

Case Number:	CM14-0208962		
Date Assigned:	02/03/2015	Date of Injury:	02/14/1998
Decision Date:	03/19/2015	UR Denial Date:	12/04/2014
Priority:	Standard	Application Received:	12/15/2014

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. 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: North Carolina

Certification(s)/Specialty: Family Practice

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 52 year old male who sustained multiple injuries in a car accident to his back, neck and head while employed as car sales associate on February 14, 1998. As a result of the industrial injuries the patient has undergone posterior L4-5 lumbar fusion, anterior C6-7 fusion with redo; bilateral carpal tunnel releases, bilateral ulnar nerve transposition, and knee surgeries. In 1998 he was diagnosed with Reflex Sympathetic Dystrophy Syndrome (RSD) and laryngeal palsy. A magnetic resonance imaging (MRI) in March 2014 demonstrated an 80% bursal sided partial thickness tear of the supraspinatus tendon with extensive fraying. The patient continues to experience numbness, tingling and pain in the right shoulder, arms and hands with conservative measures, medications and steroid injections. The injured worker was recommended for surgery. Current medications and treatment modalities consist of physical therapy, swimming, Tizanidine, Neurontin, Mirtazapine, Lidoderm 5% patches, Clonidine, Valium 10mg, OxyContin 80mg, Soma 350mg, Dilaudid 8mg, Ambien and Herbs. The treating physician requested authorization for Left transforaminal epidural injection at L5-S1; Mirtazapine 15mg #60 with 5 refills; Lidoderm 5% patches #60 with 5 refills; Neurontin 600mg #300 with 5 refills; Clonidine HCL #4 with 5 refills; Valium 10mg #120 with 5 refills; Nortriptyline 25mg #30 with 5 refills; Ambien 10mg #60 with 5 refills; Soma 350mg #180 with 5 refills; OxyContin 80mg #270; OxyContin 80mg #135; Dilaudid 8mg #240; Dilaudid 8mg #120; Tizanidine 4mg #150. On December 4, 2014 the Utilization Review denied certification for Left transforaminal epidural injection at L5-S1; Lidoderm 5% patches #60 with 5 refills; Clonidine HCL #4 with 5 refills; Ambien 10mg #60 with 5 refills; Soma 350mg #180 with 5

refills; OxyContin 80mg #270; OxyContin 80mg #135; Dilaudid 8mg #240; Dilaudid 8mg #120; Tizanidine 4mg #150. Denials were dated between 11/24/2014 and 05/25/2015. On December 4, 2014 the Utilization Review modified the certification for Mirtazapine 15mg #60 with 5 refills to Mirtazapine 15mg #60 with One (1) refill; Neurontin 600mg #300 with 5 refills to Neurontin 600mg #135 with No refills; Valium 10mg #120 with 5 refills to Valium 10mg #120 with No refills; Nortriptyline 25mg #30 with 5 refills to Nortriptyline 25mg #30 with One (1) refill. All modifications were dated between 11/24/2014 and 05/25/2015. Citations used in the decision process were the Medical Treatment Utilization Schedule (MTUS), Chronic Pain Guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Left transforaminal epidural injection at L5-S1: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines epidural steroid injections Page(s): 46.

Decision rationale: The California chronic pain medical treatment guidelines section on epidural steroid injections (ESI) states: Criteria for the use of Epidural steroid injections: Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007) 8) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections. The patient has the documentation of low back pain and lumbar disc herniation with documentation of radiculopathy on physical exam and corroboration by EMG. The patient has had physical therapy and medication. For these reasons criteria as set forth above per the California MTUS have been met. The request is certified.

Mirtazapine 15mg with 5 refills: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation insomnia

Decision rationale: The California MTUS and the ACOEM do not specifically address this medication. Per the official disability guidelines recommend pharmacological agents for insomnia only is used after careful evaluation of potential causes of sleep disturbance. Primary insomnia is usually addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. Pharmacological treatment consists of four main categories: Benzodiazepines, Non-benzodiazepines, Melatonin and melatonin receptor agonists and over the counter medications. Sedating antidepressants have also been used to treat insomnia however there is less evidence to support their use for insomnia, but they may be an option inpatients with coexisting depression. This patient does not have the diagnosis of depression. There is also no evidence or documentation of failure of first line treatment recommendations for insomnia. Therefore the request is not certified.

Lidoderm 5% patches #60 with 5 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain

disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995) The patient does have documented neuropathic pain. The patient is currently on anticonvulsant therapy. However the California MTUS states that further research is needed to recommend this agent for chronic neuropathic pain disorders other than post-herpetic neuralgia. Therefore the request is not certified.

Neurontin 600mg #30o with 5 refills: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines gabapentin Page(s): 18.

Decision rationale: The California chronic pain medical treatment guidelines section on Gabapentin states: Gabapentin (Neurontin, Gabarone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study. Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007) Specific pain states: There is limited evidence to show that this medication is effective for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness. (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005) The requested medication is a first line choice in the treatment of neuropathic pain per the California MTUS. The patient per the provided documentation has the diagnosis of neuropathic pain/CRPS. The physical exam documented corroborates the

diagnosis. The patient has no contraindications to taking this medication. Therefore the request is certified.

Valium 10,g #120 with 5 refills: Upheld

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

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 states: 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)The chronic long-term use of this class of medication is recommended in very few conditions per the California MTUS. There is no evidence however of failure of first line agent for the treatment of insomnia or anxiety in the provided documentation. For this reason the request is not certified.

Clonidine HCL #4 with 5 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines clonidine Page(s): 34-35.

Decision rationale: The California MTUS section on clonidine states: There is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Side effects include hypotension, and the medication should not be stopped abruptly due to the risk of rebound hypertension. The medication is FDA approved with an orphan drug intrathecal indication for cancer pain only. The medication is not being prescribed intrathecal for cancer pain. It is also not being prescribed to treat hypertension. Therefore the request is not medically warranted and is not certified.

Nortriptyline 25mg #30 with 5 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines tricyclic antidepressants Page(s): 15.

Decision rationale: The California MTUS section on clonidine states: There is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Side effects include hypotension, and the medication should not be stopped abruptly due to the risk of rebound hypertension. The medication is FDA approved with an orphan drug intrathecal indication for cancer pain only. The medication is not being prescribed intrathecal for cancer pain. It is also not being prescribed to treat hypertension. Therefore the request is not medically warranted and is not certified.

Ambien 10mg #60 with 5 refills: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ambien

Decision rationale: The California MTUS and the ACOEM do not specifically address the requested medication. PER the ODG: Zolpidem is a prescription short-acting non-benzodiazepine hypnotic approved for the short-term treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain. While sleeping pills, so-called minor tranquilizers and anti-anxiety medications are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. There is also concern that they may increase pain and depression over the long-term. This medication is not intended for long-term ongoing use in the treatment of insomnia. There is no documentation of failure of first line treatment choices for insomnia. Therefore the request is not certified.

Soma 350mg #180 with 5 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-65.

Decision rationale: The California chronic pain medical treatment guidelines section on muscle relaxants states: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP 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. (Homik, 2004) This medication is not intended for long-term use per the California MTUS. The medication has not been prescribed for the flare-up of chronic low back pain. This is not an approved use for the medication. For these reasons, criteria for the use of this medication have not been met. Therefore the request is not certified.

Oxycontin 80mg #270: Upheld

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

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 for ongoing management: 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 nonadherent) 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 (>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)The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. The most recent progress reports do not note the patient's work status. The patient continues to have significant pain without documented significant improvement in other outcome measures and function such as significant VAS score improvement. For these reasons the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore the request is not certified.

Oxycontin 80mg #135: Upheld

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

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 for ongoing management: 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 nonadherent) 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 dairy 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 (>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) The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. The most recent progress reports do not note the patient's work status. The patient continues to have significant pain without documented significant improvement in other outcome measures and function such as significant VAS score improvement. For these reasons the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore the request is not certified.

Dilaudid 8mg #240: Upheld

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

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 for ongoing management: 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 nonadherent) 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 (>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) The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. The most recent progress reports do not note the patient's work status. The patient continues to have significant pain without documented significant improvement in other outcome measures and function such as significant VAS score improvement. For these reasons the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore the request is not certified.

Dilaudid 8mg #120: Upheld

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

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 for ongoing management: 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 nonadherent) 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 (>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) The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. The most recent progress reports do not note the patient's work status. The patient continues to have significant pain without documented significant improvement in other outcome measures and function such as significant VAS score improvement. For these reasons the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore the request is not certified.

Tizanidine 4mg #150: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-65.

Decision rationale: The California chronic pain medical treatment guidelines section on muscle relaxants states: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP 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. (Homik, 2004) This medication is not intended for long-term use per the California MTUS. The medication has not been prescribed for the flare-up of chronic low back pain. This is not an approved use for the medication. For these reasons, criteria for the use of this medication have not been met. Therefore the request is not certified.