace, and x-rays of the cervical spine with no acute findings. The progress report dated 04/07/2015 indicates that the injured worker complained of constant neck pain, with radiation to the bilateral upper extremities with associated numbness and tingling sensation. She rated the pain 8-9 out of 10. The injured worker also complained of constant low back pain with radiation to the bilateral lower extremities with associated numbness and tingling sensation. She rated the pain 8-9 out of 10. The injured worker reported constant right shoulder pain, rated 8-9 out of 10 with radiation to the right upper extremity and constant right wrist and hand pain, rated 8-9 out of 10. The physical examination showed a clean, dry, intact, and flat surgical wound. No other objective findings were indicated. The treating physician requested Flurbiprofen 20% cream 120 grams; Ketoprofen 20%/Ketamine 10% cream 120 grams; and Gabapentin 10%/Cyclobenzaprine 10%/Capsaicin 0.0375% cream 120 grams. It was noted that the goal was to provide an additional treatment to allow a reduction in the total amount of oral medications required, minimizing the potential side effects of oral medications. On 04/20/2015, Utilization Review (UR) denied the request and noted that compound delivery systems are not generally FDA

approved as the mechanism by which the drugs are delivered and its effectiveness has not been extensively studied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen 20% cream 120gms: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. The medical records document a history of occupational injuries to the neck, right upper extremity, and lower back. Medical records document the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Long-term NSAID use is not recommended by MTUS. The request for a topical NSAID is not supported by MTUS guidelines. Therefore, the request for topical Flurbiprofen 20% cream is not medically necessary.

Ketoprofen 20%/Ketamine 10% cream 120gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Ketamine Page 56.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. MTUS Chronic Pain Medical Treatment Guidelines indicate that Ketamine is not recommended. There is insufficient evidence to support the use of Ketamine for the treatment of chronic pain. There are no quality studies that support the use of Ketamine for chronic pain. MTUS guidelines do not support the use of Ketamine. The medical records document a history of occupational injuries to the neck, right upper extremity, and lower back. Medical records document the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Long-term NSAID use is not recommended by MTUS. The request for a topical NSAID is not supported by MTUS guidelines. MTUS guidelines do not support the use of Ketamine. Per MTUS, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for topical Ketoprofen 20% / Ketamine 10% cream is not medically necessary.

Gabapentin 10%/cyclobenzaprine 10%/capsaicin 0.0375% cream 120gm: Upheld

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

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

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Gabapentin is not recommended. There is no peer-reviewed literature to support use. There is no evidence for use of any other antiepilepsy drug as a topical product. There is no evidence for use of a muscle relaxant as a topical product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The medical records document a history of occupational injuries to the neck, right upper extremity, and lower back. MTUS guidelines do not support the use of topical products containing Gabapentin. MTUS does not support the use of a topical analgesic containing the muscle relaxant Cyclobenzaprine. Per MTUS, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for topical Gabapentin 10% / Cyclobenzaprine 10% / Capsaicin 0.0375% is not medically necessary.