MAXIMUS Federal Services

Case Number:	CM13-0041217		
Date Assigned:	12/20/2013	Date of Injury:	04/14/2011
Decision Date:	02/19/2014	UR Denial Date:	10/01/2013
Priority:	Standard	Application Received:	10/11/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation and is licensed to practice in California. 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 physician 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 54-year-old male who was injured on 4/14/2011, while working for [redacted]. The patient states that he was patching a wall outside a trailer when he slipped and fell 7 feet face down, with injury to the left side of his body, and his low back. He was diagnosed with left rib fracture, right wrist injury, right knee injury, low back injury and head injury. There was an MRI performed which showed mild central canal stenosis L3-L4, L4-5, L4-5 annular disc bulge, and L5-S1 mild bulge. MRI of right knee showed severe myxoid degeneration of his medical meniscus and early chondromalacia, III- IV. The patient continues to have low back pain and upper back pains. He has numbness in both legs, He has clicking in both knees and both shoulder. The right knee is worse than the left. The patient in addition to receiving pain management treatment is also undergoing psychological and psychiatric treatment. Medical records dated-8/1/13 a psychiatric progress note stated that the patient was in severe anxiety according to the psychology test. In the medical records dated 7/18/13 an AME reports states that the patient complains of neck, low back, and knee pain. The neck pain is graded at 5/10, and low back at 8/10, and the knee pain at 5-8/10. It is noted that the medications do help with the pain. Examination revealed tenderness over the cervical spine and lower back. Neurological exam for the upper extremities was normal with normal motor and sensory components. The SLR test produced pain in the back bilaterally. There is noted decreased sensation over the right thigh. For the future medical treatment, the neck and back could undergo a multidisciplinary evaluation for possible candidacy into an FRP. He suggested surgery for the right knee is unwarranted due to lack of mechanical derangement. The current symptoms and findings are results of the osteoarthritis and chondromalacia, which would not benefit from surgery. 6/5/13 progress note indicate that the patient's psychological state has been stabilized. The patient has problems with constipation and impotence. 12/27/12 psychiatric progress note states that the patient is not sleeping well. 11/14/12 psychological evaluation note stated that the patient seems to be a poor manager of his chronic pain and reacts to pain somewhat like a

victim, engaging in passive and dependent behaviors. It is noted that due to his high level of somatic focus and somatic preoccupation, there is a recommendation to be cautious about any aggressive interventions because "he is the kind of person who gets all the side effects from the procedure while receiving little to no benefit." It is noted that the patient is depressed and mild to moderately anxious and will only get worse if not treated effectively. DIAGNOSTICS: 8/30/11 MRI of the lumbar spine impressions: Multilevel facet arthrosis and ligamentum flavum hypertrophy superimposed on congenitally short pedicles with resultant mild central canal stenosis, particularly at L3-L4 and L4-L5. There is no significant neural foraminal encroachment. The request is for retrospective review of medications: Naprosyn 500 mg one BID; Hydrocodone / APAP 10/500 one BID; Risperdal 1 mg - one- QHS; Risperidone - .5mg 2 - QHS; Trazadone 50 mg - 2 QHS; Viagra trial - 1/2 tab PRN.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Naprosyn 500mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 47. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

Decision rationale: Naprosyn 500 mg one BID. Chronic Pain Medical Treatment Guidelines (page 46); state that NSAIDS are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer Gl side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxen being the safest drug). There is no evidence of long-term effectiveness for pain or function. Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. (text, pg. 47). Non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and ibuprofen, are effective, although they can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. Therefore, they should be used only acutely. (text, page 47). ODG (Pain Chapter) states that NSAIDs are recommended for acute pain, acute LBP, short-term pain relief in chronic LBP, and short-term improvement of function in chronic LBP. There is no evidence of long-term effectiveness for pain or function. There is conflicting evidence that NSAIDs are more effective that acetaminophen for acute LBP. There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain in this condition. See NSAIDs, GI symptoms & cardiovascular risk. See also Anti-inflammatory medications and Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIOs, there are other less

well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. The documentation provided for review does not support ongoing subjective and objective functional improvements attributed to this medication such as improved ADLs, decreased pain scores, and increased physical capacity. CA MTUS states that NSAIDs are effective, although they can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. In addition, ODG states that there is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain. Therefore, the request for retrospective Naprosyn 500mg is not medically necessary and appropriate.

Retrospective Hydrocodone/APAP 10/500: 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): 79-81. Decision based on Non-MTUS Citation American Pain Society and the American Academy of Pain Medicine, in addition to review articles (see [redacted] and [redacted] review article from the New England Journal of Medicine).

Decision rationale: Chronic Pain Medical Treatment Guidelines (page 79-81) state that chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. (page 81). Additionally, CA MTUS 2009: Chronic Pain Medical Treatment Guidelines state that for 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. (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. (e) Use of drug screen'1ng 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. (pages 79-80). Opioid Treatment Guidelines from the American Pain Society and the American Academy of Pain Medicine, in addition to various review articles (see [redacted] and [redacted] review article from the New England Journal of Medicine), state that opioid doses above 200 mg of morphine (or its equivalents per day) is considered "high dose" opioid therapy and is "off-label", highly experimental and potentially dangerous. By using 300 mg of morphine equivalents/day (from Oxycontin and hydrocodone/APAP), the patient is prescribed an opioid dose that is 150% higher than the generally considered threshold for "high-dose" opioid therapy. The published literature emphasizes that use of high-dose opioid therapy rarely results in satisfactory analgesia or improved function. Guidelines also note that high-dose opioids may produce hyperalgesia,

headache, neuroendocrinologic dysfunction and immunosuppression. The CNS adverse effects (e.g., sedation, dizziness, physical impairment, mental confusion) of such large-doses should not be underappreciated. The documentation provided for review does not support ongoing subjective and objective functional improvements attributed to this medication such as improved ADLs, decreased pain scores, and increased physical capacity. There are no reports concerning urine drug screens for medication compliance or side effect monitoring. CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Therefore the request for retrospective Hydrocodone/APAP 10/500 is not medically necessary and appropriate.

Retrospective Risperdal 1mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 388. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Anti-Anxiety Medications, and Daily Med.

Decision rationale: CA MTUS 2009: Chronic Pain Medical Treatment Guidelines state that anxiety medications in chronic pain are recommend for diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications. ACOEM (2004) section on Stress related conditions page 388 suggest to limit use of anti-anxiety agents to short periods of time, i.e., periods when overwhelming anxiety limits the patient's ability to work or effectively perform the activities of daily living. ODG identifies that anxiety medications in chronic pain are recommend for diagnosing and controlling anxiety as an important part of chronic pain treatment. In addition, the FDA identifies that Risperdal is indicated for the acute and maintenance treatment of schizophrenia, the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder, and the treatment of irritability associated with autistic disorder in children and adolescents. ODG Pain Chapter (Anxiety Medications) - ODG states that anxiety medications in chronic pain are recommend for diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis. The anxiety disorders with the greatest evidence for the efficacy of pharmacotherapy are GAD, PD, and SAD, and OCD. The FDA identifies that Risperdal is indicated for the acute and maintenance treatment of schizophrenia, the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder, and the treatment of irritability associated with autistic disorder in children and adolescents. (http://www.drugs.com/pro/risperdal.html) Regarding Risperdal and Risperidone, medical necessity has not been established. The patient has been documented to have anxiety according to psychological testing. However, there is no discussion as to why there is a need for two prescriptions for the same medication. It is noted that the patient is being prescribed Risperdal 1 mg nightly. There is a duplicate request from this treating provider for 0.5 mg (two tablets at bedtime for the same dosing). [redacted] is not prescribing this medication since the RFA submitted by him in the medical report dated 6/5/2013 did not include these medications. MTUS Chronic Pain Medical Treatment Guidelines states that anxiety medications in chronic pain are recommend for diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications. ACOEM (2004) section on Stress related conditions page 388 suggest to limit use of anti-anxiety agents to short periods of time, i.e., periods when overwhelming anxiety limits the patient's ability to work or

effectively perform the activities of daily living. ODG identifies that anxiety medications in chronic pain are recommended for diagnosing and controlling anxiety as an important part of chronic pain treatment. Therefore, the request for retrospective Risperdal 1mg is not medically necessary and appropriate.

Retrospective Risperidone 5mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 388. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Anti-Anxiety.

Decision rationale: Regarding Risperidone, medical necessity has not been established. The patient has been documented to have anxiety according to psychological testing. However, there is no discussion as to why there is a need for two prescriptions for the same medication. It is noted that the patient is being prescribed Risperdal 1 mg nightly. There is a duplicate request from this treating provider for 0.5 mg (two tablets at bedtime for the same dosing). [redacted] is not prescribing this medication since the RFA submitted by him in the medical report dated 6/5/2013 did not include these medications. CA-MTUS Chronic Pain Medical Treatment Guidelines states that anxiety medications in chronic pain are recommend for diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications. ACOEM (2004) section on Stress related conditions page 388 suggest to limit use of anti-anxiety agents to short periods of time, i.e., periods when overwhelming anxiety limits the patient's ability to work or effectively perform the activities of daily living. ODG identifies that anxiety medications in chronic pain are recommended for diagnosing and controlling anxiety as an important part of chronic pain treatment. Therefore, the request for retrospective Risperidone 5mg is not medically necessary and appropriate.

Retrospective Trazadone 50mg: 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), Mental Illness & Stress Chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Mental Illness & Stress Chapter, and Daily Med.

Decision rationale: Trazadone 50 mg (2 QHS) CA MTUS (Effective July 18 2009) mute about Trazadone. According to Daily Med, Trazadone hydrochloride is indicated for the treatment of depression. The efficacy of Trazadone has been demonstrated in both inpatient and out-patient settings and for depressed patients with and without prominent anxiety. The depressive illness of patients studied corresponds to the Major Depressive Episode criteria of the American Psychiatric Association's Diagnostic and Statistical Manual, III. The mechanism of Trazadone's antidepressant action in man is not fully understood. In animals, Trazodone selectively inhibits serotonin uptake by brain synaptosomes and potentiates the behavioral changes induced by the serotonin precursor, 5-hydroxytryptophan. Cardiac conduction effects of Trazadone in the anesthetized dog are qualitatively dissimilar and quantitatively less pronounced than those seen with tricyclic antidepressants. Trazadone is not a monoamine oxidase inhibitor and, unlike

amphetamine-type drugs, does not stimulate the central nervous system. ODG Mental Illness & Stress Chapter Recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. See also Insomnia treatment, where it says there is limited evidence to support its use for insomnia, but it may be an option in patients with coexisting depression. See also Fibromyalgia in the Pain Chapter, where Trazadone was used successfully in fibromyalgia. Trazadone was approved in 1982 for the treatment of depression. It is unrelated to tricyclic or tetracyclic antidepressants and has some action as an anxiolytic. Off-label uses include alcoholism, anxiety, insomnia, and panic disorder. Although approved to treat depression, the American Psychiatric Association notes that it is not typically used for major depressive disorder. Over the period 1987 through 1996, prescribing Trazadone for depression decreased throughout the decade, while off-label use of the drug for insomnia increased steadily until it was the most frequently prescribed insomnia agent. To date there has been only one randomized, double blind, placebo-controlled trial studying Trazadone in primary insomnia. It was observed that relative to placebo, patients reported significant improvement in subjective sleep latency, sleep duration, wake time after sleep onset, and sleep quality with Trazadone and Zolpidem during week one, but during week two the Trazadone group did not differ significantly from the placebo group whereas the Zolpidem group demonstrated significant improvement compared to placebo for sleep latency and sleep duration. (Walsh, 1998) The AHRQ Comparative Effectiveness Research on insomnia concludes that Trazadone is equal to Zolpidem. (AHRQ, 2008) Evidence for the off label use of Trazadone for treatment of insomnia is weak. The current recommendation is to utilize a combined pharmacologic and psychological and behavior treatment when primary insomnia is diagnosed. Also worth noting, there has been no dose-finding study performed to assess the dose of Trazadone for insomnia in non-depressed patients. Other pharmacologic therapies should be recommended for primary insomnia before considering Trazadone, especially if the insomnia is not accompanied by comorbid depression or recurrent treatment failure. There is no clear-cut evidence to recommend Trazadone first line to treat primary insomnia. The patient uses this as a sleep aid however, there is insufficient information about the patient's sleep hygiene habits nor was there any mention of education of proper sleep hygiene. The patient is noted to have depression however; there are no evaluations or scores from testing to provide a trend of improvement. The documentation does not support ongoing subjective and objective functional improvements attributed to this medication such as improved ADLs, decreased pain scores, and increased physical capacity. ODG recommends Trazadone as an option for insomnia only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. Therefore, the request for retrospective Trazadone is not medically necessary.

Viagra trial: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation, The American Urological Association Treatment Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Daily Med, and The American Urological Association Treatment Guidelines.

Decision rationale: CA-MTUS (effective July 18, 2009) is mute about Viagra. According to Daily Med, VIAGRA, an oral therapy for erectile dysfunction, is the citrate salt of sildenafil, a selective inhibitor of cyclic guanosine monophosphate (CGMP) - specific phosphodiesterase type 5 (PDE5). VIAGRA is indicated for the treatment of erectile dysfunction. The physiologic mechanism of erection of the penis involves release of nitric oxide (NO) in the corpus

cavernosum during sexual stimulation. NO then activates the enzyme guanylate cyclase, which results in increased levels of cyclic guanosine monophosphate (CGMP), producing smooth muscle relaxation in the corpus cavernousum and allowing inflow of blood. Sildenafil has no direct relaxant effect on isolated human corpus cavernosum, but enhances the effect of nitric oxide (NO) by inhibiting phosphodiesterase type 5 (PDE5), which is responsible for degradation of CGMP in the corpus cavernosum. When sexual stimulation causes local release of NO, inhibition of PDE5 by sildenafil causes increased levels of CGMP in the corpus cavernosum, resulting in smooth muscle relaxation and inflow of blood to the corpus cavernosum. Sildenafil at recommended doses has no effect in the absence of sexual stimulation. Consistent with its known effects on the nitric oxide/CGMP pathway (see CLINICAL PHARMACOLOGY), VIAGRA was shown to potentiate the hypotensive effects of nitrates, and its administration to patients who are using organic nitrates, either regularly and/or intermittently, in any form is therefore contraindicated. After patients have taken VIAGRA, it is unknown when nitrates, if necessary, can be safely administered. Based on the pharmacokinetic profile of a single 100 mg oral dose given to healthy normal volunteers, the plasma levels of sildenafil at 24 hours post dose are approximately 2 ng/mL (compared to peak plasma levels of approximately 440 ng/mL) (see CLINICAL PHARMACOLOGY: Pharmacokinetics and Metabolism). In the following patients: age >65, hepatic impairment (e.g., cirrhosis), severe renal impairment (e.g., creatinine clearance <30 mL/min), and concomitant use of potent cytochrome P450 3A4 inhibitors (erythromycin), plasma levels of sildenafil at 24 hours post dose have been found to be 3 to 8 times higher than those seen in healthy volunteers. Although plasma levels of sildenafil at 24 hours post dose are much lower than at peak concentration, it is unknown whether nitrates can be safely co-administered at this time point. VIAGRA is contraindicated in patients with a known hypersensitivity to any component of the tablet. The patient complains of impotence. However, there is no documentation of an evaluation of sexual function, including history and physical exam, to identify comorbid conditions which may contraindicate certain drug therapies and address other causes of sexual dysfunction (including psychological). The American Urological Association Treatment Guidelines recommend phosphodiesterase type 5 inhibitors (Viagra) as a first-line therapy for erectile dysfunction, unless contraindicated following an in-person evaluation that includes sexual, medical, and psychosocial histories as well as laboratory tests thorough enough to identify co-morbid conditions that may predispose the patient to ED and that may contraindicate certain therapies. Therefore based on the available evidence, the request for Viagra trial is not medically necessary.