

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM14-0073348 | | |
| Date Assigned: | 07/16/2014 | Date of Injury: | 02/15/1991 |
| Decision Date: | 12/08/2015 | UR Denial Date: | 05/15/2014 |
| Priority: | Standard | Application Received: | 05/20/2014 |

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. 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: Colorado

Certification(s)/Specialty: Family Practice

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 59 year old female, who sustained an industrial injury on 2-15-91. The injured worker has complaints of spine pain with radiation to legs. The injured workers gait is slow, stiff and antalgic. Decreased flexion and extension of the lumbar spine are noted. The diagnoses have included lumbar postlaminectomy syndrome. Treatment to date has included duragesic patches; morphine sulfate immediate release; soma; skelaxin; cymbalta; motrin; back brace and aquatic therapy. The original utilization review (5-15-14) non-certified the request for carisoprodol 350mg #90. The request for three (3) prescriptions of fentanyl 25mcg #10 (total of 30) has been modified to 1 prescription of fentanyl 25mcg #10.

IMR ISSUES, DECISIONS AND RATIONALES

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

Carisoprodol 350mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: Per the Guidelines, muscle relaxants, comprised of anti-spasmodics and anti-spasticity drugs, can be recommended as second line, short term options for treatment of low back pain. Studies suggest that muscle relaxants can decrease pain and muscle tension, thereby improving mobility / flexibility. However, the studies do not show any benefit of muscle relaxants over non-steroidal anti-inflammatory drugs, or in combination with non-steroidal anti-inflammatory drugs, for low back pain. The effects of muscle relaxants appear to decrease over time, and none of the anti-spasmodics are recommended for use longer than 2-3 weeks. Long term use of some of the muscle relaxants, including Carisoprodol (Soma), may result in dependence. While Carisoprodol is one of the most commonly prescribed muscle relaxants, it is not recommended for use per the Guidelines, due to its potential for abuse. Carisoprodol is metabolized to meprobamate, a schedule IV substance. Carisoprodol is abused for its own effects, but it has also been shown to alter the effects of other drugs such as: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a "Las Vegas Cocktail"); (5) as a combination with codeine (referred to as "Soma Coma"). (Reeves, 1999)(Reeves, 2001) (Reeves, 2008) (Schears, 2004) There was a 300% increase in numbers of emergency room episodes related to carisoprodol from 1994 to 2005. (DHSS, 2005) Carisoprodol has also been shown to have a withdrawal syndrome characterized by insomnia, vomiting, tremor, muscle twitches, anxiety, and ataxia, with no known treatment for patients with dependence. Carisoprodol was approved before FDA required proof of efficacy and safety. Based on the Guidelines, Carisoprodol (Soma) is not a recommended medication for use in pain management. The request for Soma is not medically necessary.

Three (3) prescriptions of Fentanyl 25mcg #10 (total of 30): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Fentanyl, Opioids, criteria for use, Opioids for chronic pain, Opioids, dealing with misuse & addiction, Opioids, long-term assessment.

Decision rationale: 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 clinical assessment 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. 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. To summarize the above, the 4As 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. 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" or misuse. 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) 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? Per the records for the patient of concern, she has had no documented improvement in function with her current regimen which includes Fentanyl. Patient reports improved pain, but ratings for pain in clinic consistently 8/10 in last 6 months. There is documentation that patient has had monitoring for abuse of opioids, but mostly patient report and urine drug screens documented as "appropriate" without actual urine drug screen reports supplied for review. The record is not clear on Fentanyl dosing as most recent notes indicate patient is taking 100mcg patches and the request is for 25mcg patches. Without objective evidence that the patient has improved with regard to function and pain on opioids, and without clear dosing noted in the record, the continued use and refill of Fentanyl 25mcg is not medically necessary.