

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM15-0142352 | | |
| Date Assigned: | 10/13/2015 | Date of Injury: | 06/01/2006 |
| Decision Date: | 11/13/2015 | UR Denial Date: | 06/29/2015 |
| Priority: | Standard | Application Received: | 07/22/2015 |

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: California, Arizona, Maryland
Certification(s)/Specialty: Psychiatry

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 58-year-old male with an industrial injury dated 06-01-2006. Medical record review indicates he is being treated for major depressive disorder and post-traumatic stress disorder. In the progress note dated 06-05-2015 the injured worker reported "living on Latuda samples as he continues to have difficulty accessing his medications." The treating physician documented: "Some concerns with intermittent twitching but needing this dosing to manage paranoia and irritability." "His dose changes of both Depakote and Latuda are for breakthrough paranoia and mood instability." He continues to need higher than average doses." Objective findings are documented by the treating physician as "alert and oriented times 4, casually dressed, wearing braces on his wrists, pressured speech, psychomotor agitation, intrusive worries, paranoia, anxious and irritable mood, denies current suicidal ideation, flight of ideas." In the progress note dated 04-14-2015, the treating physician documented the injured worker presented "more pressured and agitated." "His paranoia and irritability were so severe, that he was completely disabled by these symptoms and unable to effectively advocate for himself, communicate, avoid conflicts with the police and avoid conflicts with his legal teams." "This is a very severe case it is only because of psychotropics that he has averted disaster (i.e. incarceration, hospitalization, altercations, completely alienating family supports etc.)" Physical findings (04-14-2015) are documented as "alert and oriented, casually dressed, speech is pressured today, some psychomotor agitation, intrusive, no overt delusions today, anxious and irritable mood, denies current suicidal ideation, flight of ideas." His medications included Depakote ER, Latuda, Lamotrigine, Eszopiclone and Duloxetine since at least 11-20-2014 and Lorazepam at least since 12-03-2014. Prior treatments included medications and psychiatric treatment. The treatment plan

included continue Depakote at 2000 mg at bedtime (down from 3000 mg), Latuda 400 mg per day, Lamotrigine 400 mg, Eszopiclone 3 mg at bedtime, Duloxetine 60 mg daily and Lorazepam 1 mg three times daily. Psychiatric disability status (06- 05-2015) is documented as permanent and stationary. The treatment request for the following medications was non-certified by utilization review on 06-29-2015: Lunesta 3 mg #30 with 11 refills. Latuda 80 mg #120 with 3 refills. Lamictal 200 mg #60 with 11 refills. Depakote 500 mg #180 with 11 refills. Cymbalta 60 mg #30 with 11 refills. Ativan 1 mg #90 with 11 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Latuda 80mg #120 with 3 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/latuda.html>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Mental Illness & Stress/Atypical anti-psychotics and Other Medical Treatment Guidelines FDA.gov: LATUDA.

Decision rationale: Per FDA.GOV, LATUDA is an atypical antipsychotic for the treatment of: Schizophrenia - Depressive episodes associated with Bipolar I Disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate. Per ODG, Atypical anti-psychotics: Not recommended as a first-line treatment. There is insufficient evidence to recommend atypical anti-psychotics (e.g., quetiapine, risperidone) as monotherapy for conditions covered in ODG. See PTSD pharmacotherapy. Adding an atypical anti-psychotic to an anti-depressant provides limited improvement in depressive symptoms in adults, new research suggests. The meta-analysis also shows that the benefits of anti-psychotics in terms of quality of life and improved functioning are small to nonexistent, and there is abundant evidence of potential treatment-related harm. The authors said that it is not certain that these drugs have a favorable benefit-to-risk profile. Clinicians should be very careful in using these medications. (Spielmans, 2013) The American Psychiatric Association (APA) has released a list of specific uses of common anti-psychotic medications that are potentially unnecessary and sometimes harmful. Anti-psychotic drugs should not be first-line treatment to treat behavioral problems. The injured worker has been diagnosed with major depressive disorder and post-traumatic stress disorder. Per FDA, Latuda is indicated for Depressive episodes associated with Bipolar I Disorder (bipolar depression). In this case, the injured worker has been diagnosed with Major depressive disorder and there is no report of bipolar depression for which Latuda is indicated. Thus, the request for Latuda 80mg #120 with 3 refills is not medically necessary.

Lunesta 3mg #30 with 11 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 (ODG), Lunesta (eszopiclone), Pain Chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain/ Insomnia Treatment.

Decision rationale: MTUS is silent regarding this issue. ODG states, Non-Benzodiazepine sedative-hypnotics (Benzodiazepine-receptor agonists) are First-line medications for insomnia. This class of medications includes zolpidem (Ambien and Ambien CR), zaleplon (Sonata), and eszopicolone (Lunesta). Benzodiazepine-receptor agonists work by selectively binding to type-1 benzodiazepine receptors in the CNS. All of the benzodiazepine-receptor agonists are schedule IV controlled substances, which mean they have potential for abuse and dependency. 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) According to the guidelines stated above, medications are not recommended for long-term treatment of insomnia and Lunesta has potential for abuse, dependency, withdrawal and tolerance. The request for a yearlong supply of Lunesta 3mg #30 with 11 refills is excessive and not medically necessary since this medication is not indicated for long-term use.

Ativan 1mg #90 with 11 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

Decision rationale: MTUS states, "Benzodiazepines are 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, anti-convulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Upon review of the Primary Treating Physicians' Progress Reports, the injured worker has been prescribed Ativan 1 mg three times daily on an ongoing basis with no documented plan of taper. The MTUS guidelines state that the use of benzodiazepines should be limited to 4 weeks. The request for a yearlong supply of Ativan 1mg #90 with 11 refills is excessive and not medically necessary since per guidelines benzodiazepines should be limited to 4 weeks.

Cymbalta 60mg #30 with 11 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-depressants for chronic pain, Tricyclics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Anti-depressants, Mental Illness and Stress.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Stress & Mental Illness/Anti-depressants for treatment of MDD (major depressive disorder).

Decision rationale: ODG states "MDD (major depressive disorder) treatment, severe presentations. The American Psychiatric Association strongly recommends anti-depressant

medications for severe presentations of MDD, unless electroconvulsive therapy (ECT) is being planned. (American Psychiatric Association, 2006). Many treatment plans start with a category of medication called selective serotonin reuptake inhibitors (SSRIs), because of demonstrated effectiveness and less severe side effects." The request for a yearlong supply of Cymbalta is excessive and not medically necessary, as it is not clinically recommended to continue a medication for a year without monitoring the response, tolerability etc at shorter intervals.

Lamictal 200mg #60 with 11 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-epilepsy drugs (AEDs).

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

Decision rationale: LAMICTAL is an anti-epileptic drug (AED) indicated for: Epilepsy "adjunctive therapy in patients, 2 years of age partial seizures, primary generalized tonic-clonic seizures, generalized seizures of Lennox-Gastaut syndrome. Epilepsy monotherapy in patients, 16 years of age: conversion to monotherapy in patients with partial seizures who are receiving treatment with carbamazepine, phenobarbital, phenytoin, primidone, orvalproate as the single AED. (1.1) Bipolar Disorder in patients, 18 years of age: maintenance treatment of Bipolar I Disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy. The injured worker has been diagnosed with major depressive disorder and post-traumatic stress disorder. Per FDA, Lamictal is indicated for Bipolar Disorder in patients, 18 years of age: maintenance treatment of Bipolar I Disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy. In this case, the injured worker has been diagnosed with Major depressive disorder and there is no report of bipolar depression for which Lamictal is indicated. Thus, the request for Lamictal 200mg #60 with 11 refills is not medically necessary.

Depakote 500mg #180 with 11 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/depakote.html>.

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

Decision rationale: Valproate products are FDA-approved drugs to treat seizures, and manic or mixed episodes associated with bipolar disorder (manic-depressive disorder), and to prevent migraine headaches. They are also used off-label (for unapproved uses) for other conditions, particularly for other psychiatric conditions. Valproate products include: valproate sodium (Depacon), divalproex sodium (Depakote, Depakote CP, and Depakote ER), valproic acid (Depakene and Stavzor), and their generics. The injured worker has been diagnosed with major depressive disorder and post-traumatic stress disorder. Per FDA, depakote is indicated for manic or mixed episodes associated with bipolar disorder (manic-depressive disorder). In this case, the injured worker has been diagnosed with Major depressive disorder and there is no report of bipolar depression for which Depakote is indicated. Thus, the request for Depakote 500mg #180 with 11 refills is not medically necessary.