

Case Number:	CM15-0206571		
Date Assigned:	10/23/2015	Date of Injury:	02/04/2003
Decision Date:	12/08/2015	UR Denial Date:	09/22/2015
Priority:	Standard	Application Received:	10/21/2015

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: Physical Medicine & Rehabilitation

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 63 year old male who sustained a work-related injury on 2-4-03. Medical record documentation on 9-10-15 revealed the injured worker was being treated for post laminectomy syndrome of the lumbar region, lumbago, thoracic-lumbosacral neuritis - radiculitis and sacroilitis. He reported no significant changes in his low back and bilateral leg pain and reported being stable with his medications. He reported his medications were helping with his overall pain; however his sleep was not good due to pain and stress. His average pain since his previous evaluation was 8 on a 10-point scale (9-10-15, 7-14-15, 3-3-15). His medication regimen included Ambien 10 mg, Baclofen 20 mg, Cialis 5 mg, Cymbalta 60 mg (since at least 3-3-15), Lyrica 150 mg, Nucynta 75 mg (since at least 3-3-15), Nucynta ER 250 mg and Zanaflex 4 mg (since at least 3-3-15). Objective findings included ongoing baseline pain in the lumbar region with left greater than right leg pain to the level of the foot consistent with radiculopathy and increasing numbness. He had a positive straight leg raise. He reported that his low back pain was worse with walking and he had a decreased active range of motion in the lumbar region. A urine drug screen on 3-3-15 was consistent for Nucynta. A request for Zanaflex 4 mg #60, Nucynta 75 mg #100 and Cymbalta 60 mg #60 was received on 9-16-15. On 9-22-15, the Utilization Review physician determined Zanaflex 4 mg #60 was not medically necessary and modified Nucynta 75 mg #100 to #50 and Cymbalta 60 mg #60 to #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zanaflex 4mg #60: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: Based on the 09/10/15 progress report provided by treating physician, the patient presents with chronic low back and leg pain rated 8/10. The patient is status post L4-S1 fusion/hardware removal on unspecified date. The request is for ZANAFLEX 4MG #60. RFA with the request not provided. Patient's diagnosis on 09/10/15 includes lumbar region post-laminectomy syndrome, lumbago, thoracic/lumbosacral neuritis/radiculitis, and sacroiliitis. Physical examination to the lumbar spine on 09/10/15 revealed decreased active range of motion and decreased deep tendon reflexes. Positive straight leg raise test. Treatment to date has included surgery, imaging studies, SCS trial, and medications. Patient's medications include Nucynta, Zanaflex, Cymbalta, Baclofen, Ambien, and Lyrica. The patient is permanent and stationary with [REDACTED], per 09/10/15 report. MTUS Chronic Pain Medical Treatment Guidelines for Muscle Relaxants for pain, pg 66: "ANTISPASTICITY/ANTISPASMODIC DRUGS: Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain." MTUS p60 also states, "A record of pain and function with the medication should be recorded," when medications are used for chronic pain. Zanaflex (Tizanidine) has been included in patient's medications, per progress reports dated 03/03/15, 07/14/15, and 09/10/15. It is not known when this medication was initiated. Per 09/10/15 report, treater states the patient "is stable with his current medications. The meds are helping." Treater states in 03/03/03 report that "medications are maintaining [the patient's] pain at a tolerable level." Zanaflex is allowed for myofascial pain, low back pain and fibromyalgia conditions per MTUS. Given documentation of benefit, this request appears reasonable and in accordance with guidelines. Therefore, the request IS medically necessary.

Nucynta 75mg #100: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic) Tapentadol (Nucynta).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Medications for chronic pain, Opioids, criteria for use, Opioids for chronic pain.

Decision rationale: Based on the 09/10/15 progress report provided by treating physician, the patient presents with chronic low back and leg pain rated 8/10. The patient is status post L4-S1 fusion/hardware removal on unspecified date. The request is for NUCYNTA 75MG #100. RFA with the request not provided. Patient's diagnosis on 09/10/15 includes lumbar region post-laminectomy syndrome, lumbago, thoracic/lumbosacral neuritis/radiculitis, and sacroiliitis. Physical examination to the lumbar spine on 09/10/15 revealed decreased active range of motion and decreased deep tendon reflexes. Positive straight leg raise test. Treatment to date has included surgery, imaging studies, SCS trial, and medications. Patient's medications include Nucynta, Zanaflex, Cymbalta, Baclofen, Ambien, and Lyrica. The patient is permanent and stationary with [REDACTED], per 09/10/15 report. MTUS, CRITERIA FOR USE OF

OPIOIDS Section, pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS, CRITERIA FOR USE OF OPIOIDS Section, page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS, CRITERIA FOR USE OF OPIOIDS Section, p77, states that "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS, MEDICATIONS FOR CHRONIC PAIN Section, page 60 states that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." MTUS, OPIOIDS FOR CHRONIC PAIN Section, pages 80 and 81 states "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Nucynta has been included in patient's medications, per progress reports dated 03/03/15, 07/14/15, and 09/10/15. It is not known when this medication was initiated. Per 09/10/15 report, treater states the patient "is stable with his current medications... The meds are helping. Today informed consent is reestablished for medical management and the 4As (A-analgesia, A-adverse effect/side effect, A-activity level, A-abuse/addiction) are discussed and met/documented. Repeat UDT done 3/3/15. Confirmation consistent for Nucynta." Treater states in 03/03/03 report that "medications are maintaining [the patient's] pain at a tolerable level." In this case, treater provides general statements and has not discussed how Nucynta reduces pain and significantly improves patient's activities of daily living. There are no before and after pain scales or validated instruments addressing analgesia. MTUS states that "function should include social, physical, psychological, daily and work activities." There are no specific discussions regarding aberrant behavior, adverse reactions, ADL's, etc. MTUS requires appropriate discussion of the 4A's. Furthermore, MTUS does not clearly support chronic opiate use for this kind of condition, chronic low back pain and radiculopathy. In addition, this patient has been prescribed narcotic medications long term based on date of injury, and is not presumed to be suffering from nociceptive pain. While this patient presents with significant chronic complaints, without evidence of an existing condition which could cause nociceptive pain (such as cancer), continuation of this medication is not appropriate. Therefore, the request IS NOT medically necessary.

Cymbalta 60mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Duloxetine (Cymbalta).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Duloxetine (Cymbalta).

Decision rationale: Based on the 09/10/15 progress report provided by treating physician, the patient presents with chronic low back and leg pain rated 8/10. The patient is status post L4-S1 fusion/hardware removal on unspecified date. The request is for CYMBALTA 60MG #60. RFA with the request not provided. Patient's diagnosis on 09/10/15 includes lumbar region post-laminectomy syndrome, lumbago, thoracic/lumbosacral neuritis/radiculitis, and sacroiliitis. Physical examination to the lumbar spine on 09/10/15 revealed decreased active range of motion and decreased deep tendon reflexes. Positive straight leg raise test. Treatment to date has included surgery, imaging studies, SCS trial, and medications. Patient's medications include

Nucynta, Zanaflex, Cymbalta, Baclofen, Ambien, and Lyrica. The patient is permanent and stationary with [REDACTED], per 09/10/15 report. MTUS, Duloxetine: Specific antidepressants Section, pages 15-16 states: "Duloxetine (Cymbalta) is FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy... Trial period: Some relief may occur in first two weeks; full benefit may not occur until six weeks." MTUS page 60 also states, "A record of pain and function with the medication should be recorded," when medications are used for chronic pain. Cymbalta has been included in patient's medications, per progress reports dated 03/03/15, 07/14/15, and 09/10/15. It is not known when this medication was initiated. Per 09/10/15 report, treater states the patient "is stable with his current medications... The meds are helping." Treater states in 03/03/03 report that "medications are maintaining [the patient's] pain at a tolerable level." Given patient's continued symptoms, diagnosis and documentation of benefit, this request appears reasonable and in accordance with guidelines. Therefore, the request IS medically necessary.