

Case Number:	CM15-0174810		
Date Assigned:	09/25/2015	Date of Injury:	07/09/2013
Decision Date:	11/20/2015	UR Denial Date:	08/18/2015
Priority:	Standard	Application Received:	09/04/2015

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 43 year old male injured worker suffered an industrial injury on 7-9-2013. The diagnoses included cervicgia, shoulder pain and headache. On 9-23-2014 the provider noted the pain in the head and neck had improved. Terocin and TENS unit had been in use since at least 9-23-2014. On 4-7-2015 the treating provider reported continued neck and back pain with intermittent numbness in the hands and that medications help with pain 20% to 30%. He stated the Lidopro ointment was very helpful. On 6-22-2015 the provider reported the medications help with pain and functions. He recommended stopping the Naproxen due to history of Diabetes to avoid any renal complications and to stop Flexeril. Naproxen and Cyclobenzaprine had been in use since at least 2-2-2015. On 7-31-2015 the provider noted neck pain that radiated to the shoulders rated 10 out of 10. The left shoulder pain radiated down to the left arm with numbness and tingling. The documentation provided did not indicate the TENS unit provided and functional improvement. Diagnostics included electromyography studies 3-24-2015 revealing evidence consistent with a cervical radiculopathy on the left. The Utilization Review on 8-18-2015 determined non-certification for modification for Retrospective DOS (9-23-2014) Terocin 120mg, Retrospective DOS (9-23-2014) 2 pairs of TENS patches, Retrospective Lidopro cream 121gm DOS (4-7-15), Naproxen Sodium 550mg #60, Cyclobenzaprine 7.5mg #60, Retro 2 pairs of TENS patches DOS (4-7-15), Retro Lidopro cream 121gm DOS (6-22-15) and Orthopedic surgeon consult.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro Terocin 120mg 9/23/14: 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 diagnosis and treatment duration. As such, the request is not medically necessary.

Retro 2 pairs of TENS patches DOS 9/23/14: Upheld

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

MAXIMUS guideline: Decision based on MTUS Neck and Upper Back Complaints 2004, Section(s): Initial Care.

Decision rationale: The request is for TENS unit use to aid in pain relief. The MTUS guidelines state the following regarding this topic: "There is no high-grade scientific evidence to support the effectiveness or ineffectiveness of passive physical modalities such as traction, heat/cold applications, massage, diathermy, cutaneous laser treatment, ultrasound, transcutaneous electrical neurostimulation (TENS) units, and biofeedback. These palliative tools may be used on a trial basis but should be monitored closely. Emphasis should focus on functional restoration and return of patients to activities of normal daily living." In this case, the request is not indicated. This is secondary to poor high-grade evidence to support its use. As such, the request is not medically necessary.

Retro Lidopro cream 121gm DOS 4/7/15: 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 topical lidocaine. The MTUS guidelines state the following: Lidocaine Indication: Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, as stated above, the patient does not meet the criteria for use of this product in this formulation. There is a requirement of documentation of a first-line therapy trial prior to use of a lidocaine dermal patch. There is also no other commercially approved topical formulations of lidocaine indicated for neuropathic pain other than Lidoderm. As such, the request is not medically necessary.

Naproxen Sodium 550mg #60: 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)/NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip): 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, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although 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 naproxen being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain: Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative 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) Back Pain: Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009) As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is not indicated. This is secondary to inadequate documentation of pain and functional improvement benefit seen. Also, the duration of use places the patient at risk for gastrointestinal and cardiovascular side-effects. In addition, it is known that use of NSAIDs delays the healing of soft tissue including ligaments, tendons, and cartilage. As such, the request is not medically necessary.

Cyclobenzaprine 7.5mg #60: 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): 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.

Retro 2 pairs of TENS patches DOS 4/7/15: Upheld

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

MAXIMUS guideline: Decision based on MTUS Neck and Upper Back Complaints 2004, Section(s): Initial Care.

Decision rationale: The request is for TENS unit use to aid in pain relief. The MTUS guidelines state the following regarding this topic: "There is no high-grade scientific evidence to support the effectiveness or ineffectiveness of passive physical modalities such as traction, heat/cold applications, massage, diathermy, cutaneous laser treatment, ultrasound, transcutaneous electrical neurostimulation (TENS) units, and biofeedback. These palliative tools may be used on a trial basis but should be monitored closely. Emphasis should focus on functional restoration and return of patients to activities of normal daily living." In this case, the request is not indicated. This is secondary to poor high-grade evidence to support its use. As such, the request is not medically necessary.

Retro Lidopro cream 121gm DOS 6/22/15: 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 topical lidocaine. The MTUS guidelines state the following: Lidocaine Indication: Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, as stated above, the patient does not meet the criteria for use of this product in this formulation. There is a requirement of documentation of a first-line therapy trial prior to use of a lidocaine dermal patch. There is also no other commercially approved topical formulations of lidocaine indicated for neuropathic pain other than Lidoderm. As such, the request is not medically necessary.

Orthopedic surgeon consult: Upheld

Claims Administrator guideline: Decision based on MTUS Neck and Upper Back Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Neck and Upper Back Complaints 2004, Section(s): General Approach.

Decision rationale: The request is for an orthopedic surgery consultation. The ACOEM guidelines state the following regarding this topic: Within the first three months of neck and upper back symptoms, the only patients who can be expected to benefit from surgery are those with evidence of severe spinovertebral disease (tumor, infection, major trauma, or progressive neurologic deficit) or with severe, debilitating symptoms and physiologic evidence of specific nerve root or spinalcord compromise, corroborated by appropriate imaging studies. In this case, the criteria are not met by the guidelines. This is secondary to inadequate documentation of progressive neurologic deficit seen. As such, the request is not medically necessary.