

Case Number:	CM15-0141290		
Date Assigned:	09/03/2015	Date of Injury:	01/31/2013
Decision Date:	10/26/2015	UR Denial Date:	07/07/2015
Priority:	Standard	Application Received:	07/21/2015

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:

The injured worker is a 43 year old male with a date of injury as 01-31-2013. The current diagnoses include status post anterior and posterior fusion at C3-C7 with post-operative complications including DVT requiring a stent, CSF leak, and injury to spinal cord resulting in post-operative plegia of the left upper and lower extremity, thoracic sprain, and discogenic lumbar condition with disc disease. Previous treatments included medications, H-wave unit, surgical intervention, trigger point injection, psychotherapy, trigger point injections, and in-home physical therapy. Previous diagnostic studies included MRI's and nerve studies. Report dated 07-01-2015 noted that the injured worker presented with complaints that included back pain. It was noted that the injured worker has improvement with showering more independently and can brush his teeth, able to roll in bed, can stand for 7 minutes now at the sink, stand in a frame for an hour, and able to lift his leg when transferred into bed. The injured worker has noticed significant improvement in strength. Current medications include Nucynta, Cymbalta, gabapentin, Voltaren, and Senna. Pain level was not included. Physical examination revealed grip strength on the left to be 2 and right grip strength was 58, muscle contraction when forced, slight contractures, and significant swelling in the bilateral lower extremity which is symmetric. The injured worker uses an electric wheelchair. Treatment plan included a request for continued in-home care by both the wife and outside home care, continue physical therapy, continue H-wave, and request for pool lift. The injured worker is temporarily totally disabled. Disputed treatments included Cymbalta, Nucynta, and Diclofenac.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta 30mg #30 with 5 refills: Overturned

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004, and Chronic Pain Medical Treatment 2009.

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

Decision rationale: Based on the 06/17/15 progress report provided by treating physician, the patient presents with low back pain rated 2/10. The patient is status post anterior and posterior fusion at C3-C7 with post-operative complications including DVT requiring a stent, CSF leak, and injury to spinal cord resulting in post-operative plegia of the left upper and lower extremity. The request is for CYMBALTA 30MG #30 WITH 5 REFILLS. Patient's diagnosis per Request for Authorization form dated 06/17/15 includes lumbar spondylosis. Diagnosis on 06/17/15 includes incomplete spinal cord injury probably Brown-Sequard in nature, lumbar facet arthropathy, chronic pain, diabetes and fluctuating blood pressure. The patient uses an electric wheelchair. Treatment to date has included surgical intervention, imaging studies, trigger point injection, psychotherapy, trigger point injections, in-home physical therapy, H-wave unit, psychotherapy, and medications. Patient's medications include Nucynta, Cymbalta, gabapentin, Voltaren, and Senna. The patient is temporarily totally disabled. 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 was included in patient's medications, per progress reports dated 06/03/15, 06/26/15, and 07/01/15. Per 06/17/15 report, treater states the patient "is currently on the Nucynta five a day with good benefit no adverse effects reported also on the Gabapentin and Cymbalta, all of which is helping with his pain without any reported adverse effect." Given the patient's continued symptoms, diagnosis which includes diabetes, and documentation of medication efficacy, this request appears reasonable and in accordance with guidelines. Therefore, the request for is medically necessary.

Nucynta 50mg #180: Upheld

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

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

Decision rationale: Based on the 06/17/15 progress report provided by treating physician, the patient presents with low back pain rated 2/10. The patient is status post anterior and posterior

fusion at C3-C7 with post-operative complications including DVT requiring a stent, CSF leak, and injury to spinal cord resulting in post-operative plegia of the left upper and lower extremity. The request is for NUCYNTA 50MG #180. Patient's diagnosis per Request for Authorization form dated 06/17/15 includes lumbar spondylosis. Diagnosis on 06/17/15 includes incomplete spinal cord injury probably Brown-Sequard in nature, lumbar facet arthropathy, chronic pain, diabetes and fluctuating blood pressure. The patient uses an electric wheelchair. Treatment to date has included surgical intervention, imaging studies, trigger point injection, psychotherapy, trigger point injections, in-home physical therapy, H-wave unit, psychotherapy, and medications. Patient's medications include Nucynta, Cymbalta, gabapentin, Voltaren, and Senna. The patient is temporarily totally disabled. 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 4 A's (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." Nucynta was included in patient's medications, per progress reports dated 04/09/15, 06/03/15, and 07/01/15. Per 06/17/15 report, treater states the patient "is currently on the Nucynta five a day with good benefit no adverse effects reported also on the Gabapentin and Cymbalta, all of which is helping with his pain without any reported adverse effect." In this case, treater has not stated how Nucynta reduces pain and significantly improves patient's activities of daily living. There are no pain scales or validated instruments addressing before and after analgesia. MTUS states, "Function should include social, physical, psychological, daily and work activities." There are no specific discussions regarding aberrant behavior, adverse reactions, ADL's, etc. No UDS report results provided, either. MTUS requires appropriate discussion of the 4 A's. Given the lack of documentation as required by guidelines, the request is not medically necessary.

Diclofenac 100mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter, under Diclofenac.

Decision rationale: Based on the 06/17/15 progress report provided by treating physician, the patient presents with low back pain rated 2/10. The patient is status post anterior and posterior fusion at C3-C7 with post-operative complications including DVT requiring a stent, CSF leak, and injury to spinal cord resulting in post-operative plegia of the left upper and lower extremity.

The request is for DICLOFENAC 100MG #30. Patient's diagnosis per Request for Authorization form dated 06/17/15 includes lumbar spondylosis. Diagnosis on 06/17/15 includes incomplete spinal cord injury probably Brown-Sequard in nature, lumbar facet arthropathy, chronic pain, diabetes and fluctuating blood pressure. The patient uses an electric wheelchair. Treatment to date has included surgical intervention, imaging studies, trigger point injection, psychotherapy, trigger point injections, in-home physical therapy, H-wave unit, psychotherapy, and medications. Patient's medications include Nucynta, Cymbalta, gabapentin, Voltaren, and Senna. The patient is temporarily totally disabled. MTUS guidelines page 67 and 68 recommend NSAIDs (non-steroidal anti-inflammatory drugs) as an option for short-term symptomatic relief. ODG-TWC, Pain (Chronic) Chapter, under Diclofenac states: "Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients, as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%. For a patient who has a 5% to 10% risk of having a heart attack, that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option. (McGettigan, 2011)" Voltaren is included in progress report dated 07/01/15. It is not known when this medication was initiated. MTUS supports NSAIDs, given patient's diagnosis and symptoms. However, ODG supports Voltaren (Diclofenac) when other NSAIDs have failed and the patient is at a very low risk profile. The patient has a diagnosis of diabetes and fluctuating hypertension, per 05/14/15 report. There is no evidence in provided medical records that other NSAID's have been trialed and failed, and patient's risk profile has not been addressed. Given lack of documentation, this request cannot be warranted based on guidelines. Therefore, the request is not medically necessary.