

Case Number:	CM14-0206939		
Date Assigned:	12/18/2014	Date of Injury:	03/05/1998
Decision Date:	02/12/2015	UR Denial Date:	11/25/2014
Priority:	Standard	Application Received:	12/10/2014

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. The expert reviewer is Board Certified in Family Practice, and is licensed to practice in North Carolina. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is a 48-year-old with a reported date of injury of 03/05/1998. The patient has the diagnoses of failed back surgery syndrome, chronic pain syndrome, lumbago, lumbosacral radiculitis, L4/5 disc herniation and T7/8 disc herniation. The patient had epidural steroid injection on 05/28/2014 and had planned repeat injection scheduled for 11/10/2014. The provider notes submitted for review are all hand written and mostly illegible. The most recent note is dated 10/13/2014 and states the patient was doing a little better and pain was at a moderate level. The physical exam noted muscle spasm. Treatment plan recommendation's included continuation of medications and repeat epidural injections.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol 50 mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states:On-Going Management. Actions Should Include:(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. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: 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 for documentation of the clinical use of these controlled drugs. (Passik, 2000)(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to nonopioid means of pain control.(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids(a) If the patient has returned to work(b) If the patient has improved functioning and pain(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long term efficacy is unclear (greater than 16 weeks), but also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of re-assessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007) The long-term use of this medication is not recommended unless certain objective outcome measures have been met as defined above. There is no provided objective outcome measure that shows significant improvement in function, besides being able to drive, while on the medication. The most recent progress notes do not mention work status. There is a noted improvement in VAS scores from 7-8 to 5-6/10 with medications and a 10% reduction of pain. For these reasons all criteria for ongoing and continued use of the medication have not been met. Therefore the request is not medically necessary.

Talwin NX #240: 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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states: On-Going Management. Actions Should Include: (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. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: 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 for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids (a) If the patient has returned to work (b) If the patient has improved functioning and pain (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long term efficacy is unclear (greater than 16 weeks), but also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande,

2007)The long-term use of this medication is not recommended unless certain objective outcome measures have been met as defined above. There is no provided objective outcome measure that shows significant improvement in function, besides being able to drive, while on the medication. The most recent progress notes do not mention work status. There is a noted improvement in VAS scores from 7-8/10 to 5-6/10 with medications and a 30% reduction in pain. For these reasons all criteria for ongoing and continued use of the medication have not been met. Therefore the request is not medically necessary.

Xanax 1 mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: The California chronic pain medical treatment guidelines section on benzodiazepines stated: Benzodiazepines. Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005). This medication is not recommended per the California MTUS for chronic ongoing use. They are the treatment of choice in very few instances. There is no indication of failure of other first line anxiety medications. Therefore the request is not medically necessary.

Diazepam 5 mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: The California chronic pain medical treatment guidelines section on benzodiazepines stated: Benzodiazepines: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005). This medication is not recommended per the California

MTUS for chronic ongoing use. They are the treatment of choice in very few instances. There is no indication of failure of other first line anxiety medications. Therefore the request is not medically necessary.

Cymbalta 60 mg #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cymbalta Page(s): 43-44.

Decision rationale: The California chronic pain medical treatment guidelines section on duloxetine states: Recommended as an option in first-line treatment option in neuropathic pain. Duloxetine (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). The starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. The medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. (Arnold, 2005) The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The side effect profile of Duloxetine is thought to be less bothersome to patients than that of tricyclic antidepressants. Note: On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the Precautions/Hepatotoxicity section of the prescribing information for Cymbalta. The patient has the diagnosis of neuropathic pain in the form of radiculitis. The patient does not have any recorded liver problems. The included documentation objective measures improvement in pain and function on the patient's current medications. Therefore criteria for the use of this medication have been met and the request is medically necessary.