

Case Number:	CM14-0154001		
Date Assigned:	09/23/2014	Date of Injury:	12/03/2002
Decision Date:	11/05/2014	UR Denial Date:	09/16/2014
Priority:	Standard	Application Received:	09/22/2014

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 Family Medicine and is licensed to practice in Colorado. 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:

60 year old male with low back pain that radiates to both legs following occupational injury 12/3/2002, continues care with treating physician. Injured worker is status post L5-S1 fusion 5/20/2006, and has post laminectomy syndrome with chronic back pain. Injured worker has had epidural steroid injections and trial percutaneous spinal cord stimulator, and is maintained on long term opioid therapy. The documents supplied for review do not specify how long injured worker has been on opioids, but it has been greater than 6 months. Injured worker also follows with the treating physician for medication management of Mood Disorder, per the records. With the mood disorder, injured worker has difficulty sleeping as well. Injured worker does see a Psychiatrist, but reported to the treating physician that he receives no medications from that provider. No records from the Psychiatrist were available for review. Injured worker's treating physician prescribed Cymbalta, Abilify, and Deplin for mood, though did not specify how long injured worker has been taking these medications. Injured worker's mood is not directly addressed at his follow up visits, but it is noted that he chronically has poor quality sleep. Injured worker also has Diabetes Mellitus which has been deemed to be industrially-caused. The current request from the treating physician is for Kadian (PM dose), Abilify, Deplin, and Dilaudid.

IMR ISSUES, DECISIONS AND RATIONALES

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

Kadian Er 30mg Capsule; 1 tablet PM #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of Opioids Page(s): 74-82.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments, Page(s): 79-83,86.

Decision rationale: Per the guidelines, opioids are recommended for chronic pain as second-line treatment, after first-line treatments fail. Unless there are contraindications, first-line treatment for nociceptive pain should be acetaminophen and/or non-steroidal anti-inflammatory drugs, and first-line therapy for neuropathic pain should be tricyclic antidepressants and anticonvulsants. Opioids then would be added to the existing therapy to improve pain and function if needed. Opioids have been shown to help improve pain and function in chronic back pain, but only in the short term (less than 16 weeks), with long term efficacy not established due to lack of quality studies. Likewise, there is little data to support the use of opioids long term in lumbar root pain / neuropathy. Furthermore, in one of the few studies available, morphine was the least effective opioid for lumbar radiculopathy (decreasing leg and back pain by only 1-7%). When using opioids, it is recommended not to exceed total 120 mg oral morphine equivalents per day. Per the guidelines, consultation with pain specialist or weaning of opioids should be considered at 120mg-180mg total morphine equivalents per day. Per the records supplied for review, the injured worker has been on opioids for an unspecified time, but at least 6 months. It is not clear from the records if injured worker ever tried acetaminophen or non-steroidal anti-inflammatory drugs and he is not currently taking either. The treating physician notes continued complaints of pain and no changes in activity / work over time. The records do not indicate that function has been assessed by a validated clinical tool. The physical exam does not change, per the notes, over time. Injured worker has been taking Kadian 80mg in AM and 30mg in PM for unspecified time, in addition to Dilaudid 4mg up to 3 times per day for breakthrough pain. It is unclear from the records if injured worker needs the Dilaudid 3 times per day every day, or just periodic, as should be the case with medication for breakthrough pain. At his current daily dosing (158mg morphine equivalents), injured worker exceeds the recommended maximum morphine equivalents per day. As injured worker has shown little improvement in pain with opioids, exceeds maximum recommended total daily dosing, and has no documented objective assessment of functional improvement, it is recommended to wean off opioids at this time, per the guidelines. As injured worker already has Kadian 80mg tablets, the Kadian 30mg tablets should be discontinued as part of the weaning process. The request for the Kadian 30mg tablets then is not medically necessary.

Abilify 15mg tablet; 1 daily in morning #30 refill: 3: 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), Treatment Index, 11th Edition (web), 2013, Mental Illness & Stress Chapter, Abilify and Chronic Pain Chapter, Medical Food.

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

Decision rationale: MTUS Guidelines do not address atypical antipsychotics in general or Abilify in specific, so alternate source utilized. Abilify is classified as an atypical antipsychotic, and has indication to be used in schizophrenia, bipolar disorder, and as adjunct therapy to antidepressants in Major Depressive Disorder in adults. While the injured worker of concern is noted to have depressed mood, in some records supplied for review, his actual / ICD9 diagnoses submitted do not include Major Depressive Disorder. His Psychiatric diagnosis that is included, Mood disorder due to General Medical Disorder, is not an FDA indication for use of Abilify. Therefore, without documentation specifying that injured worker meets criteria for diagnosis of Major Depressive Disorder, the request for Abilify is not medically necessary.

Deplin 15mg tablet; 1 daily #30 refill: 3: 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), Treatment Index, 11th Edition (web), 2013, Mental Illness & Stress Chapter, Abilify and Chronic Pain Chapter, Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation The role of folate in depression and dementia. Mischoulon D1, Raab MF, J Clin Psychiatry. 2007;68 Suppl 10:28-33. The role of folic acid in prevention and treatment of depression: an overview of existing evidence and implications for practice. Lazarou C1, Kapsou M. Complement Ther Clin Pract. 2010 Aug;16(3):161-6. doi: 10.1016/j.ctcp.2010.01.003. Epub 2010 Mar 25. Augmenting antidepressants with folate: a clinical perspective. Fava M. J Clin Psychiatry. 200

Decision rationale: MTUS Guidelines do not address Deplin, or other medical foods, so alternative sources were used, including the FDA Acts and Amendments that address medical foods, and MEDLINE articles applicable to folate and depression. In Amendment to the FDA Orphan Drug Act, medical food is defined as "a food which is formulated to be consumed or administered orally or by tube feedings, under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." (21 U.S.C. 360ee (b)(3)) The FDA Nutrition Labeling and Education Act included the medical foods definition and established criteria for use: 1) Medical foods must be processed products, not used in naturally occurring state. 2) Medical foods are intended for "dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone" 3) Medical foods provide nutritional support specifically for the need a patient has based on medical evaluation 4) Medical foods are only to be used under medical supervision. 5) Medical foods are only to be used by patients in ongoing medical care. Folic acid deficiency and its relationship to depression have been studied since the 1960's (Young, 2007), without clear conclusion as to management of the deficiency and the depression together. (Lazarou and Kapsou, 2010) It has been suggested that patients who fail to respond to antidepressants, or who respond incompletely to antidepressants, and are folate deficient be supplemented with folate, but the studies supporting this approach are

few, and low-powered. (Fava 2007; Farah 2009; Mischoulon 2007) One researcher recommends supplementing with folate in depression even if not folate deficient, but acknowledges that more study is needed to support that view with evidence. (Young, 2007) There is no documentation supplied indicating injured worker has ever been tested for folate levels or found to be deficient. As the FDA clearly indicates that medical foods are only to be used in deficiency states, and the evidence is inconclusive to recommend folate supplementation in treatment of depression, even if deficient, the request for Deplin is not medically necessary.

Dilaudid 4mg tablet; 1 three times a day as needed #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of Opioids Page(s): 74-82.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments, Page(s): 79-83,86.

Decision rationale: Per the guidelines, opioids are recommended as second-line treatment for chronic pain, after first-line treatments fail. Unless there are contraindications, first-line treatment for nociceptive pain should be acetaminophen and/or non-steroidal anti-inflammatory drugs, and first-line therapy for neuropathic pain should be tricyclic antidepressants and anticonvulsants. Opioids then would be recommended as addition to the existing therapy to improve pain and function. Opioids have been shown to help improve pain and function in chronic back pain, but only in the short term (less than 16 weeks), with long term efficacy not established due to lack of quality studies. Likewise, there is little data to support the use of opioids long term in lumbar root pain / neuropathy. When using opioids, it is recommended to not exceed total 120 mg oral morphine equivalents per day. Per the guidelines, consultation with pain specialist or weaning of opioids should be considered at 120mg-180mg total morphine equivalents per day. Per the records supplied for review, the injured worker has been on routine opioids for an unspecified time, but at least 6 months. It is not clear from the records if injured worker ever tried acetaminophen or non-steroidal anti-inflammatory drugs, and he is not currently taking either. It is not clear in the records how often injured worker actually needs the Dilaudid which is to be taken only as needed for breakthrough pain. The treating physician notes continued complaints of pain and no changes in activity / work over time. The records do not indicate that function has been assessed by a validated clinical tool. The physical exam does not change, per the notes, over time. Injured worker has been taking Kadian 80mg in AM and 30mg in PM for unspecified time, in addition to Dilaudid 4mg up to 3 times per day for breakthrough pain. At his current daily dosing (158mg morphine equivalents), injured worker exceeds the recommended maximum morphine equivalents per day. As injured worker has shown little or no improvement in pain with opioids, exceeds maximum recommended total daily dosing, and has no documented objective assessment of functional improvement, it is recommended to wean off opioids at this time, per the guidelines. To proceed with weaning of opioids, injured worker is to be given a 30 day supply of medication with no refills and followed by the treating physician with a weaning schedule. As the stated request for Dilaudid does not clarify an endpoint for the medication (for example, 30 day supply with no refills), it is not medically necessary.