

<b>Case Number:</b>	CM14-0171899		
<b>Date Assigned:</b>	10/23/2014	<b>Date of Injury:</b>	02/11/2011
<b>Decision Date:</b>	12/03/2014	<b>UR Denial Date:</b>	09/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/17/2014

### 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:

38 year old male with date of injury 2/11/2011 continues follow up with the treating physician. Patient has chronic low back pain with radiation into legs. Per the records, MRI shows annular tear at L5-S1 and disc bulge at L3-L4, and electrodiagnostic studies confirm bilateral S1 radiculitis. He has failed conservative therapy including physical therapy, pain medications, and epidural steroid injection, and has surgery authorized. Per the records, patient continues to have pain not relieved by his current regimen of Norco and Butrans. At 8/14/2014 office visit, pain was rated 8/10 and "unchanged." Treating physician notes also indicate patient unable to tolerate higher doses of Butrans. The treating physician requests approval of Butrans patch.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Butrans 10mg #4:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Buprenorphine Page(s): 26-27.

**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 is 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, the Butrans has not helped decrease his pain at current dosing, and he has been unable to tolerate higher doses of Butrans. Furthermore, the records do not include a validated objective evaluation verifying functional improvement with the Butrans, and do not include screening for aberrant drug-taking behavior. 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 pain decrease, so the Butrans 10mg #4 is not medically necessary and appropriate.