MAXIMUS Federal Services

Case Number:	CM14-0163280		
Date Assigned:	10/08/2014	Date of Injury:	09/29/2011
Decision Date:	11/12/2014	UR Denial Date:	09/06/2014
Priority:	Standard	Application Received:	10/03/2014

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 56-year old pallet assembler reported a repetitive strain injury of his neck, lower back, bilateral shoulders and ribs on 9/29/11. Current diagnoses include cervical disc herniation, lumbar disc herniation with radiculopathy, and history of gastritis. A 7/12/14 progress note from the primary provider documents that the patient has constant neck and back pain. Exam findings include tenderness and limited range of motion of the neck and back. Medications dispensed at the visit included Tramadol, Naproxen, Cyclobenzaprine and Menthoderm. Authorization was requested for a lumbosacral epidural injection at the same visit. The patient was advised to return to work with restrictions. However, the patient is not working according to a 5/20/14 supplemental orthopedic QME evaluation in the records. The 9/6/14 UR report makes reference to multiple documents that are not contained in the records available to me including reports from the secondary physician dated 8/15/14, 7/18/14 and 5/23/14, as well as requests for authorization dated 8/28/14 and 8/19/14. Apparently the secondary physician requested the two topical creams concerned in this review, but there is no documentation of the request or of the rationale for it.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen/Capsaicin/Camphor 10/0.25%2%1% (120gm) for the lumbar and cervical spine: 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 Medications for Chronic PainTopical 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 second 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. 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. Capsaicin is recommended as an option in patients who have not responded to or are intolerant to other treatments. There is no evidence supporting formulations which contain over 0.025% capsaicin. It has been shown to have some efficacy in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. Even with the limited clinical information available to me, it is clear that topical flurbiprofen/capsaicin/camphor is not medically indicated. Using this medication means that three 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 an NAID. It is not medically indicated in this case because the patient has a diagnosis of radiculopathy and can be presumed to have radicular pain, for which topical NSAIDs are not recommended. In addition, 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.The requested compound appears to contain either 0.25% or 2% capsaicin. As noted above, there is no evidence supporting formulations which contain over 0.025% capsaicin. This medication contains at least ten times that amount, and is therefore not medically necessary. Based on the evidence-base guidelines cited above and the clinical documentation in this case, Flurbiprofen/Capsaicin/Camphor is not medically necessary because it contains three medications which are being started at once and which cannot be monitored individually, and because it contains one medication that is not FDA-approved for topical use and another with a concentration that exceeds that for which there is supporting evidence. The request is considered not medically necessary.

Ketoprofen/Cyclobenzaprine/lidocaine 10%/3%/5% (120 gm) for the cervical and lumbar spine: 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 Medications for Chronic PainTopical 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 second 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. Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. (Note that Cyclobenzaprine is a muscle relaxant.) 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 product 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.Even with the limited clinical information available to me, it is clear that topical Ketoprofen/Cyclobenzaprine/lidocaine is not medically indicated. Using this medication means that three 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. Ketoprofen is not FDA-approved for topical use, Cyclobenzaprine. The only FDA-approved form of topical Lidocaine is the Lidoderm patch, so this lidocaine used in this product is not FDA-approved. Topical Ketoprofen/Cyclobenzaprine/lidocaine is not medically necessary because it contains three medications which are being started at once and which cannot be monitored individually, and because it contains two medication that are not FDA-approved for topical use and another that is not recommended by MTUS guidelines. The request is not medically necessary.