

Case Number:	CM13-0061539		
Date Assigned:	12/30/2013	Date of Injury:	08/04/2010
Decision Date:	06/13/2014	UR Denial Date:	11/15/2013
Priority:	Standard	Application Received:	12/05/2013

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain 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:

The patient is a 57 year old male injured on 08/04/10 when he was loading a machine and felt acute low back pain. The patient received conservative therapy to include medications, physical therapy, and epidural steroid injections. Clinical documentation indicates previous history of suicidal ideation, depression, anxiety, and recreational drug abuse to include methamphetamine. The patient indicated in the 10/31/13 clinical note that the Celebrex and Gabapentin were significantly helpful and he felt the Savella was helping a little bit. The clinical note dated 12/03/13 indicated the patient presented complaining of low back pain and leg pain with intermittent numbness and burning of his right leg. The patient rated his pain at 6-8/10 without medications and 3-5/10 with medications. He indicated the medications are helpful. Physical examination revealed 5/5 bilateral lower extremity strength, normal sensation, tenderness over the paraspinals, increased pain with flexion, and positive straight leg on the right. Current medications include Gabapentin, Terocin, Celebrex, Elavil, and Savella.

IMR ISSUES, DECISIONS AND RATIONALES

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

CYMBALTA 60MG, #30 WITH ONE (1) REFILL: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 15-16.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duloxetine (Cymbalta Â®), Page(s): 28-29, 44, 105, 112-113.

Decision rationale: As noted on page 44 of the Chronic Pain Medical Treatment Guidelines, Cymbalta is recommended as a first-line treatment option in neuropathic pain. Duloxetine (CymbaltaÂ®) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for the treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy. The patient was approved for the use of Savella which is utilized in the treatment of both fibromyalgia and depression. Concurrent use of Cymbalta would be a redundancy in medication management. As such, the request for Cymbalta 60MG, #30 with One (1) Refill cannot be recommended as medically necessary.

TEROCIN 120ML: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topical. Page(s): 105,112, 113. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=41055>; and CA MTUS 2009: 9792.24.2 Chronic Pain Medical Treatment Guidelines, Pages 105, 112-113, Salicylate topical.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Page(s): 28-29, 105, 111-113.

Decision rationale: Terocin lotion/cream is a topical formulation consisting of Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. The Chronic Pain Medical Treatment Guidelines on page 111 states "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Thus, each active ingredient should be analyzed in making a determination of medical necessity. Final Determination Letter for IMR Case Number CM13-0061539 4 For topical Lidocaine, the Chronic Pain Medical Treatment Guidelines on pages 112-113 states the following: "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 (LidodermÂ®) 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. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical Lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% Lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995)" For topical methyl salicylate, the Chronic Pain Medical Treatment Guidelines on page 105 states the

following with regard to salicylate topicals: "Recommended - Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004) See also Topical analgesics; & Topical analgesics, compounded." For topical capsaicin, the Chronic Pain Medical Treatment Guidelines state on pages 28-29 the following regarding topical capsaicin: "Recommended only as an option in patients who have not responded or are intolerant to other treatments. On page 113 of the Chronic Pain Medical Treatment Guidelines, additional commentary on capsaicin includes the following: "Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) See also Capsaicin." In the case of this injured worker, there is documentation of musculoskeletal low back pain as well as neuropathic pain in the form of lumbar radiculitis. This is documented in multiple progress notes including a progress note on date of service August 8, 2013. The patient is on neuropathic pain medications including Neurontin, Cymbalta, and Savella. Although these medications are documented to be helpful and allow the patient "to be more active" as per a progress note on date of service August 8, 2013, the patient still continues with pain. Therefore topical alternatives are reasonable. As per the guidelines cited above, Savella and Lidocaine are helpful for neuropathic pain. The methyl salicylate is indicated for musculoskeletal pain, but it should be noted that topical NSAIDs should not be used greater than 12 weeks. Given the nature of this injured worker's pain, and documentation that she is already on neuropathic pain medications, this request is medically necessary.