

Case Number:	CM14-0070566		
Date Assigned:	07/14/2014	Date of Injury:	07/15/2001
Decision Date:	09/11/2014	UR Denial Date:	04/15/2014
Priority:	Standard	Application Received:	05/15/2014

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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 52-year old reservation agent reported injuries to both knees after a slip and fall on 7/15/01. She has also claimed a low back injury sustained in 2010 due to a motor vehicle accident on her way to treatment for the 7/15/01 injury. She apparently had a second motor vehicle accident in 2013 that increased her back symptoms. Treatment has included medications including Oxycontin and Soma, physical therapy and acupuncture. Left knee surgeries have been performed including a total knee replacement on 1/14/09, manipulation of the knee on 4/10/09, and arthroscopy with retinacular release on 2/3/10. She has multiple Synvisc and Euflexxa injections to the right knee, as well as arthroscopic surgeries. She had multiple lumbar epidural steroid injections without lasting effect. Her current primary treater saw her on 2/28/14. Her current complaints included constant, very severe (10/10) pain with radiation to the left lower extremity and groin. The provider noted that she was on very strong pain medications. No physical exam is documented. He performed x-rays of her lumbar spine that included flexion and extension views, and stated that they demonstrated degenerative disc disease, spondylosis, "multi-factorial multi-foraminal narrowing" and disc collapse with foraminal compression at L5-S1. He diagnosed lumbar spine stenosis, lumbar spine disc herniation, and lumbar radiculopathy. He recommended obtaining a lumbar MRI. He noted that the patient was not tolerating the previously prescribed oral medications, which he listed as "NSAIDs, muscle relaxants and Ultram", especially while trying to work and perform activities of daily living, and that therefore he has prescribed topical NSAIDs and analgesics. Two topical compounded medications were dispensed. An RFA was submitted for topical flurbiprofen cream and for tramadol cream the same day. This request was denied in UR on 4/15/14. An IMR request for "Prescription drug, generic" was received on 5/15/14 for the UR determination of 4/15. I am unable to find any documentation that this patient is currently working.

IMR ISSUES, DECISIONS AND RATIONALES

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

**RETRO: Tramadol/Dextromethorphan/Capsaicin (DOS: 02/28/2014 and 03/06/2014)
(duration unknown and frequency unknown): Upheld**

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, Capsaicin.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Capsaicin, topical; Topical Analgesi Page(s): 60; 28; 111-113. Decision based on Non-MTUS Citation UptoDate, an evidence based on-line review service for clinicians (www.uptodate.com) Dextromethorphan: Drug Information, and Tramadol: Drug Information.

Decision rationale: The first MTUS guideline cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The other MTUS guidelines cited above state that topical capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. It is indicated for neuropathic pain, osteoarthritis, fibromyalgia, and chronic non-specific back pain, for patients whose pain has not been controlled successfully with conventional therapy. The other guidelines also state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. These references do not address topical dextromethorphan or tramadol. The Up-to-date reference cited above lists a single clinical use for dextromethorphan: cough suppression. It cautions that even in therapeutic doses it may cause confusion, excitement, irritability, nervousness, and serotonin syndrome. If abused, it can cause irregular heartbeat, loss of consciousness, seizure, brain damage and death. Tramadol can also cause multiple central nervous system side effects that include agitation and seizures. I have done an exhaustive review of the medical literature in regards to dextromethorphan. Its only FDA-approved uses include those related to cough suppression and treatment of the symptoms of respiratory infections. There is also an FDA-approved product containing dextromethorphan and quinidine used for the treatment of a neurological condition called pseudobulbar affect. Dextromethorphan has been abused for its hallucinatory effects and has caused multiple deaths. There are no high-quality studies that support the use of topical dextromethorphan for pain. The requested compound clearly contains multiple medications. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. Capsaicin has some indications, in the standard formulations readily available without custom compounding. It is not clear what the indication is in this case, as the patient does not appear to have the necessary indications per the MTUS. The MTUS also states that capsaicin is only recommended when other treatments have failed. The treating physician did not discuss the failure of other, adequate trials of other treatments.

Capsaicin is not medically necessary based on the lack of indications per the MTUS. The clinical records do not contain a clear description of the tramadol/dextromethorphan/capsaicin product in question. It is not clear how much of each medication it contains, or how much of it is to be applied how often. It should not be assumed that because a medication is topical, it couldn't produce systemic side effects. (For example, there is at least one recorded case of a death from topical methyl salicylate, i.e. Ben Gay.) This preparation contains two medications that may cause serious neurological side effects including seizures. There is no information on how they act together topically. Based on the above evidence-based criteria and the clinical findings in this case, the use of tramadol/dextromethorphan/capsaicin cream is not medically necessary because of the lack of evidence to support its use and because of its potential toxicity. In addition, several medications are being started simultaneously, which is not in accordance with guidelines. Therefore, this request is not medically necessary.

RETRO: Flurbiprofen/Lidocaine/Menthol/Camphor (DOS: 02/28/14) (duration unknown and frequency unknown): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, NSAIDs, Lidocaine Indication. Decision based on Non-MTUS Citation FDA - Topical lidocaine.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Topical Analgesics Page(s): 60; 111-113.

Decision rationale: The first MTUS guideline cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. According to the second guideline cited above, topical analgesics are 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical NSAIDs: may be recommended, but only for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for osteoarthritis of the spine, hip or shoulder, and they are not recommended for neuropathic pain, as there is no evidence to support their use. Lidocaine is indicated for localized neuropathic pain if there is evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Only FDA-approved products are indicated, and no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Topical lidocaine is not indicated for non-neuropathic pain. The requested compound clearly contains multiple medications. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The treating physician did not provide any indications or body part intended for the NSAID flurbiprofen. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. It is not clear whether this patient is being treated for neuropathic pain. Her knee pain is not neuropathic, but some of her back-related symptoms might be. The requested compound contains a non-FDA-

approved form of lidocaine. Lidocaine in any other form besides Lidoderm patches (the only FDA-approved form of topical lidocaine) is not recommended. Even Lidoderm patches are recommend for neuropathic pain only after a trial of a first-line oral agent has occurred. There is no documentation of such a trial in this case. The guideline quoted above and the clinical records in this case do not support the use of Flurbinophen/Lidocaine/Menthol/Camphor. This product is medically not necessary because it contains ingredients that are not recommended by high-quality evidence-based guidelines. In addition, several medications are being started simultaneously, which is not in accordance with guidelines. Therefore, this medication is not medically necessary.