

Case Number:	CM14-0156572		
Date Assigned:	10/24/2014	Date of Injury:	04/08/1997
Decision Date:	12/02/2014	UR Denial Date:	09/03/2014
Priority:	Standard	Application Received:	09/24/2014

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:

53 year old male with date of injury 4/8/1997 continues care with treating physician. Patient has had years of chronic back pain and left leg pain, and years of treatments including non-steroidal anti-inflammatory drugs, narcotics and surgery. Patient has diagnoses of Chronic Pain and Opioid Dependence, and Failed Back Syndrome. Per the records supplied, patient has completed a Functional Rehabilitation Program and an outpatient detoxification program, and no longer requires opioid agonists. He is maintained on Suboxone, Tizanidine, and Valium. The treating physician is requesting continuation of Suboxone to control pain and prevent recidivism.

IMR ISSUES, DECISIONS AND RATIONALES

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

Suboxone 4mg #120 with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 26-27; 75, 79-80; 88, 94-95.

Decision rationale: Per the Guidelines, Suboxone (Buprenorphine) is a recommended treatment for opioid addiction as well as a treatment option for chronic pain relief. Suboxone is classified as a partial agonist-antagonist opioid that has less potential for abuse than pure agonist opioids.

(Side effects include hallucinations and dysphoria.) It can be particularly useful in patients with a history of detoxification from opioid addiction. Suboxone is FDA approved for treatment of opiate agonist dependence: Prescribers must be in compliance with the Drug Addiction Treatment Act of 2000. (SAMHSA, 2008) Suboxone has a specific pharmacological design that limits likelihood of overdose or abuse. While few studies support the use of Suboxone, or other medications to completely wean from opioids, Suboxone is known to have milder withdrawal syndrome, so is the best choice for opiate addiction treatment. However, Suboxone is an opioid, and needs to be managed as such. The Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive behavior should be addressed if present. (Address diversion or procuring prescriptions from more than one provider.) Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. The exact frequency will be per provider discretion based on need. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate dosing or under-dosing of opioids 2) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient. Per the Guidelines, Chelminski defines "serious substance misuse" as meeting ANY of the following criteria: (a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed. (Chelminski, 2005) 3) Consider discontinuation if there has been no improvement in overall function, or a decrease in function. 4) Patient has evidence of unacceptable side effects. 5) Patient's pain has resolved. 6) Patient exhibits "serious non-adherence" (including urine drug testing negative for prescribed substances on 2 occasions). 7) Patient requests discontinuing opioids. 8) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction. 9) Document the basis for decision to discontinue opioids. Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work? Has patient had improved function

and decreased pain with the opioids? For those at high risk of opioid abuse, the following are recommended to prevent misuse/addiction: a) Opioid therapy contracts. See Guidelines for Pain Treatment Agreement. b) Limitation of prescribing and filling of prescriptions to one pharmacy. c) Frequent random urine toxicology screens. d) Frequent evaluation of clinical history, including questions about cravings for the former drug of abuse (a potential early sign of relapse). e) Frequent review of medications (including electronic medical record evaluation when f) Communication with pharmacists. g) Communication with previous providers and other current providers, with evidence of obtaining medical records. (It has been recommended that opioids should not be prescribed on a first visit until this step has been undertaken.) h) Evidence of participation in a recovery program (12-step or follow-up with a substance abuse counselor), such as speaking to his/her sponsor for the 12-step program. i) Establishment of goals of treatment that can be realistically achieved. j) Initiation of appropriate non-opioid adjunct medications and exercise programs. k) Utilize careful documentation, and in particular, that which is recommended in the State in which opioids are prescribed. l) Incorporate family and friends for support and education. (Chabel, 1997) (Michna, 2004) (Weaver, 2002) For the patient of concern, he does have documented history of opiate addiction and has completed detoxification, so meets criteria for Suboxone for opiate addiction treatment. However, he is also using Suboxone for chronic pain relief, and there is no documentation of objective, quantifiable improvement in function. Pain is not rated at each visit, though most recent visit notes 30% reduction in pain. The Functional Rehabilitation Program is referenced several times in the record, and patient noted to be using the "self-management tools" he learned there. However, what those tools are and how they improve function / decrease relapse is unclear. Based on the records supplied for review, the patient is not being monitored closely for signs of misuse / addiction as the Guidelines recommend. There are no urine toxicology screens, and no evidence that patient has continued to follow up on his recovery program (Functional Rehabilitation Program). As the records do not indicate that patient is being monitored in accordance with the guidelines recommended for chronic opioid use, the Suboxone is not medically indicated.