

Case Number:	CM15-0117027		
Date Assigned:	06/25/2015	Date of Injury:	04/07/1999
Decision Date:	08/07/2015	UR Denial Date:	06/11/2015
Priority:	Standard	Application Received:	06/17/2015

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: Emergency 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 56 year old male, who sustained an industrial injury on April 7, 1999. He reported injury to his back. The injured worker was diagnosed as having chronic lumbar discogenic pain secondary to lumbar degenerative disc disease at L4-L5 and L5-S1, chronic pain related anxiety, and sinus bradycardia secondary to Atenolol. Treatment to date has included chiropractic treatments, physical therapy, gastric emptying study, and medication. Currently, the injured worker complains of mild to occasional moderate stiffness with dull achy pain in the lower back associated with paresthesias in both lower extremities, and chronic headaches. The Treating Physician's report dated May 11, 2015, noted the injured worker ambulating with a single point cane for safe ambulation, independent with his self-care and activities of daily living (ADLs). The injured worker's current medications were listed as Opana Extended release, Cymbalta, Tizanidine, Protonix, Trazodone, and Atenolol sustained release. Physical examination was noted to show the injured worker anxious, with the lumbosacral spine showing a loss of lumbar lordosis and tender points on palpation without spasm. The injured worker was noted to be able to maintain his functional activities of daily living (ADLs) and independent status using his current medications. The treatment plan was noted to include continuation of Opana Extended Release, with any further weaning needing to be done in a detox facility, Protonix, Tizanidine, and Cymbalta.

IMR ISSUES, DECISIONS AND RATIONALES

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

2 prescriptions for Opana 20mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 93.

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 guidelines note to continue opioids when the injured worker has returned to work, and if the injured worker has improved functioning and pain. Oxymorphone (Opana)/ Oxymorphone Extended Release (Opana ER) is not intended for as needed use. The injured worker was noted in September 2013, to have been on Dilaudid for a "long time", also getting medication from Canada. On May 22, 2014, the injured worker was noted to have been tapered down on the Dilaudid, currently on Opana, which was noted to be helpful, with the plan to taper him down to a minimum narcotic use in the next two to three months. The injured worker has continued with the Opana ER 20mg twice daily. The documentation provided did not include documentation of objective, measurable pain assessments, functional assessments, or any indications of recent attempts at weaning. There was no laboratory or urine toxicology information included in the documentation provided. Based on the MTUS guidelines, the documentation did not support the medical necessity of the request for 2 prescriptions for Opana 20mg #60. Therefore, the request is not medically necessary.

1 prescription for Tizanidine 4mg #30: Upheld

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

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

Decision rationale: The CA 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 on Tizanidine since December 19, 2013, with no documentation submitted of liver function testing. Physical examination was noted to show no muscle spasms, and no exacerbation of symptoms. The documentation provided noted the injured worker prescribed the Tizanidine as needed, without documentation of the injured worker's frequency of use, response to use of the medication, or objective, measurable improvement in functionality with use of the Tizanidine. Based on the MTUS guidelines, the documentation did not support the medical necessity of the request for 1 prescription for Tizanidine 4mg #30. Therefore, the request is not medically necessary.

1 prescription for Opana ER 20mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78, 93.

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 guidelines note to continue opioids when the injured worker has returned to work, and if the injured worker has improved functioning and pain. Oxymorphone (Opana)/ Oxymorphone Extended Release (Opana ER) is not intended for prn use. Patients are to avoid alcohol while on Opana ER due to increased (possibly fatal) plasma levels. The injured worker was noted in September 2013, to have been on Dilaudid for a "long time", also getting medication from Canada. On May 22, 2014, the injured worker was noted to have been tapered down on the Dilaudid, currently on Opana, which was noted to be helpful, with the plan to taper him down to a minimum narcotic use in the next two to three months. The injured worker has continued with the Opana ER 20mg twice daily. The documentation provided did not include documentation of objective, measurable pain assessments, functional assessments, or any indications of recent attempts at weaning. There was no laboratory or urine toxicology information included in the

documentation provided. Based on the MTUS guidelines, the documentation did not support the medical necessity of the request for 1 prescription for Opana ER 20mg. Therefore, the request is not medically necessary.

1 prescription for Tizanidine 4mg: Upheld

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

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 on Tizanidine since December 19, 2013, with no documentation submitted of liver function testing. Physical examination was noted to show no muscle spasms and no new exacerbation of symptoms. The documentation provided noted the injured worker prescribed the Tizanidine as needed, without documentation of the injured worker's frequency of use, response to use of the medication, or objective, measurable improvement in functionality with use of the Tizanidine. Based on the MTUS guidelines, the documentation did not support the medical necessity of the request for 1 prescription for Tizanidine 4mg. Therefore, the request is not medically necessary.

1 prescription for Cymbalta 90mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants, Cymbalta Page(s): 13-16, 42-44.

Decision rationale: The CA MTUS Chronic Pain Medical Treatment Guidelines recommends "Duloxetine (Cymbalta) as an option in first-line treatment option in neuropathic pain." Cymbalta is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has

FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain). SNRIs have not been evaluated for low back pain. No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. On June 11, 2015, the UR review # 1136632, using the December 11, 2014 date of report containing request for authorization, certified the prescriptions for Cymbalta 60mg #30 and Cymbalta 30mg #30, for the dates of December 11, 2014, to August 8, 2015. The UR noted that future requests must be accompanied by clinical documentation demonstrating objective measures of improvement in depression and/or anxiety. As the medication has just been approved for the injured worker until August 8, 2015, the request for Cymbalta 90mg between March 28, 2015, and August 8, 2015, relating to the UR #1136634 dated June 11, 2015, from the March 28, 2015 date of report containing request for authorization, is not medically necessary.