

<b>Case Number:</b>	CM15-0123364		
<b>Date Assigned:</b>	07/07/2015	<b>Date of Injury:</b>	11/14/1997
<b>Decision Date:</b>	08/10/2015	<b>UR Denial Date:</b>	05/23/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/26/2015

### 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: Pediatrics, Internal Medicine

### 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 58 year old male, who sustained an industrial injury on November 14, 1997. He reported waking one morning and was unable to move his right arm because of pain. The injured worker was diagnosed as having cervical radiculopathy, muscle spasm, lumbar spine radiculopathy, myofascial pain, and fibromyalgia/myositis. Treatments and evaluations to date have included physical therapy, electromyography (EMG)/nerve conduction velocity (NCV), gym therapy, TENS, cervical spine fusion, stress echocardiogram, transthoracic echocardiogram, upper gastrointestinal (GI) series, abdominal sonogram, and medication. Currently, the injured worker complains of more pain in the low back. The Treating Physician's report dated May 18, 2015, noted the injured worker with chronic back pain, having had trigger point injections at the previous appointment which was noted to help relieve the sciatic pain. physical examination was noted to show positive bilateral straight leg raise, pain over the lumbar intervertebral spaces on palpation, palpation of the lumbar facets with pain on both sides at the L3-S1 region, and pain noted with anterior flexion of the neck and anterior flexion and extension of the lumbar spine. The injured worker received trigger point injections. The treatment plan was noted to include prescriptions for Fentanyl patch, Norco, Flector patch, and Zanaflex. The Treating Physician's report dated May 18, 2015, noted the injured worker reported little change in his symptoms since last visit, continuing to report significant functional or symptomatic improvement from his medications without distressing side effects. The injured worker was noted to have some episodes where for several days his activities become limited by increasing pain, being on relatively large doses of opioid analgesics with the same doses for quite some time. The injured

worker rated his pain a 7 on the pain scale, 10 at its worst. The physical examination noted the injured worker in no acute distress without any apparent loss of coordination. The Physician noted it had been awhile since there had been a trial of weaning of the injured worker's opioid dose, with an online pharmacy report was obtained that showed no evidence of doctor shopping. The treatment plan was noted to include the injured worker's plan to experiment with trying a slightly smaller dose of opioid analgesics.

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

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

#### **One (1) prescription of Fentanyl patch 75mcg #15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Fentanyl, Opioids Page(s): 47, 74-96.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines notes that ongoing management of opioid therapy should include the lowest possible dose prescribed to improve pain and function, and ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. On-going management should include ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain, the least reported pain over the period since last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain lasts. Satisfactory response to treatment may be indicated by the injured worker's decreased pain, increased level of function, or improved quality of life. Fentanyl is an opioid analgesic with a potency eighty times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as fentanyl. Patches are worn for a 72-hour period. The injured worker was noted to have significant functional or asymptomatic improvements from his medications; however the documentation provided did not include objective, measurable improvements in the injured worker's pain, activities of daily living (ADLs), function, or quality of life with the use of the Fentanyl patch. There was no documentation of the least reported pain over the period since last assessment, average pain, intensity of pain after taking the Fentanyl patch, how long it takes for pain relief, or how long the pain lasts. The injured worker was noted to use his fentanyl transdermal patch every 48 hours, with the guideline recommendation of every 72 hours. Therefore, based on the MTUS guidelines, the documentation provided did not support the request for one (1) prescription of Fentanyl patch 75mcg #15 and is not medically necessary.

#### **One (1) prescription of Norco 10/325mg #180: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids  
Page(s): 74-96.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines notes that ongoing management of opioid therapy should include the lowest possible dose prescribed to improve pain and function, and ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. On-going management should include ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain, the least reported pain over the period since last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain lasts. Satisfactory response to treatment may be indicated by the injured worker's decreased pain, increased level of function, or improved quality of life. The injured worker was noted to have significant functional or asymptomatic improvements from his medications, however the documentation provided did not include objective, measurable improvements in the injured worker's pain, activities of daily living (ADLs), function, or quality of life with the use of the Norco. There was no documentation of the least reported pain over the period since last assessment, average pain, and intensity of pain after taking the Norco, how long it takes for pain relief, or how long the pain lasts. The injured worker was not noted to have improvements with the Norco, rather there was documentation that the injured worker's pain was improved with trigger point injections. Therefore, based on the MTUS guidelines, the documentation provided did not support the request for one (1) prescription of Norco 10/325mg #180 and is not medically necessary.

**One (1) prescription of Flector 1.3% patch #60 with 1 refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Flector patch (diclofenac epolamine).

**Decision rationale:** The MTUS is silent on Flector patches. The Official Disability Guidelines (ODG) notes the Flector patch (diclofenac epolamine) is not recommended as a first-line treatment. Topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, after considering the increased risk profile with diclofenac, including topical formulations. Flector patch is FDA indicated for acute strains, sprains, and contusions. On 12/07/09, the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac. Post-marketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. The efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In addition, there is no data that substantiate

Flector efficacy beyond two weeks. The documentation provided did not identify the injured worker with osteoarthritis, or an acute strain, sprain, or contusion. The injured worker was noted to have been taking the Flector patch since at least December 2014, without documentation of monitoring of transaminases. Therefore, based on the MTUS guidelines, the documentation provided did not support the request for one (1) prescription of Flector 1.3% patch #60 with 1 refill and is not medically necessary.

**One (1) prescription of Zanaflex 4mg #120 with 1 refill: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxant.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 63, 66.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines notes all chronic pain therapies are focused on the goal of functional restoration rather than merely the elimination of pain, and assessment of treatment efficacy is accomplished by reporting functional improvement. The guidelines recommend non-sedating muscle relaxants 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, however, in most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Tizanidine (Zanaflex) is FDA approved for management of spasticity, with unlabeled use for low back pain, and with recommendation for liver function testing monitored baseline at 1, 3, and 6 months to monitor for side effects, including hepatotoxicity. The injured worker was noted to have been taking the Zanaflex since at least December 2014, with no documentation of objective, measurable improvements in the injured worker's pain, muscle tension, mobility, activities of daily living (ADLs), or function. There was no documentation of liver function laboratory monitoring. Based on the extended duration of use, the lack of documentation of laboratory monitoring, and the lack of objective improvements, the documentation provided did not support the request for one (1) prescription of Zanaflex 4mg #120 with 1 refill and is not medically necessary.