

Case Number:	CM15-0011564		
Date Assigned:	01/30/2015	Date of Injury:	04/30/2008
Decision Date:	03/18/2015	UR Denial Date:	01/13/2015
Priority:	Standard	Application Received:	01/21/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 year old male, who sustained an industrial injury on 4/30/2008. He has reported cervical injuries after several accidents at work. The diagnoses have included pseudoarthrosis, foraminal stenosis and complicated pain syndrome. Surgeries included anterior cervical discectomy and fusion with removal of anterior plate. Treatment to date has included medications, diagnostics, conservative measures and surgery. Currently, the injured worker complains of increased neck pain with limited range of motion. He continues to have a lot of neck pain and difficulty sleeping at night with change in position causing increased neck pain. Physical exam revealed spasm and tenderness at the neck with limited motion. The x-ray of cervical spine dated 12/3/14 revealed consolidation on the bone graft. Request was for Tylenol, atarax, and zanaflex. On 1/13/15 Utilization Review non-certified a request for Tylenol #4 with 3 refills, Atarax 25mg # 30 with 3 refills and Zanaflex 4mg #60 with 3 refills, noting the requested medications are not medically necessary. The guidelines do not support the long term use of muscle relaxants. There was no documentation of significant change in pain relief, objective improvement in function to warrant the continued use of the medications. The (MTUS) Medical Treatment Utilization Schedule and Official Disability Guidelines (ODG) were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tylenol #4 with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Codeine Page(s): 35. Decision based on Non-MTUS Citation Pain; Tylenol with Codeine

Decision rationale: MTUS and ODG state regarding codeine, "Recommended as an option for mild to moderate pain, as indicated below. Codeine is a schedule C-II controlled substance. It is similar to morphine. 60 mg of codeine is similar in potency to 600 mg of acetaminophen. It is widely used as a cough suppressant. It is used as a single agent or in combination with acetaminophen (Tylenol with Codeine) and other products for treatment of mild to moderate pain." ODG further states regarding opioid usage, "Not recommended as a first-line treatment for chronic non-malignant pain, and not recommended in patients at high risk for misuse, diversion, or substance abuse. Opioids may be recommended as a 2nd or 3rd line treatment option for chronic non-malignant pain, with caution, especially at doses over 100 mg morphine equivalent dosage/day (MED)." The medical records do not indicate what first-line treatment was tried and failed. Additionally, medical records do not detail how the patient's pain and functional level with Tylenol with Codeine has improved. As such, the request for Tylenol with Codeine is not medically necessary.

Atarax 25mg # 30 with 3 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain; anxiety medications in chronic pain

Decision rationale: Atarax is a medication used for anxiety. Regarding this, MTUS is silent, but ODG states: "commend diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Benzodiazepines are not recommended for longer than two weeks. Definition of anxiety disorders: Anxiety disorders for this entry include (1) generalized anxiety disorder (GAD); (2) panic disorder (PD); (3) post-traumatic stress disorder (PTSD); (4) social anxiety disorder (SAD); & (5) obsessive-compulsive disorder (OCD). Descriptions of each are included below. Anxiety affects millions of Americans and leads to a decreased quality of life and productivity. In any given year approximately 40 million American adults ages 18 and older have an anxiety disorder (approximately 18.1 percent). Approximately 62% of anxiety disorders are associated with other mental health disorders, in particular depression. Substance abuse is also a frequent co-morbid condition. Anxiety and chronic pain: Anxiety is commonly found in patients with chronic pain, with the most common disorders being specific phobia (12.5% to 15.7%), SAD (8.3% to 11.8%) and PTSD (7.3% to 10.7%). These rates are higher than those found in the general US population. There is some evidence to suggest that anxiety disorders precede the onset of pain. Research is still needed to determine the temporal sequence. (Roy-

Byrne, 2008) (Baldwin, 2005) (Bandelow, 2002) (Hoffman, 2008) Overview of pharmacotherapy: The anxiety disorders with the greatest evidence for the efficacy of pharmacotherapy are GAD, PD, and SAD, and OCD. There is more limited evidence for pharmacotherapy for PTSD. Many antidepressants, in particular the Selective Serotonin Reuptake Inhibitors (SSRIs) are considered first-line agents in the treatment of most forms of anxiety. They have a more favorable side-effect profile than monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants (TCAs). (1) Generalized Anxiety Disorder (GAD): GAD is characterized by anxiety/tension, excessive worry, restlessness, fatigability, poor concentration, irritability, muscle tension and poor sleep. Treatment for GAD is patient specific and the following serves only as a guide in providing pharmacotherapy. Some patients may require adjunctive psychotherapy, such as cognitive behavioral therapy (CBT) or may prefer psychotherapy, instead of pharmacotherapy. (Zwanzger, 2008) SSRIs or SNRIs are typically first line agents for GAD. TCAs such as imipramine have been shown to be somewhat effective, but are not recommended as first-line agents due to side effects in particular. Outcomes are measured with tests such as the Hamilton Rating Scale for Anxiety (HAM-A), the Clinical Global Impression Improvement (CGI-I) scale and Clinical Global Impression Severity (CGI-S) scale. (Hoffman, 2008) (Kapczinski-Cochrane, 2003) (Schmitt, 2005) (a) SSRIs: Escitalopram (Lexapro, no generic available): also approved for major depressive disorder. Dosing information: 10-20 mg once daily. Paroxetine (Paxil, generic available): Also recommended for PD, SAD, OCD, and PTSD as well as major depressive disorder. Dosing information: 20-50 mg daily. (Package insert, GlaxoSmithKline) Setraline (Zoloft, generic available): Studies have shown effectiveness but not FDA-approved for this indication. Dosing information: 50-150 mg daily. (b) SNRIs: Duloxetine (Cymbalta, no generic available): also approved for major depressive disorder. Dosing information: 30-120 mg daily. Venlafaxine extended release (Effexor XR, generic available): also recommended for PD and SAD as well as major depressive disorder. Dosing information: 75-225 mg daily. It may be recommended for some patients to start at 37.5 mg for the first 4 to 7 days. (Package insert) (c) 5-HT1A Agonist: Buspirone (Buspar, generic available): also approved for short-term relief of anxiety symptoms. Efficacy is decreased in patients with recent prior benzodiazepine use. (Chessick, 2006) Dosing information: 5-15 mg three times daily. (Package insert) (d) Benzodiazepines: Effective for acute treatment. Long-term use is problematic as few patients achieve and sustain remission with monotherapy. These agents are used primarily as an adjunct for stabilization during initiation of an SSRI or SNRI. The disadvantage of use is the risk of abuse and physiological dependence with long-term use. These drugs also have no anti-depressant effect. Diazepam (Valium, generic available): Dosing information: 5-15 mg daily. Clonazepam (Klonopin, generic available): Dosing information: 1-2 mg up to TID. (e) TCAs (Tricyclic antidepressants): This class of medications is an effective treatment for GAD but few studies have investigated their use for DSM-IV defined GAD. Their use is limited by poorer tolerability. (f) Other medications that may be useful: Hydroxyzine (Atarax, generic available): Dosing information: 50 mg/day. Pregabalin (Lyrica, generic available): Non-FDA approved indication. Dosing information: 50-200mg three times daily (with a general range of 200-450 mg a day) Atypical antipsychotics: Olanzapine (Zyprexa) and Risperidone (generic available): used as an adjunct agent."There is no medical evidence of a generalized anxiety disorder diagnosis or treatment from a psych professional. Therefore, the request for Atarax 25mg #30 with 3 refills is not medically necessary.

Zanaflex 4mg #60 with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 63-67.

Decision rationale: Zanaflex is the brand name version of tizanidine, which is a muscle relaxant. MTUS states concerning muscle relaxants "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) (VanTulder, 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) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)."MTUS further states, "Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007)." Refills are not appropriate for Zanaflex due to the need for medical monitoring. As such, the request for Zanaflex 4mg #with 3 refills is not medically necessary.