

Case Number:	CM14-0045864		
Date Assigned:	07/02/2014	Date of Injury:	05/20/2010
Decision Date:	12/31/2014	UR Denial Date:	03/31/2014
Priority:	Standard	Application Received:	04/14/2014

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 Colorado. 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:

72 year old male with date of injury 5/20/2010 continues follow up with treating physician. As of 12/4/2013 clinic visit patient complained of Low back pain. (The exam note is largely illegible, but no evidence of radiation of pain noted. The treating physician ordered acupuncture, chiropractic care, Topical analgesics PT, and Orthopedic consult for Functional Capacity Evaluation at that visit. Follow up visits documented continued low back pain with tingling in right leg, as well as pain in right knee and pain in right wrist. Follow up visits 1/8/2014 and 2/5/2014 indicate no real changes in history, examination, or plan, and treating physician requests same interventions after each visit. Per the records, patient has had ESI, with no indication in the records of improvement. Urine drug screen ordered at 2/5/2014 office visit, but the results were not available for review. The treating physician requests refills on Topical analgesics.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen/Capsaicin/Menthol/Camphor 120mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 111-113.

Decision rationale: Per the MTUS Guidelines, topical analgesics are largely experimental, but may be indicated for specific conditions when other therapies have failed. However, the guidelines make it clear that if a drug or drug class in a given topical compound is "not recommended," then the entire topical treatment is not recommended. Topical Non-steroidal anti-inflammatory drugs have been studied, but only short term in small numbers, so no substantive evidence supports long term use. Use of topical non-steroidal anti-inflammatory drugs can be recommended, after first line therapies fail, for less than 12 weeks, for treatment of osteoarthritis, specifically related to the knee or elbow. No consistent quality evidence exists to use topical non-steroidal anti-inflammatory drugs for treatment of osteoarthritis of the spine, hip or shoulder, or for treatment of neuropathic pain, including radiculopathy. The only FDA-approved Topical Non-steroidal anti-inflammatory agent is Voltaren Gel 1% (Diclofenac). Per the MTUS guidelines, Capsaicin topical can only be recommended for those who have failed to respond to or are intolerant of other options for pain relief. Some good randomized studies suggest that Capsaicin is useful for osteoarthritis, fibromyalgia and chronic non-specific back pain (consistent with patient of concern). However, higher doses of Capsaicin (anything over 0.025% based on available studies) are considered experimental and have no studies to support use in the above conditions. It is noted that Capsaicin has moderate to poor efficacy, but can work, alone or in compound, for patients whose pain has not been controlled with conventional therapies. Capsaicin produces "highly selective regional anesthesia by causing degeneration of Capsaicin-sensitive nociceptive nerve endings, which can produce significant and long lasting increases in nociceptive thresholds." (Maroon, 2006) The above statements, it should be noted, support only the use of 0.025% dose Capsaicin. For the patient of concern, the records supplied do not indicate any previous treatment tried and failed prior to the topical analgesic. Furthermore, the records do not specify a requested duration or frequency of use for the topical analgesic, so short term use, which is the only recommended term of use for non-steroidal anti-inflammatory drugs (Flurbiprofen), cannot be verified. Finally, the records are not clear as to which area is to be treated by the topical analgesic (back, wrist, or knee) The Capsaicin strength is not included in the request, so it cannot be recommended. (No strength > 0.025% Capsaicin is recommended) The MTUS Guidelines do not address topical Menthol or Camphor, which in this case is not relevant because the Flurbiprofen and Capsaicin of unknown strength would not be recommended for this patient / diagnosis based on the records supplied. The Flurbiprofen/Capsaicin/Menthol/Camphor topical preparation, therefore, is not recommended and not medically necessary.

Ketoprofen/Cyclobenzarpine/Lidocaine 120mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 111-113.

Decision rationale: Per the MTUS Guidelines, topical analgesics are largely experimental, but may be indicated for specific conditions when other therapies have failed. However, the guidelines make it clear that if a drug or drug class in a given topical compound is "not

recommended," then the entire topical treatment is not recommended. Topical Non-steroidal anti-inflammatory drugs have been studied, but only short term in small numbers, so no substantive evidence supports long term use. Use of topical non-steroidal anti-inflammatory drugs can be recommended, after first line therapies fail, for less than 12 weeks, for treatment of osteoarthritis, specifically related to the knee or elbow. No consistent quality evidence exists to use topical non-steroidal anti-inflammatory drugs for treatment of osteoarthritis of the spine, hip or shoulder, or for treatment of neuropathic pain, including radiculopathy. The only FDA-approved Topical Non-steroidal anti-inflammatory agent is Voltaren Gel 1% (Diclofenac). All topical muscle relaxers (Cyclobenzaprine), are not recommended, per the guidelines and have no evidence-based support for their use. Per the guidelines, Lidocaine, in the formulation of a dermal patch (Lidoderm), is recommended for " localized peripheral pain" (neuropathy) after failure of or contraindication to first line therapy (Tricyclic Antidepressants, SNRI Antidepressants or Anti-epilepsy drugs), and has FDA orphan status for that indication. No other topical formulations of Lidocaine (creams, lotions, gels) are indicated for neuropathic pain. (Other formulations of Lidocaine can be used as local superficial anesthetics) Lidocaine, in any formulation, is not recommended for non-neuropathic pain due to lack of evidence for its efficacy and safety. The records from the treating physician do not indicate that patient has had a trial of first line therapies for neuropathic pain (Tricyclic Antidepressants, SNRI Antidepressants or Anti-epilepsy drugs), or nociceptive pain. The requested topical analgesic includes Lidocaine in a formulation which is not approved for use in neuropathic pain, or non-neuropathic pain. As patient has not tried and failed alternative treatments, and as the Cyclobenzaprine component and Lidocaine component are not recommended, the Ketoprofen / Cyclobenzaprine / Lidocaine topical analgesic is not medically necessary.