

<b>Case Number:</b>	CM14-0193128		
<b>Date Assigned:</b>	11/26/2014	<b>Date of Injury:</b>	12/16/1994
<b>Decision Date:</b>	01/14/2015	<b>UR Denial Date:</b>	11/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/18/2014

### 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:

This 64 year old female was a kitchen worker and school bus driver when she sustained an injury on December 16, 1994. The injured worker's right knee buckled and she fell onto a cement pad. The injured worker reported injury of bilateral knees and back. Diagnoses included lumbar degenerative joint disease (DJD), chronic back pain, left lumbar radiculitis, fibromyalgia, general anxiety disorder, Graves Disease, asthma, and hypothyroidism. The injured worker has been medically disabled since December 16, 1994. The injured worker was previously treated with anti-epilepsy, anti-inflammatory, anti-anxiety, and topical and oral pain medications, epidural steroid injections, and anti-inflammatory and Hyaluronic acid knee injections. On March 7, 2014, the orthopedic physician noted that x-rays of the knees revealed bilateral degenerative arthritis, worse on the right. The injured worker wanted to proceed with a right total knee replacement instead of further anti-inflammatory injections and physical therapy. On April 14, 2014, the injured worker underwent a right total knee arthroplasty (TKA). Postoperatively, the injured worker received physical therapy in a rehabilitation hospital. On July 29, 2014, the pain management physician noted the injured worker complained her pain medications were not providing her adequate pain relief, pain on the inside of the right knee, and her back was bothersome. The physical exam revealed tenderness of the inside of the right knee, and back pain was predominant. The physician recommended restarting an anti-inflammatory ointment, decreasing the anti-epilepsy medication because of side effects, and continuing the Butrans patches. On August 11, 2014, the treating orthopedic physician noted the injured worker reported doing quite well overall. The injured worker had completed physical therapy and was continuing her home exercise program. The physical exam revealed the surgical wound was well-healed, with mildly decreased range of motion of the right knee, no instability of the knee, intact neurovascular, good strength with dorsiflexion and plantar flexion, a negative Homan's sign, and

steady and non-atlagic gait. Right knee x-rays revealed the right total knee arthroplasty is in good alignment and position. The physician has recommended continuing the home exercise program, activities as tolerated, and follow up in three or four months. On November 11, 2014 Utilization Review modified a prescription for Butrans patches 20mg #4. The Butrans patches prescription was modified based on a lack of evidence of a trial of non-opioid treatment or failure of non-opioid trials. There was no documentation of an opioid treatment plan with functional goals or plan for monitoring for compliance. Utilization Review had previously modified a request for Butrans patches for the purpose of weaning the injured worker as there was no documentation to support the Butrans patches and no documentation Butrans patches were being used according to medical guidelines.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Butran patches 20 mcg, # 4:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-77.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 26-27, 79-80, 85 and 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 with the Butrans. (Some notes indicate pain better and some notes indicate much worse without inciting events.) Furthermore, the records do not include a validated objective evaluation verifying functional improvement with the Butrans, and do not include screening (in the history) for aberrant drug-taking behavior. (2 urine drug screens are referenced both of which have findings not addressed in the treating physician notes.) 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, so the Butrans is not medically indicated.