

<b>Case Number:</b>	CM15-0022121		
<b>Date Assigned:</b>	02/11/2015	<b>Date of Injury:</b>	11/12/1990
<b>Decision Date:</b>	03/27/2015	<b>UR Denial Date:</b>	01/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/05/2015

### 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: District of Columbia, Virginia  
 Certification(s)/Specialty: Internal Medicine

### 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 56 year old female with an industrial injury dated 11/12/1990 when she fell injuring coccyx and sacrum. Her diagnoses include chronic low back pain, sacroiliitis, sprain/strain of the sacroiliac region, lumbar spondylosis without myelopathy, COAT, degenerative disc disease, radiculopathy thoracic or lumbosacral, and chronic pain syndrome. Recent diagnostic testing has included a MRI of the lumbar spine (no date) showing lumbar spondylosis with degenerative disc disease, degenerative joint disease, facet arthropathy, and sacroiliitis. Previous treatments have included conservative care, medications, and injections. In a progress note dated 12/22/2014, the treating physician reports moderately severe persistent upper and lower back pain with radiation to the right arm, left calf, left foot, right foot and right thigh with a severity rating of 5/10 with medications, and 9/10 without medications. The objective examination revealed limited range of motion in the lumbar spine. The treating physician is requesting Butrans patches which were denied by the utilization review. On 01/07/2015, Utilization Review non-certified a prescription for Butrans patch 10mcg #4, noting the absence of documented attempt of first-line treatment options were attempted prior to Butrans, and no evidence of an opiate addiction or prior detoxification requiring specialized medicine regimens. The MTUS ACOEM ODG Guidelines were cited. On 02/05/2015, the injured worker submitted an application for IMR for review of Butrans patch 10mcg #4.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **Butrans patch 10mcg #4: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792  
Page(s): 26-27,111.

**Decision rationale:** Per MTUS: Buprenorphine, Recommended for treatment of opiate addiction. Also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction (see below for specific recommendations). A schedule-III controlled substance, buprenorphine is a partial agonist at the mu-receptor (the classic morphine receptor) and an antagonist at the kappa receptor (the receptor that is thought to produce alterations in the perception of pain, including emotional response). In recent years, buprenorphine has been introduced in most European countries as a transdermal formulation ("patch") for the treatment of chronic pain. Proposed advantages in terms of pain control 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) Available formulations:

Buprenorphine hydrochloride: Buprenex: Supplied as an injection solution; Subutex: Supplied as a sublingual tablet in 2 daily dosage strengths (2 mg or 8 mg). Buprenorphine hydrochloride and naloxone hydrochloride: Suboxone: Also supplied as a sublingual tablet in 2 dosage strengths (2/0.5 mg or 8/2 mg). Developed to have a lower intravenous (IV) misuse potential. When injected IV, naloxone is intended to cause withdrawal effects in individuals who are opiate-dependent, and to prevent the "high-effect" related to opioids such as euphoria.

Pharmacokinetics: After sublingual administration the onset of effect occurs in 30 to 60 minutes. Peak blood levels are found at 90 to 100 minutes, followed by a rapid decline until 6 hours, and then a gradual decline over more than 24 hours. (Helm, 2008) (Koppert, 2005) Indications:

Treatment of opiate agonist dependence (FDA Approved indication includes sublingual Subutex and Suboxone): Recommended. When used for treatment of opiate dependence, clinicians must be in compliance with the Drug Addiction Treatment Act of 2000. (SAMHSA, 2008)

Buprenorphine's pharmacological and safety profile makes it an attractive treatment for patients addicted to opioids. Buprenorphine's usefulness stems from its unique pharmacological and safety profile, which 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 efficacy of buprenorphine for completely withdrawing patients from opioids. In general, the results of studies of medically assisted withdrawal using opioids (e.g., methadone) have shown poor outcomes. Buprenorphine, however, is known to cause a milder withdrawal syndrome compared to methadone and for this reason may be the better choice if opioid withdrawal therapy is elected. (McNicholas, 2004) (Helm, 2008) The patient had ongoing pain despite multiple interventions. The patient had been given Norco which did not provide relief. Buprenorphine, while not first line therapy, would be appropriate given the patient had tried first line therapy and did not achieve relief of symptoms.

