

Case Number:	CM15-0091384		
Date Assigned:	05/15/2015	Date of Injury:	07/18/1994
Decision Date:	06/23/2015	UR Denial Date:	05/01/2015
Priority:	Standard	Application Received:	05/12/2015

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 Jersey, Alabama, California
 Certification(s)/Specialty: Neurology, Neuromuscular 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 53 year old female who sustained an industrial injury on 7/18/94. The injured worker was diagnosed as having chronic pain syndrome, degeneration of cervical intervertebral disc, knee pain, and shoulder joint pain. Currently, the injured worker was with complaints of joint point, muscle aches and arthralgias. Previous treatments included oral pain medication, topical patches, and a left knee brace. Previous diagnostic studies included radiographic studies. Physical examination was notable for tenderness noted to paraspinal region at L5, decreased sensation noted to the radial forearm, thumb and index finger, sole of foot and posterior leg, tenderness to palpation to the paracervicals, trapezius and rhomboid. The plan of care was for medication prescriptions.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fentanyl transdermal patch 50mcg #10 per 04/24/15 order: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list Page(s): 91 and 93.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Fentanyl <http://www.odg-twc.com/index.html>.

Decision rationale: According to ODG guidelines, Fentanyl "Not recommended for musculoskeletal pain. 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. Due to significant side effects, not for use in routine musculoskeletal pain. For more information and references, see Opioids for general guidelines, as well as specific Fentanyl listing for more information and references. See also Actiq; (fentanyl lollipop); Duragesic; (fentanyl transdermal system); Fentora; (fentanyl buccal tablet); & Onsolis (fentanyl buccal film). On Jan 7, 2011, the FDA approved an immediate-release transmucosal tablet formulation of fentanyl (Abstral; ProStraken, Inc) for the management of breakthrough cancer pain. Because Abstral is subject to abuse and misuse, the product was approved with a risk evaluation and mitigation strategy (REMS) that includes a restricted distribution program requiring registration of prescribers, pharmacies, and patients. It is not recommended as a first-line agent for musculoskeletal pain. (FDA, 2011) The DEA has issued a nationwide alert about the dangers of fentanyl, saying that drug incidents and overdoses related to fentanyl are occurring at an alarming rate throughout the U.S. and represent a significant threat to public health and safety. According to the National Forensic Laboratory Information System, state and local laboratories reported 3,344 fentanyl submissions in 2014, up from 942 in 2013. Fentanyl is the most potent opioid available for use in medical treatment, 50 to 100 times more potent than morphine, and 30 to 50 times more potent than heroin. Fentanyl is extremely dangerous to law enforcement and anyone else who may come into contact with it. (DEA, 2015)" There is no documentation of the need for high dose of opioids. There is no justification for the use of high dose of opioids including fentanyl. There is no documentation of efficacy and safety with previous use of Fentanyl. There is no documentation of monitoring for side effects and compliance of the patient with her medications. Therefore, the request for Fentanyl transdermal patch 50mcg #10 per 04/24/15 order is not medically necessary.

Norco 10/325 #60 per 04/24/15 order: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 78-80 and 124.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids Page(s): 76-79.

Decision rationale: According to MTUS guidelines, Norco (Hydrocodone/Acetaminophen) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: "(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non adherent) drug-

related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework." According to the patient file, there is no objective documentation of pain and functional improvement to justify continuous use of Norco. Norco was used for longtime without documentation of functional improvement or evidence of return to work or improvement of activity of daily living. There is no documentation of compliance of the patient with his medications. Therefore, the prescription of Norco 10/325 #60 per 04/24/15 order is not medically necessary.

Trazodone 50mg #30 with 1 refill per 04/24/15 order: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-depressants for chronic pain Page(s): 13-14. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Insomnia treatment - Online Version.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Trazodone (Desyrel) ODG <http://www.odg-twc.com/index.html>.

Decision rationale: According to ODG guidelines, trazodone is recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. See also Insomnia treatment, where it says there is limited evidence to support its use for insomnia, but it may be an option in patients with coexisting depression. See also Fibromyalgia in the Pain Chapter, where trazodone was used successfully in fibromyalgia. Trazodone was approved in 1982 for the treatment of depression. It is unrelated to tricyclic or tetracyclic antidepressants and has some action as an anxiolytic. Off-label uses include alcoholism, anxiety, insomnia, and panic disorder. Although approved to treat depression, the American Psychiatric Association notes that it is not typically used for major depressive disorder. Over the period 1987 through 1996, prescribing trazodone for depression decreased throughout the decade, while off-label use of the drug for insomnia increased steadily until it was the most frequently prescribed insomnia agent. To date, there has been only one randomized, double blind, placebo-controlled trial studying trazodone in primary insomnia. It was observed that relative to placebo, patients reported significant improvement in subjective sleep latency, sleep duration, wake time after sleep onset, and sleep quality with trazodone and zolpidem during week one, but during week two the trazodone group did not differ significantly from the placebo group whereas the zolpidem group demonstrated significant improvement compared to placebo for sleep latency and sleep duration. (Walsh, 1998) The AHRQ Comparative Effectiveness Research on insomnia concludes that trazodone is equal to zolpidem. (AHRQ, 2008) Evidence for the off-label use of trazodone for treatment of insomnia is weak. The current recommendation is to utilize a combined pharmacologic and psychological and behavior treatment when primary insomnia is diagnosed. Also worth noting, there has been no dose-finding study performed to assess the dose of trazodone for insomnia in non-depressed patients. Other pharmacologic therapies should be recommended for primary insomnia before considering trazodone, especially if the insomnia is not accompanied by comorbid depression or recurrent treatment failure. There is no clear-cut evidence to recommend trazodone first line to treat primary insomnia. (Mendelson, 2005) There is no documentation that the patient is suffering

from a major depression diagnosed by a formal psychiatric evaluation. There is no documentation that the patient is suffering from insomnia or failed first line treatment of insomnia. The latter was not characterized. There is no documentation of efficacy of previous use of trazodone. Therefore, the request for Trazodone 50mg #30 with 1 refill per 04/24/15 order is not medically necessary.