

Case Number:	CM15-0083196		
Date Assigned:	05/08/2015	Date of Injury:	04/01/2001
Decision Date:	09/10/2015	UR Denial Date:	04/16/2015
Priority:	Standard	Application Received:	04/30/2015

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 60-year-old male, who sustained an industrial injury on 4/01/2001. Diagnoses include cervical herniated nucleus pulposus, history of lumbar herniated nucleus pulposus, radiculopathy, degenerative lumbar disc disease, chondromalacia left knee, and osteoarthritis left hip and left shoulder sprain, impingement and bursitis. Treatment to date has included chiropractic, diagnostics and medications. Per the most recent submitted hand written Primary Treating Physician's Progress Report dated 4/25/2013, the injured worker reported left total hip pain rated as 2/10 and left knee pain and swelling. Physical examination revealed positive straight leg raise and sensory deficit bilaterally. There was sacroiliac joint pain. The plan of care included medications and heating pad. Authorization was requested for Ibuprofen, Tramadol/Dextromethorphan, Hydrocodone/APAP, Omeprazole, and compound creams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro Keto/Caps/Cyclo/Tram 24gm, DOS: 12/2/11: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 111-113 of 127.

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 muscle relaxant is not indicated for use for the patient's condition. The MTUS states the following: "There is no evidence for use of any other muscle relaxant as a topical product." As such, the request is not medically necessary.

Retro Menth/Camph/Flurbi/Lido 24gm, DOS: 5/16/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 111-113 of 127.

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 lends 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 diagnosis and treatment duration. As such, the request is not medically necessary.

Retro Tram/Dextro/Caps 30gm, DOS: 5/16/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 111-113 of 127.

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 Capsaicin. Qualifying factors for this product is indicated by the following per the guidelines: Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) In this case, as stated above, the patient would not qualify for the use of capsaicin based on the diagnosis. As such, the request is not medically necessary.

Retro Butal/Acet/Caff 50/325/40mg #30, DOS: 5/16/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines BCAs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 23 of 127.

Decision rationale: The request is for the use of a barbiturate containing analgesic medication. The MTUS states the following regarding this topic: Not recommended for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents. (McLean, 2000) There is a risk of medication overuse as well as rebound headache. (Friedman, 1987) In this case, as indicated above, the use of this medication is not recommended. Any barbiturate medication is not advised for chronic pain and has a high abuse potential. As such, the request is not medically necessary.

Retro Meth/Camph/Flurbi/Lido, DOS: 7/2/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 111-113 of 127.

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 lends 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 diagnosis and treatment duration. As such, the request is not medically necessary.

Retro Tram/Dextro/Caps 20gm, DOS: 7/2/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 111-113 of 127.

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 Capsaicin. Qualifying factors for this product is indicated by the following per the guidelines: Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor

efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) In this case, as stated above, the patient would not qualify for the use of capsaicin based on the diagnosis. As such, the request is not medically necessary.

Retro Keto/Acet/Caps/Tram/Cyclo 24gm, DOS: 2/27/12: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 111-113 of 127.

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: "There is no evidence for use of any other muscle relaxant as a topical product." As such, the request is not medically necessary.

Retro Ibuprofen 800mg #60, DOS: 2/26/13, 3/21/13, 4/25/13, 5/16/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 67-68 of 127.

Decision rationale: The request is for the use of NSAIDs to aid in pain relief. NSAIDs are usually used to aid in pain and inflammation reduction. The MTUS guidelines states that for osteoarthritis NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen especially for patients with moderate to severe pain. There is no evidence to support one drug in this class over another based on efficacy. In particular, there appears to be no difference between NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects, with COX-2 NSAIDs having fewer GI side effects at the risk of increased cardiovascular side effects. The FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain and function. (Chen, 2008) (Laine, 2008) For back pain, NSAIDs are recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP.

(Van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain, this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) In this case, there is inadequate documentation of functional improvement to justify continued use, as the guidelines recommend the lowest dose for the shortest period of time. The significant side effect profile of medications in this class put the patient at risk when used chronically. As such, the request is not medically necessary.

Retro Hydrocodone Bit Acet. 7.5/325mg #60, DOS: 2/26/13, 3/21/13, 4/25/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids; CharFormat

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 78 of 127.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement, which should eventually lead to medication discontinuation. The records also do not reveal screening measures as discussed above for continued use of a medication in the opioid class. As such, the request is not medically necessary.

Retro Butal/Acet/Caff 50/325/40mg #30, DOS: 2/26/13, 3/21/13, 4/25/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines BCAs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 23 of 127.

Decision rationale: The request is for the use of a barbiturate containing analgesic medication. The MTUS states the following regarding this topic: Not recommended for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents. (McLean, 2000) There is a risk of medication overuse as well as rebound headache. (Friedman, 1987) In this case, as indicated above, the use of this medication is not recommended. Any barbiturate medication

is not advised for chronic pain and has a high abuse potential. As such, the request is not medically necessary.

Retro Ibuprofen 800mg #60, DOS: 9/26/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 67-68 of 127.

Decision rationale: The request is for the use of NSAIDs to aid in pain relief. NSAIDs are usually used to aid in pain and inflammation reduction. The MTUS guidelines states that for osteoarthritis NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen especially for patients with moderate to severe pain. There is no evidence to support one drug in this class over another based on efficacy. In particular, there appears to be no difference between NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects, with COX-2 NSAIDs having fewer GI side effects at the risk of increased cardiovascular side effects. The FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain and function. (Chen, 2008) (Laine, 2008) For back pain, NSAIDs are recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. (Van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain, this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) In this case, there is inadequate documentation of functional improvement to justify continued use, as the guidelines recommend the lowest dose for the shortest period of time. The significant side effect profile of medications in this class put the patient at risk when used chronically. As such, the request is not medically necessary.

Retro Hydrocodone Bit Acet 7.5/325mg #60, DOS: 5/16/13, 9/26/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 78 of 127.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement, which should eventually lead to medication discontinuation. The records also do not reveal screening measures as discussed above for continued use of a medication in the opioid class. As such, the request is not medically necessary.

Retro Omeprazole 20mg #60, DOS: 4/25/13, 5/16/13: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 68 of 127.

Decision rationale: The request is for the use of a medication in the class of a proton pump inhibitor. This is usually given as an acid reducing medication for patients with esophageal reflux, gastritis, or peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: "(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)." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.