

Case Number:	CM14-0178434		
Date Assigned:	10/31/2014	Date of Injury:	03/02/2009
Decision Date:	12/08/2014	UR Denial Date:	10/07/2014
Priority:	Standard	Application Received:	10/28/2014

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 Psychiatry & Neurology and Addiction Medicine, has a subspecialty in Geriatric Psychiatry 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 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:

Records reviewed include 316 pages of medical and administrative records. The injured worker is a 35 years old male whose date of injury is 03/02/2009, which occurred after lifting a heavy object weighing over 50 lbs. The patient's job entailed standing, bending, walking, lifting, and driving. His diagnosis is major depressive disorder single episode severe. A PR2 of 08/14/14 shows subjective/objective findings of impairments of sleep, energy, concentration, memory, emotional control, and stress tolerance. He was anxious and had low back pain. The patient was worried about his future and financial issues, and felt that the surgeries of his right arm were not helping. He had been unable to come to therapy due to having only one car and his wife was also injured. He was continued on Wellbutrin SR 150mg three QAM, Celexa 40mg QHS, Klonopin TID prn anxiety, and Ambien 10mg at HS prn insomnia, each with two refills. A pain medicine re-evaluation of 10/08/2014 indicated a pain rating of 6-7/10 with medications, 9-10 without medications, which had worsened recently. He also reported moderate nausea. He described neck pain as severe and burning, pins and needles, and radiating bilaterally down the upper extremities with constant tingling up the right upper extremity to the fingers, associated with bilateral occipital headaches. He also complained of constant low back pain which is aching, burning, stabbing, and severe, radiating bilaterally to the lower extremities accompanied by numbness to the toes bilaterally. He reported difficulty sleeping due to pain. Ambulation, activity, hand function, sleep, and sex are limited. Diagnoses were thoracic disc displacement, lumbar disc degeneration, chronic pain other, lumbar radiculopathy, fibromyalgia, failed epidurals, CESI and LESI, right index finger partial amputation, status post carpal tunnel surgery, and status post shoulder and ankle surgeries. He had developed opiate tolerance due to long term use. He was on home exercise. Medications included gabapentin, hydrocodone, Nucynta, Norco, Flexeril, and

Xanax. There is a letter of objection to the defendant's denial of medication refill of 10/16/2014 stating that if the patient is forced to go without his Wellbutrin SR and Celexa (ordered on 08/14/2014) he will be at risk of becoming acutely suicidal. This report indicates that on 06/23/2011 the patient was seen in initial psychological evaluation by [REDACTED]. He underwent outpatient psychiatric and psychological treatment, having developed major depressive disorder. There was another report of 09/05/2011 report indicating that the patient received psychotropic medications and cognitive behavioral psychotherapy. On 03/28/2012 the patient was on Celexa, Wellbutrin, Ativan, and Ambien, and he found psychotherapy beneficial. He was having panic attacks, suicidal ideation was successfully managed. From 11/01/2012 medications had consisted of Klonopin 1mg TID, Ambien 10mg at HS, Wellbutrin SR 150mg QAM, and Celexa 50mg QHS. On 03/28/2014 it was noted that the patient required two antidepressants and Wellbutrin 450mg per day due to the patient's relative intractability of industrially related major depressive disorder by other therapies, and that various antidepressants and various doses had established that no one medication was sufficient. The clonazepam was necessary daily to manage his frequent panic attacks and allow him to perform the relaxation exercises learned in psychotherapy (apparently he is able to do so with medication). Without Ambien the patient's mind raced with worry, he was unable to find sufficient comfort in bed to fall asleep within a reasonable period of time, and tosses and turns. Diagnoses were major depressive disorder and atypical anxiety disorder with panic attacks. A utilization review and notice of denial of 10/7/2014 indicated that the case was reviewed with [REDACTED]. The patient had already attended 20 psychotherapy sessions

IMR ISSUES, DECISIONS AND RATIONALES

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

Wellbutrin 150mg SR #270: 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 Official Disability Guidelines (ODG) Mental Illness & Stress, Antidepressants for treatment of MDD major depressive disorder

Decision rationale: The patient has been on this treatment regimen of Wellbutrin and Celexa, with increased dosage of Wellbutrin. It is common practice in the community to prescribe antidepressants from two classes of medications in a patient with difficult to treat symptoms. However, no evidence or description was provided of the stated failure of various other antidepressants at various dosages, length of time of these trials, or if augmentation strategies were attempted. Cymbalta and Effexor have been FDA approved for anxiety, depression, and neuropathic pain, and Effexor for panic disorder. No documentation was provided as to a baseline level of symptoms, the severity of his symptoms, or level of improvement in his symptoms. While it would be contraindicated to abruptly discontinue medications in a depressed patient, a request for #270 is excessive until supporting documentation is provided. This request therefore is not medically necessary.

Celexa 40mg #90: 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 Official Disability Guidelines (ODG) Mental Illness & Stress, Antidepressants for treatment of MDD major depressive disorder

Decision rationale: The patient has been on this treatment regimen of Wellbutrin and Celexa, with increased dosage of Wellbutrin. It is common practice in the community to prescribe antidepressants from two classes of medications in a patient with difficult to treat symptoms. However, no evidence or description was provided of the stated failure of various other antidepressants at various dosages, length of time of these trials, or if augmentation strategies were attempted. Cymbalta and Effexor have been FDA approved for anxiety, depression, and neuropathic pain, and Effexor for panic disorder. In any case, symptoms reported were impairments of sleep, energy, concentration, memory, emotional control, and stress tolerance on 08/14/14, along with a letter of 10/16/14 indicating that the patient would be put at risk without antidepressant medications. No documentation was provided as to a baseline level of symptoms (e.g. rating scales), the severity of his symptoms, or level of improvement in his symptoms. While it would be contraindicated to abruptly discontinue medications in a depressed patient, a request for #90 is excessive until supporting documentation is provided. This request therefore is not medically necessary. MTUS does not specifically reference Celexa, a SSRI antidepressant. It references SSRI's in general as they relate to psychological factors related to chronic pain. ODG was utilized in this decision. ODG: Recommended for initial treatment of presentations of Major Depressive Disorder (MDD) that are moderate, severe, or psychotic, unless electroconvulsive therapy is part of the treatment plan. Not recommended for mild symptoms. Professional standards defer somewhat to patient preference, allowing for a treatment plan for mild to moderate MDD to potentially exclude antidepressant medication in favor of psychotherapy if the patient favors such an approach. (American Psychiatric Association, 2006) A randomized controlled trial has indicated that the patient's smoking status is a credible factor that can be considered in the treatment plan. Specifically, antidepressant medication (fluoxetine/Prozac) has been found to compromise the success of smoking cessation efforts. (Spring, 2007) Consequently, if the patient is attempting to quit smoking, that effort causes anti-depressant medication to be a less attractive treatment option than standards typically indicate (this consideration will be most relevant to presentations of MDD which are mild to moderate in current severity). Drug selection criteria. The American Psychiatric Association has published the following considerations regarding the various types of anti-depressant medications: (1) Many treatment plans start with a category of medication called selective serotonin reuptake inhibitors (SSRIs), because of demonstrated effectiveness and less severe side effects; (2) In addition to the SSRIs, other anti-depressant medications that are likely to be optimal for most patients include desipramine, nortriptyline, bupropion, and venlafaxine; (3) Another group of antidepressant medications, called monoamine oxidase inhibitors (MAOIs), are not recommended as a primary treatment option, because they are associated with serious side effects, and they necessitate dietary restrictions. This category of medication should be considered only for cases that do not respond to other options. American Psychiatric Association, 2006.

Klonopin 1mg #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 Benzodiazepines Page(s): 24 of 127.

Decision rationale: Klonopin is a benzodiazepine, which is not recommended for long term use per MTUS. In addition, again per MTUS and community standard, the treatment of choice for anxiety disorders is an antidepressant. No medication history has been provided to show whether or not the patient's anxiety responded to antidepressants (e.g. Cymbalta or Effexor, as noted above), or if a nonbenzodiazepine medication (e.g. buspirone) was attempted. No documentation was provided as to a baseline level of symptoms (e.g. rating scales), the severity of his symptoms, or quantitative level of improvement in his symptoms. While it would be contraindicated to abruptly discontinue a benzodiazepine such as Klonopin due to the risk of seizure, the request for #270 is excessive. This request therefore is not medically necessary. MTUS: 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.

Ambien 10mg #90: 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 Official Disability Guidelines (ODG) Pain, Insomnia treatment

Decision rationale: The patient has been prescribed Ambien for insomnia since at least 03/2012. Per community standard, as well as ODG, insomnia is best treated in the long term based on etiology-in this patient's case, pain management and anxiety control. Per ODG, prescribing medication will not work indefinitely. Records do not reflect whether or not other sleep agents were attempted, e.g. Rozarem, sedating antidepressants such as trazodone or mirtazapine (which may have the added benefit of augmenting his existing antidepressant regimen), or Lunesta-which is the only nonbenzodiazepine approved for use for greater than 35 days. Other techniques to aid insomnia would include sleep hygiene and CBT skills, which the patient attested to having learned. It is unclear what functional benefit the patient is deriving from his current medication regimen, given his ongoing difficulties, and he may benefit from a

pharmacologic consultation. As such, this request therefore is not medically necessary. MTUS does not reference insomnia treatment or Ambien, ODG was utilized in this decision. ODG: Recommend that treatment be based on the etiology, with the medications recommended below. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. (Lexi-Comp, 2008) Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Pharmacologic Treatment: There are four main categories of pharmacologic treatment: (1) Benzodiazepines; (2) Non-benzodiazepines; (3) Melatonin & melatonin receptor agonists; & (4) Over-the-counter medications. The majority of studies have only evaluated short-term treatment (i.e., 4 weeks) of insomnia; therefore more studies are necessary to evaluate the efficacy and safety of treatments for long-term treatment of insomnia. In 2007, the FDA requested that manufacturers of all sedative-hypnotic drugs strengthen product labeling regarding risks (i.e., severe allergic reactions and complex sleep-related behaviors, such as sleep driving). It is recommended that treatments for insomnia should reduce time to sleep onset, improve sleep maintenance, avoid residual effects and increase next-day functioning. (Morin, 2007) (Reeder, 2007) (1) Benzodiazepines: FDA-approved benzodiazepines for sleep maintenance insomnia include estazolam (ProSom), flurazepam (Dalmane), quazepam (Doral), and temazepam (Restoril). Triazolam (Halcion) is FDA-approved for sleep-onset insomnia. These medications are only recommended for short-term use due to risk of tolerance, dependence, and adverse events (daytime drowsiness, anterograde amnesia, next-day sedation, impaired cognition, impaired psychomotor function, and rebound insomnia). These drugs have been associated with sleep-related activities such as sleep driving, cooking and eating food, and making phone calls (all while asleep). Particular concern is noted for patients at risk for abuse or addiction. Withdrawal occurs with abrupt discontinuation or large decreases in dose. Decrease slowly and monitor for withdrawal symptoms. Benzodiazepines are similar in efficacy to benzodiazepine-receptor agonists; however, the less desirable side-effect profile limits their use as a first-line agent, particularly for long-term use. (Holbrook, 2000) (Ramakrishnan, 2007) (Buscemi, 2007) (Morin, 2007) (Wafford, 2008) (Benca, 2005). (2) Non-Benzodiazepine sedative-hypnotics (Benzodiazepine-receptor agonists): First-line medications for insomnia. This class of medications includes zolpidem (Ambien and Ambie CR), zaleplon (Sonata), and eszopicolone (Lunesta). All of the benzodiazepine-receptor agonists are schedule IV controlled substances, which means they have potential for abuse and dependency. Although direct comparisons between benzodiazepines and the non-benzodiazepine hypnotics have not been studied, it appears that the non-benzodiazepines have similar efficacy to the benzodiazepines with fewer side effects and short duration of action. (Ramakrishnan, 2007) (Halas, 2006) (Buscemi, 2007) (Morin, 2007) (Erman, 2005) Zolpidem [Ambien (generic available), Ambien CR] is indicated for the short-term treatment of insomnia with difficulty of sleep onset (7-10 days). Ambien CR is indicated for treatment of insomnia with difficulty of sleep onset and/or sleep maintenance. Longer-term studies have found Ambien CR to be effective for up to 24 weeks in adults. (Buscemi, 2005) (Ramakrishnan, 2007) (Morin, 2007). The extended-release dual-layer tablet (Ambien CR) has a biphasic release system; an initial release of zolpidem reduces sleep latency and a delayed release facilitates sleep maintenance. Side effects: headache, daytime drowsiness, dizziness, blurred vision, confusion, abnormal thinking and bizarre behavior have occurred. Sleep driving and other activities for which the

patient has no recollection may occur. The medication should be discontinued if the latter occurs. Abrupt discontinuation may lead to withdrawal. Dosing: Ambien 5 to 10 mg at bedtime (5 mg in women, the elderly and patients with hepatic dysfunction); Ambien CR 6.25 to 12.5 mg at bedtime (6.25 mg in women, the elderly and patients with hepatic dysfunction) (Morin, 2007). Adults who use zolpidem have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. (Kripke, 2012) Due to adverse effects, FDA now requires lower doses for zolpidem. The dose of zolpidem for women should be lowered from 10 mg to 5 mg for IR products (Ambien, Edluar, Zolpimist, and generic) and from 12.5 mg to 6.25 mg for ER products (Ambien CR). (FDA, 2013) See also Zolpidem. Zaleplon (Sonata) reduces sleep latency. Side effects: headache, drowsiness, dizziness, fatigue, confusion, abnormal thinking. Sleep-related activities have also been noted such as driving, cooking, eating and making phone calls. Abrupt discontinuation may lead to withdrawal. Dosing: 10 mg at bedtime (5 mg in the elderly and patients with hepatic dysfunction). (Morin, 2007) Because of its short half-life (one hour), may be readministered upon nocturnal waking provided it is administered at least 4 hours before wake time. (Ramakrishnan, 2007) This medication has a rapid onset of action. Short-term use (7-10 days) is indicated with a controlled trial showing effectiveness for up to 5 weeks. Eszopicolone (Lunesta has demonstrated reduced sleep latency and sleep maintenance. (Morin, 2007) The only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. A randomized, double blind, controlled clinical trial with 830 primary insomnia patients reported significant improvement in the treatment group when compared to the control group for sleep latency, wake after sleep onset, and total sleep time over a 6-month period. (Walsh, 2007) Side effects: dry mouth, unpleasant taste, drowsiness, dizziness. Sleep-related activities such as driving, eating, cooking and phone calling have occurred. Withdrawal may occur with abrupt discontinuation. Dosing: 1-2 mg for difficulty falling asleep; 2-3 mg for sleep maintenance. The drug has a rapid onset of action. (Ramakrishnan, 2007) Sedating antidepressants (e.g., amitriptyline, trazodone, mirtazapine) have also been used to treat insomnia; however, there is less evidence to support their use for insomnia (Buscemi, 2007) (Morin, 2007), but they may be an option in patients with coexisting depression. (Morin, 2007) Trazodone is one of the most commonly prescribed agents for insomnia. Side effects of this drug include nausea, dry mouth, constipation, drowsiness, and headache. Improvements in sleep onset may be offset by negative next-day effects such as ease of awakening. Tolerance may develop and rebound insomnia has been found after discontinuation. (3) Melatonin-receptor agonist: Ramelteon (Rozerem is a selective melatonin agonist (MT1 and MT2) indicated for difficulty with sleep onset; is nonscheduled (has been shown to have no abuse potential). One systematic review concluded that there is evidence to support the short-term and long-term use of ramelteon to decrease sleep latency; however, total sleep time has not been improved. (Reynoldson, 2008) (Zammit, 2007) Ramelteon is not a controlled substance. Side effects: CNS depression, somnolence, dizziness, fatigue, abnormal thinking and bizarre behavior have occurred. Use with caution in patients with depression, hepatic impairment, and respiratory conditions such as COPD or sleep apnea. Dosing: 8mg within 30 minutes of bedtime; recommended for short-term (7 - 10 days) use only. (4) Over-the-counter medications: Sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. Non-pharmacologic treatment: Empirically supported treatment includes stimulus

control, progressive muscle relaxation, and paradoxical intention. Treatments that are thought to probably be efficacious include sleep restriction, biofeedback, and multifaceted cognitive behavioral therapy. Suggestions for improved sleep hygiene: (a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping. (Benca, 2005) In a head-to-head comparison of treatment approaches to determine separate and combined effects on insomnia, adding a prescription sleeping pill to cognitive behavioral therapy (CBT) appeared to be the optimal initial treatment approach in patients with persistent insomnia, but after 6 weeks, tapering the medication and continuing with CBT alone produced the best long-term outcome. These results suggest that there is a modest short-term added value to starting therapy with CBT plus a medication, especially with respect to total sleep gained, but that this added value does not persist. In terms of first-line therapy, for acute insomnia lasting less than 6 months, medication is probably the best treatment approach, but for chronic insomnia, a combined approach might give the best of both worlds; however, after a few weeks, the recommendation is to discontinue the medication and continue with CBT. Prescribing medication indefinitely will not work. The authors said that the conclusion that patients do better in the long term if medication is stopped after 6 weeks and only CBT is continued during an additional 6-month period is an important new finding. Morin, 2009.

Cognitive Behavioral Therapy Psychotherapy for 2 sessions: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Cognitive Behavioral Therapy (CBT) guidelines for chronic pain

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, Cognitive Therapy for Depression

Decision rationale: Per UR mentioned above, the patient has used 20 sessions of psychotherapy. No recent records were provided beyond 08/14/2014. No records were provided to show the patient's baseline symptoms with objective functional improvement with treatment. This request therefore is not medically necessary. MTUS references CBT as it relates to chronic pain, therefore ODG was utilized in this decision. ODG Recommended. Cognitive behavior therapy for depression is recommended based on meta-analyses that compare its use with pharmaceuticals. Cognitive behavior therapy fared as well as antidepressant medication with severely depressed outpatients in four major comparisons. Effects may be longer lasting (80% relapse rate with antidepressants versus 25% with psychotherapy). (Paykel, 2006) (Bockting, 2006) (DeRubeis, 1999) (Goldapple, 2004) It also fared well in a meta-analysis comparing 78 clinical trials from 1977 -1996. (Gloaguen, 1998) In another study, it was found that combined therapy (antidepressant plus psychotherapy) was found to be more effective than psychotherapy alone. (Thase, 1997) A recent high quality study concluded that a substantial number of adequately treated patients did not respond to antidepressant therapy. (Corey-Lisle, 2004) A recent meta-analysis concluded that psychological treatment combined with antidepressant

therapy is associated with a higher improvement rate than drug treatment alone. In longer therapies, the addition of psychotherapy helps to keep patients in treatment. (Pampallona, 2004) For panic disorder, cognitive behavior therapy is more effective and more cost-effective than medication. (Royal Australian, 2003) The gold standard for the evidence-based treatment of MDD is a combination of medication (antidepressants) and psychotherapy. The primary forms of psychotherapy that have been most studied through research are: Cognitive Behavioral Therapy and Interpersonal Therapy. Maintenance cognitive-behavioral therapy (CBT) to prevent recurrent depression is most effective in patients at highest risk for relapse, defined as those with 5 or more previous depressive episodes. For individuals at more moderate risk for recurrence (fewer than 5 prior episodes), structured patient psychoeducation may be equally effective. High-risk patients in particular may benefit from specific elements of maintenance CBT by reducing cognitive vulnerability factors for recurrent depression, such as ruminating, negative attributions and memories, and dysfunctional beliefs, or by maintaining positive emotions when experiencing stress. (Stangier, 2013).