

Case Number:	CM14-0208471		
Date Assigned:	12/19/2014	Date of Injury:	05/12/1997
Decision Date:	02/13/2015	UR Denial Date:	12/04/2014
Priority:	Standard	Application Received:	12/11/2014

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 Practice 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 63-year old pharmacy assistant reported injuries to her neck low back, wrists and hands, and internal organs with a date of 5/12/97. The mechanism of injury is not described in the available records. Past treatment has apparently included 9 separate surgeries on her upper extremities, including bilateral carpal tunnel release, as well as surgeries on both shoulders, the right elbow, and several fingers. The most recent progress note in the records from the primary treater's office is dated 11/12/14. It documents that the patient continues to have low back and left hip pain. Physical findings include back tenderness and limited range of motion, and bilateral negative straight leg raise. Diagnoses include multilevel lumbar disc herniations, with lumbar facet syndrome at L5-S1, lumbar radiculopathy, status post right rotator cuff repair, chronic cervical myofascial pain, peripheral neuropathy and diabetes. The treatment plan includes a request for authorization of lumbar facet injection, and prescriptions for Norco 5/325 #90 with no refills and for LF520 (lidocaine 5%, flurbiprofen 20%) apply 2-3 times per day, 120 grams with 2 refills. A review of previous progress notes reveals that "LF520" was first prescribed on 8/13/14 with the rationale that the patient is unable to tolerate oral NSAIDs, and has been prescribed at all subsequent visits. The records also contain an 8/7/14 progress report from a pain specialist who documents that the patient is using Voltaren gel prescribed by a third provider. The request for Lidocaine 5%, Flurbiprofen 20% was non-certified in UR on 12/4/14 on the basis that its use is not supported by MTUS Chronic Pain guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded medication(Lidocaine 5%, Flurbiprofen 20%) 120 gm with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

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

Decision rationale: The first reference 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 Topical analgesics guideline states 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. 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. 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 FDA notified consumers about the risks of topical lidocaine in 2007. Patients who use large quantities of topical lidocaine over extended time periods are at risk for systemic side effects of lidocaine, which include seizures and cardiac arrhythmias. The clinical documentation in this case does not support the provision of topical lidocaine/flurbiprofen to this patient. Using this medication means that two medications are being started simultaneously. The medications cannot be monitored individually and it would be impossible to tell which medication caused any side effect or any functional improvement that might result. Flurbiprofen is not FDA-approved for topical use. In addition, it appears that the patient may be simultaneously using Voltaren gel, which would put her at increased risk for NSAID side effects. The only FDA-approved form of topical Lidocaine is the Lidoderm patch, so the lidocaine used in this product is not FDA-approved. This patient has pain in many body areas, and thus has increased potential to use large quantities of topical lidocaine, with the attendant risks discussed above. Even an FDA-approved form of topical lidocaine is not medically indicated for this patient, since there is no documentation that she has not responded to a trial of a first-line agent such as gabapentin. Based on the MTUS citations above and on the clinical documentation provided for my review, compounded topical lidocaine 5% and flurbiprofen 20%, 120 grams with 2 refills is not medically necessary. It is not medically necessary because its use means that two medications are being started simultaneously, because topical flurbiprofen is not FDA-approved and may be being used simultaneously with another topical NSAID, because the patient does not appear to have failed a trial of a first-line agent for neuropathic pain before beginning topical lidocaine, and because the topical lidocaine is in a form that is not FDA-approved and that may put the patient at risk for serious side effects.