

<b>Case Number:</b>	CM15-0192858		
<b>Date Assigned:</b>	10/06/2015	<b>Date of Injury:</b>	07/19/1999
<b>Decision Date:</b>	11/16/2015	<b>UR Denial Date:</b>	09/30/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/01/2015

### 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: California

Certification(s)/Specialty: 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 51 year old male, who sustained an industrial injury on 7-19-99. Current diagnoses or physician impression includes thoracic-lumbosacral neuritis-radiculitis (unspecified), lumbar region sprain-strain and lumbar degenerative disc disease. Notes dated 8-25-15 - 9-10-15 reveals the injured worker presented with complaints of constant low back, right hip and bilateral feet pain. The pain is described as sharp, dull, aching, throbbing, pins and needles, stabbing, numbness, pressure, electrical, shooting, burning, stinging, cramping, spasms and weakness and is rated at 6-10 out of 10. The pain is increased by cold, activity, lying down and sitting and relieved by heat, rest, quiet, standing and medication. Physical examinations dated 8-25-15 - 9-10-15 revealed decreased sensory at T6 (right). The lumbar spine reveals severe (right greater than left) lumbar tenderness and spasm, decreased range of motion and sciatic notch tenderness on the left. He has an altered gait, decreased strength in the bilateral lower extremities and decreased internal rotation and adduction in the right hip. Treatment to date has included surgical intervention, transforaminal epidural steroid injection controlled his pain, medications; Zipsor, Soma, Trazodone (at least 9 months), Norco (at least 9 months) and MS Contin allows for improved function and ability to engage in activities of daily living (able to volunteer at his church) and home exercise program helps relieve the pain per note dated 9-10-15. The note also states the injured worker has self-weaned off over 50% of his medication. A recent urine toxicology screen was consistent, per note dated 9-10-15. A request for authorization dated 9-22-15 for Norco 10-325 mg #120 is modified to #90 and Trazodone HCL 100 mg #90 with 1 refill is non-certified, per Utilization Review letter dated 9-30-15.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325 mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic): Opioids for chronic pain.

**Decision rationale:** Based on ODG guideline, opioids for chronic low back pain are not recommended as a first-line treatment for chronic non-malignant pain, and not recommended in patients at high risk for misuse, diversion, or substance abuse. Opioids may be recommended as a 2nd or 3rd line treatment option for chronic non-malignant pain, with caution, especially at doses over 100 mg morphine equivalent dosage/day (MED). Risks of adverse effects are documented in the literature at doses as low as 50 MED. At this dose of MED, prescribing clinicians should begin to use caution in terms of any additional escalation of dose. At doses of 100 mg MED it is recommended that reassessment of use of this class of drugs should be made due to limited evidence for improved pain control and function with continued use as well as evidence of substantial adverse risks with higher MEDs. Escalation of doses beyond the 50 to 100 MED range should be done with caution, and generally under the care of pain specialists. In certain cases, addiction specialists may need to evaluate patients, with the understanding that many patients who progress to chronic opioid therapy have underlying psychiatric disease and substance abuse issues. See Opioid, dosing for details on how these values were derived based on current literature. Risk-benefit of use should be carefully weighed for substance abuse and overdose risks, including risk of death, and this information should be provided to the patient as part of informed decision-making. Extreme caution is required for any opioid use in patients with the following: (1) Individuals with a high risk for misuse or diversion; (2) Individuals with evidence of substance abuse issues; (3) Individuals with a family history of substance abuse; (4) Individuals with underlying psychiatric disease. An accurate diagnosis should be established. At the minimum, screening for opioid risk and psychological distress inventories should occur before starting this class of drugs and a psychological evaluation is strongly recommended. While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective in achieving the original goals of complete pain relief and functional restoration. For patients now on high opioid doses who are not benefiting from this class of drugs there is some evidence that dose reduction does not increase pain levels or decrease function, and in fact, may provide improvement of these outcomes. In this case the patient has been on Norco for at least 9 months, and was recently given a modified refill approval to accomplish weaning and cessation of this medication. There is no good data to suggest that long-term use of short acting opioids are indicated or recommended for use of chronic pain. Therefore, based on the ODG guidelines and the evidence in this case, the request for Norco 10/325 mg #120 is not medically necessary.

**Trazodone HCL 100 mg #90 with 1 refill: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental/Stress Chapter: Trazodone (Desyrel).

**Decision rationale:** Based on ODG guidelines, Trazodone, is recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. Not recommended as a first-line treatment for insomnia in patients generally, or as a first-line treatment for depression or for pain. See 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 Antidepressants for treatment of MDD (major depressive disorder), which recommends starting with either SSRIs, or desipramine, nortriptyline, bupropion, and venlafaxine. See also Anxiety medications in the Pain Chapter, where other medications are recommended as first-line agents, and Fibromyalgia in the Pain Chapter, where trazodone was used successfully in a small study for 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. This patient has been on trazodone at least 9 months. Neither ODG nor MTUS recommend the use of trazodone for chronic pain. Trazodone is indicated for insomnia and or depression, neither of which are documented as a diagnosis for this patient. Therefore, the request for trazodone 100 mg #90 with one refill is not medically necessary.

