

<b>Case Number:</b>	CM15-0140295		
<b>Date Assigned:</b>	07/30/2015	<b>Date of Injury:</b>	08/13/2003
<b>Decision Date:</b>	09/02/2015	<b>UR Denial Date:</b>	07/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/20/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: New York

Certification(s)/Specialty: Anesthesiology

### 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 injured worker is a 56 year old female, who sustained an industrial injury on 8-13-2003. The mechanism of injury is unclear. The injured worker was diagnosed as having reflex sympathetic dystrophy of upper limb, chronic pain syndrome. Treatment to date has included medications, left wrist surgery (12-16-2003 and 8-31-2004), left stellate ganglion block, functional restoration program, home exercise program, and splints. The request is for Cyclobenzaprine (Flexeril), and Flector patch. She is noted to have been utilizing Flexeril and Flector patches since at least October 2014, possibly longer. On 1-29-2015, she reported left hand and wrist pain with radiation up to the elbow and upper arm. Her left upper extremity continued to have burning, numbness, and tingling. She indicated the Butrans patch to give her about 60% pain reduction and helps her with mobility of the left arm. She reported having decreased sensitivity in the left hand. She denies side effects with the patch. The treatment plan included refill of Butrans patches. On 3-31-2015, she reported continued left hand and wrist pain with radiation at times up to the elbow and upper arm. She also reported left shoulder pain with radiation into the left shoulder. She indicated Lyrica to not be helping with the neuropathic pain. She indicated she continued to get 60% pain relief with Butrans patches. The treatment plan included a trial of increased dosage of Lyrica. On 6-22-2015, she reported continued left upper extremity and hand pain. She indicated she was having more stabbing and burning pain in the left elbow, and has not been able to sleep. She indicated Lyrica is helping with the numbness and tingling, and that the increase of 50mg had provided better pain relief to her hand pain. She indicated Butrans patches to reduce her pain from 8 out of 10 down to 3-4 out of 10. Her current medications are:

Capsaicin cream, Lyrica, Flexeril, Flector patch, Butrans patch, Lyrica, Celexa, Lisinopril, Lipitor, Divalproex, Risperidone, Triamcinolone, and Trazodone. The objective findings noted tenderness and hyper-tonicity with trigger points in the left trapezius. The treatment plan included: refills on Butrans, Lyrica, Flexeril, Flector, with an increase in Butrans noted. Her work status is permanent and stationary with permanent disability.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Cyclobenzaprine - Flexeril 7.5mg, QTY: 90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41, 64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (2009), 9792.20; Functional restoration approach to chronic pain management; Cyclobenzaprine (Flexeril); Muscle relaxants Page(s): 1, 8-9, 63-66, 41-42.

**Decision rationale:** Per the CA MTUS, Cyclobenzaprine is an antispasmodic muscle relaxant. Non-sedating muscle relaxants are recommended with caution as a second line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. Antispasmodics are used to decrease muscle spasm in conditions such as low back pain although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. Cyclobenzaprine is recommended for a short course therapy. There is limited, mixed evidence that does not allow for recommendation for chronic use. The CA MTUS states, Cyclobenzaprine (Flexeril) is recommended as an option, using a short course of therapy. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant. According to the CA MTUS all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit; and a reduction in the dependency on continued medical treatment. In this case, there is indication of hypertonicity of her left trapezius. However, she has been utilizing Flexeril (Cyclobenzaprine) since at least October 2014, with no

documented benefit. This is in excess of the short-term therapy recommendations as per the guidelines. The records do not discuss her functional status or activities of daily living. She has reported improved mobility of her left arm with the use of Butrans patches, and Lyrica helps with her neuropathic symptoms. Her work status is noted as permanent and stationary with permanent disability. She continues to report pain despite having had surgery and functional restoration program treatment. Her medications of Butrans and Lyrica have been increased which indicates there to be no reduction in the dependency on continued medical treatment. Based on these findings functional improvement has not been established. The requested medication is not medically necessary.

**Flector Patch 1.3%, QTY: 240:** 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; MTUS (2009), 9792.20; Functional restoration approach to chronic pain management Page(s): 111-113, 1, 8-9. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low back pain, Flector patch.

**Decision rationale:** According to California MTUS Guidelines, oral NSAIDs are recommended for the treatment of chronic pain and control of inflammation as a second-line therapy after acetaminophen. The ODG states that NSAIDs are recommended for acute pain, acute low back pain (LBP), short-term pain relief in chronic LBP, and short-term improvement of function in chronic LBP. There is no evidence of long-term effectiveness for pain or function. According to ODG, the use of a Flector patch (Diclofenac) is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs. According to the California MTUS Guidelines, topical non-steroidal anti-inflammatory drug (NSAIDs) are used for the treatment of osteoarthritis and tendonitis, in particular, knee and elbow joints that are amenable to topical treatment. There is little evidence that supports topical NSAIDs as a treatment option for spine and shoulder conditions. There is no data that substantiate Flector patch efficacy beyond two weeks. There is little evidence that supports the medication use in the treatment of chronic low back pain. The indications for topical NSAIDs are for: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. It is not recommended for neuropathic pain as there is no evidence to support its use. According to the CA MTUS all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit; and a reduction in the dependency on continued medical treatment. In this case, the documentation is unclear regarding the specific use of the Flector patch, and to which body part it is to be

applied. There is no discussion regarding the efficacy of the Flector patch. The patient has utilized the Flector patch since at least October 2014, with no noted benefit. There is no discussion of functional improvement with the use of this topical agent. The patient's work status is permanent and stationary with permanent disability. In addition, the dosages of Butrans and Lyrica have been increased, which indicates no reduction in the dependency on continued medical treatment. Medical necessity for the requested topical medication has not been established. The requested Flector patch is not medically necessary.