MAXIMUS Federal Services

Case Number:	CM15-0036185		
Date Assigned:	03/04/2015	Date of Injury:	07/26/1998
Decision Date:	04/14/2015	UR Denial Date:	02/19/2015
Priority:	Standard	Application Received:	02/26/2015

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: 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 64-year-old female, who sustained an industrial injury on 07/26/1998. Diagnoses include chronic neck pain with moderate to severe degenerative disc narrowing at cervical four to five, cervical five to six, and cervical six to seven and mild disc bulging and spurring as seen on cervical magnetic resonance imaging; chronic lumbar sacral pain with minimal degenerative disc desiccation at lumbar three to four and lumbar four to five, and mild diffuse bulge at lumbar four to five as seen on magnetic resonance imaging; opiate pain management; residual of left total hip replacement from 2007 with hip pain and mild periosteal reaction in the femur below the level of the greater trochanter and extending towards the tip of the prosthesis as seen on computed tomography; and residual of the right wrist injury from 2005 with pain and reduced flexion. Treatment to date has included medication regimen, acupuncture, TENS unit, and a home exercise program. In a progress note dated 02/03/2015, the treating provider reports complaints of pain that range from a four to six out of ten. The treating physician requested the below listed medications noting that patient function is better with these medications. On 02/18/2015 Utilization Review modified the requested treatment of Butrans 20mg with a quantity of 4 to Butrans 20mg with a quantity of 2 between the dates of 02/03/2015 and 04/14/2015 and non-certified the requested treatments of Gabapentin 300mg with a quantity of 120, Oxycodone 10mg with a quantity of 120, and Tramadol 50mg with a quantity of 240 between the dates of 02/03/2015 and 04/14/2015, noting the California Chronic Pain Medical Treatment Guidelines (May 2009) and Official Disability Guidelines, Pain (Chronic). Oxycodone 10mg quantity #120 was later approved on 3/11/2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol 50mg #240: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 79-80, 85, 88-89, 93.

Decision rationale: Tramadol is a synthetic opioid that exerts its effect on the central nervous system. The MTUS 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 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. 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, although the records state she has had 50% improvement in pain symptoms, the pain ratings in the record do not show consistent improvement in pain over time. Also, there is no validated clinical tool documented as utilized to assess improvement in function with current regimen which includes Tramadol. There is documentation of discussion of side effects and aberrant drug-taking behavior, but there is no documentation that urine drug screen has ever been performed. As there is no documentation of consistent objective improvement in pain or function and no documentation of monitoring as recommended by the guidelines, the request for Tramadol is not medically necessary.

Butrans 20mg #4: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Buprenorphine. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 26-27, 79-80, 85. 88-89.

Decision rationale: Per the Guidelines, Buprenorphine, partial agonist-antagonist analgesic (agents that stimulate the analgesic portion of opioid receptors while blocking or having little or no effect on toxicity) available in patch formulation, Butrans, is recommended for treatment of opiate addiction, and as an option for treatment of chronic pain, especially after detoxification in patients who have a history of opiate addiction (see below for specific recommendations). Possible advantages to use of Buprenorphine include the following: (1) No analgesic ceiling; (2) A good safety profile (especially in regard to respiratory depression); (3) Decreased abuse potential; (4) Ability to suppress opioid withdrawal; & (5) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor). (Kress, 2008) (Heit, 2008) (Johnson, 2005) (Landau, 2007) Per the Guidelines, Buprenorphine's pharmacological and safety profile encourages treatment adherence and reduces the possibilities for both abuse and overdose. Studies have shown that buprenorphine is more effective than placebo and is equally as effective as moderate doses of methadone in opioid maintenance therapy. Few studies have been reported on the effects of Buprenorphine when completely withdrawing patients from opioids. Buprenorphine, however, is known to cause a milder withdrawal syndrome compared to methadone and for this reason may be a better choice to maintain patient off pure opioid agonist. As with use of any opioid, the Guidelines recommend the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors). 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. 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.' 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, there is no documentation of maintained improvement in pain. The pain ratings are not significantly different over time in general, though the subjective history indicates 50% improvement in pain. (Contradictory information) Furthermore, the records do not include a validated objective evaluation verifying functional improvement with the Butrans. Though an opiate contract is referenced in the record, there is no documentation of urine drug screens which would be part of the contract, and should be part of ongoing monitoring, particularly for patient's on multiple controlled substances who would be at high risk for aberrant behavior / diversion. While Butrans can be used for chronic pain treatment, even when not managing opioid addiction, the same criteria apply for its use as for that of other opioids. Based on the records supplied for review, the patient has not achieved objective functional improvement or evidence of consistent pain decrease, and ongoing monitoring is not documented, so the Butrans is not medically indicated.