MAXIMUS Federal Services

Case Number:	CM15-0083563		
Date Assigned:	05/05/2015	Date of Injury:	06/20/2007
Decision Date:	06/30/2015	UR Denial Date:	04/03/2015
Priority:	Standard	Application Received:	05/01/2015

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
Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 female, who sustained an industrial injury on 6/20/2007. Diagnoses include major depressive disorder single episode, generalized anxiety disorder and psychological factors affecting medical treatment. Treatment to date has included diagnostics and medications. Per the Primary Treating Physician's Progress Report dated 3/20/2015, the injured worker reported depression, changes in appetite, lack of motivation and sleep disturbances. Physical examination revealed depressed facial expressions, visible anxiety and a soft spoken affect. The plan of care included medications and authorization was requested for Cymbalta, Nuvigil, Cerefolin,, Estazolam and Alprazolam.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nurigil 250mg #30 with two 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain Chapter, Provigil.

Decision rationale: The patient was injured on 06/20/07 and presents with low back pain. The request is for NUVIGIL 250 MG #30 WITH 2 REFILLS. The RFA is dated 03/20/15 and the patient is permanent and stationary. The report with the request is not provided and there is only one progress report provided from 11/07/14. The ACOEM and MTUS guidelines do not discuss Armodafinil. However, ODG, Pain Chapter, Provigil guidelines have the following regarding Provigil (Modafinil): "Not recommended solely to counteract sedation effects of narcotics." Modafinil is used to treat excessive sleepiness caused by narcolepsy, obstructive sleep apnea or shift work sleep disorder. It is very similar to Amodafinil. Studies have not demonstrated any difference in efficacy and safety between armodafinil and modafinil. The patient is diagnosed with major depressive disorder single episode, generalized anxiety disorder, and psychological factors affecting medical treatment. Treatment to date has included diagnostics and medications. As of 11/07/14, the patient is taking Norco, Celebrex, Xanax, and Ambien. The report with the request is not provided, nor is there any discussion regarding this medication in the report provided. ODG indicates this medication for excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work sleep disorder, and none of these conditions are documented in the progress reports. Therefore, the requested Nuvigil IS NOT medically necessary.

Cerefolin NAC #30 with two 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/mtm/multivitamin.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain chapter, Medical Food The American Journal of Psychiatry. 2012 Dec; 169 (12):1267-74.

Decision rationale: The patient was injured on 06/20/07 and presents with low back pain. The request is for CEREFOLIN NAC #30 WITH 2 REFILLS. The utilization review denial rationale is that "there is no documentation of vitamin deficiencies." The RFA is dated 03/20/15 and the patient is permanent and stationary. The report with the request is not provided and there is only one progress report provided from 11/07/14. Cerefolin NAC is a medical food containing L-methylfolate (as Metafolin) 5.6 mg, methylcobalamin 2 mg, N-acetylcysteine 600 mg. It is FDA approved for the treatment of vitamin deficiency and is under study for use as an adjunct to SSRI medications in patients with major depressive disorder. ODG Medical food guidelines apply. ODG Pain chapter, under Medical Food states that it is intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must meet the following criteria: 1. The product must be a food for oral or tube feeding. 2. The product must be labeled for dietary management of a specific medical disorder. 3. The product must be used under medical supervision. A recent study, L-methylfolate as adjunctive therapy for SSRI-resistant major depression: results of two randomized, double-blind, parallel-sequential trials from The American Journal of Psychiatry. 2012 Dec; 169 (12):1267-74 concludes: "Adjunctive L-methylfolate at 15 mg/day may constitute an effective, safe, and relatively well tolerated treatment strategy for patients with major depressive disorder who have a partial response or no

response to SSRIs." The patient is diagnosed with major depressive disorder single episode, generalized anxiety disorder, and psychological factors affecting medical treatment. Treatment to date has included diagnostics and medications. As of 11/07/14, the patient is taking Norco, Celebrex, Xanax, and Ambien. The report with the request is not provided, nor is there any discussion regarding this medication in the report provided. While MTUS and ODG are silent on the use of this medication, the aforementioned study from the American Journal of Psychiatry has found L-methylfolate to be a safe and well tolerated adjunct to SSRI medications in patient's whose condition is not resolved by SSRI's alone. Given this patient's unresolved depression and recent peer-reviewed research from a major scientific journal, L-methylfolate may be appropriate but the other ingredients in this compounded medications are not. Furthermore, there is no discussion regarding this medical food, how it is being used and with what efficacy. Without such documentation, it cannot be supported. The request IS NOT medically necessary.

Estazolam 2mg #30 with two refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepine. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24. Decision based on Non-MTUS Citation Official disability guidelines Pain (Chronic) Chapter under Insomnia treatment.

Decision rationale: The patient was injured on 06/20/07 and presents with low back pain. The request is for ESTAZOLAM 2 MG #30 WITH 2 REFILLS. The RFA is dated 03/20/15 and the patient is permanent and stationary. The report with the request is not provided and there is only one progress report provided from 11/07/14.MTUS Chronic Pain Medical Treatment Guidelines page 24 for Benzodiazepines states: "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.ODG-TWC, Pain (Chronic) Chapter under Insomnia treatment states: "(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)."The patient is diagnosed with major depressive disorder single episode, generalized anxiety disorder, and psychological factors affecting medical treatment. Treatment to date has included diagnostics and medications. As of 11/07/14, the patient is taking Norco, Celebrex, Xanax, and Ambien. The report with the request is not provided, nor is there any discussion regarding this medication in the report provided. Neither MTUS nor ODG guidelines recommend benzodiazepine for long-term use. It is not known when Estazolam has been initiated. In this case, there is no diagnosis of insomnia or any sleep issues, as required by ODG guidelines. Furthermore, MTUS guidelines do not recommend benzodiazepines use for long-term and limits use to 4 weeks. The requested 30 tablet prescription with 2 refills does not indicate intended short-term use of this medication and

exceeds the 4 week limit by MTUS guidelines. The requested Estazolam IS NOT medically necessary.

Alprazolam 0.5mg #60 with two refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepine. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepine Page(s): 24. Decision based on Non-MTUS Citation Official disability guidelines Mental Illness & Stress Chapter under Benzodiazepine.

Decision rationale: The patient was injured on 06/20/07 and presents with low back pain. The request is for Alprazolam 0.5mg #60 with two refills. The RFA is dated 03/20/15 and the patient is permanent and stationary. The report with the request is not provided and there is only one progress report provided from 11/07/14.MTUS guidelines state on page 24 that 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, 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."ODG-TWC, Mental Illness & Stress Chapter under Benzodiazepine states: "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction." The patient is diagnosed with major depressive disorder single episode, generalized anxiety disorder, and psychological factors affecting medical treatment. Treatment to date has included diagnostics and medications. As of 11/07/14, the patient is taking Norco, Celebrex, Xanax, and Ambien. The report with the request is not provided, nor is there any discussion regarding this medication in the report provided. It is not known when Alprazolam has been initiated. Neither MTUS nor ODG guidelines recommend benzodiazepine for long-term use. It is not known when this medication was initiated. The requested 60 tablet prescription with 2 refills does not indicate intended short-term use of this medication and exceeds the 4 week limit by MTUS guidelines. The requested Alprazolam IS NOT medically necessary.