

Health Decisions, Inc.

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Notice of Independent Review Decision

August 31, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Buprenex 0.3mg/ml sol (buprenorphine hd) 1 amp IM QID, 2 Amp IM HS #180x12 to be dispensed for a period of 1 year (for a total of 2160)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: Board Certified Physician in Anesthesiology with experience in Pain Management with over 6 years' experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adversedeterminations should be:

Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who is reported to have a date of injury xx/xx/xx. On the date of injury she is reported to have been struck by an oxygen concentrator which hit the inside of her knee. Records of past UR's indicate that the patient was diagnosed with complex regional pain syndrome. The Records also indicate that she has undergone extensive conservative management which included a left peripheral nerve stimulator lead placement trial, exploration of the saphenous vein neuroplasty and neurolysis on 07/01/04, manipulation of the left knee under anesthesia and later implantation of the peripheral nerve stimulator in the left thigh, additional manipulations of the knee, and revision of the battery placement in the left thigh on 08/30/04. She has undergone selective nerve root blocks, femoral nerve root blocks, and a spinal cord stimulator trial on 05/06/10.

07/31/12: IRO: The request for Buprenex 0.3mg IM qid Lumbar spine is recommended as medically necessary and the previous utilization review determination are overturned. The available medical records indicate the claimant has a longstanding history of CRPS II. She is noted to have had chronic intractable pain for which she has undergone multiple interventional procedures without substantive improvement. It is further noted she has undergone stellate ganglion blocks without evidence of pain relief. She later underwent peripheral nerve stimulation which does not appear to have been any substantive benefit and had paradoxical reaction to trial of spinal cord stimulation. The records indicate the claimant has been on this medication and dose for several years with benefit. There is sufficient historical information to support the continued use of this medication to treat the claimants sympathetically mediated pain.

03/13/15: Letter of Medical Necessity; This is an appeal for the approval for IM Buprenex. Discontinuation of this

medication would not be beneficial to her and would most likely cause her undue harm by increasing her pain levels and decreasing function. It would quite possibly necessitate visits to the Emergency Room to try to control her pain. has been taking this medication in 2010 due to lack of effect or intolerance to multiple immediate-release medications. This medication combined with Lidoderm patches increase her quality her quality of life and allows her to perform activities of daily living. has suffered since August 2001 with CRPS Type II due to an injury suffered at work as an EMT. has been through multiple interventional procedures including conservative management selective nerve root blocks, placement of a peripheral nerve stimulator, removal of this, manipulation of the knee under anesthesia as well as a spinal cord stimulator trial and without appreciable effect. In regards to medication, Ms. Woodard has taken the following medications which have either been ineffective, caused undesirable side effects or allergic reactions: Lyrica, Keppra, Gabapentin, OxyIR, Oxycontin, Hydcodone, Topamax, Methadone, Butrans patch, Morphine, and Cymbalta. The reaction to the Butrans patch was felt to be either the adhesive or the carrier compound since she has taken Buprenex injections for several years without allergic reactions. It should be noted that lack of evidence does not mean lack of efficiency. This medication has been effective for this patient for many years and we would like for you to overturn the initial denial and approve this medication as soon as possible

03/27/15: UR: Of note, Buprenex is listed as an "N" drug on the ODG drug Formulary. IM is not differentiated from other formulations, including patch or oral. This medication is recommended for detox purposes, not as treatment for chronic pain. Nonetheless, it remains relevant that long-term use of opioid medication for chronic non-malignant pain is not strongly supported by evidence-based guidelines. The ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases, as there is little research to support use. The research available does not support overall general effectiveness and indicates numerous adverse effects with long-term use. The latter includes the risk of ongoing psychological dependence and difficulty weaning. Long-term opioid use increases the risk for frank dependence and addiction, as well as adverse events including tolerance, hyperalgesia, morbidity, and mortality. This patient has been utilizing opiates since at least 2010. Given these reasons, continued use of an opioid medication by this patient is not considered medically appropriate. As such, prior review recommendations stand. Since this medication has already been certified for the weaning purposes, another prescription at this time is not medically indicated. Therefore, my recommendation is to NON-CERTIFY the request for Buprenex 0.3mg/ml, on appeal.

04/13/15: UR: The ODG regarding Buprenorphine for chronic pain states, "Recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first line for all patients)." In the case of this patient, the current clinical documentation indicates that her pain level was rated as a 7-8/10 with an increase of up to 9-10/10 and no statement that the previous use of the Buprenex had been the reason for a best pain level of 4/10 to 5/10. The prior request for this medication had been declined as the last notification for the Buprenex with the intention of weaning from the medication. With this information, the current request cannot be supported without a more recent comprehensive physical examination identifying the patient as having significant improvement of pain and other symptoms post-injection to support ongoing use of the medication. Additionally, with opioids not intended for long term use under the medical guidelines and without indication that this patient would be weaning for this medication, the request cannot be supported and is, therefore, given an adverse determination.

08/04/15: Follow up visit notes: I saw in the office today for a follow up visit. She is a woman with the complaint of: left leg pain. Patient is here for medication evaluation and refills. She reports pain is currently well managed with current therapy. Patient denies negative side effects. Patient had increased function and improved quality of life on current medical management. She is having some difficulty with getting her medications pre-certified through workers comp. Limited ROM of the left knee with about 10 degrees flexion loss of muscle mass of the left thigh. Problem #1 chronic pain syndrome: Patient currently is stable on medical therapy. It should again be noted that the patient has tried all the following medications without any benefit: Lyrica, Keppra, Gabapentin, OxyIR, Oxycontin, Hydcodone, Topamax, Methadone, Butrans patch, Morphine, and Cymbalta. Refill buprenorphine, tizanidine, trazadone, Lidoderm, and syringes and needles. Return to clinic in 3 months. Problem #2: Reflex sympathetic Dystrophy. Problem #3: Muscle Spasm. Problem #4: Insomnia.

08/10/15: Peer Clinical Review Report: Peer discussion was performed on 8/7/15 and the case was reviewed. It was noted that the patient has a diagnosis of CRPS, with failure of SCS implant. Various pain medications have been

trialed. The patient was eventually placed on IM Buprenex (buprenorphine). Apparently, the transdermal Butrans formulation irritated her skin. Oral injectable buprenorphine is not felt supported. If this drug must be continued, an oral delivery is preferable. Alternative oral opioids can also be considered including Methadone for chronic neuropathic pain. Therefore, my recommendation is to NON-CERTIFY the request for Buprenex 0.3mg/ml Sol (Buprenorphine HCL) 1 Amp IM QID, 2 Amp IM Hs #180 x 12 to be Dispensed for a period of 1 Year. (for a total of 2160)

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Per ODG, Buprenorphine should be used as an option in chronic pain patients, but not as a first line treatment. Claimant has continued pain with demonstration of failure with other oral medications. Given most recent physical examination and failure with the transdermal formulation of this medication, it is appropriate to trial the IM injectable formulation. Therefore, this request is **certified**.

Per ODG:

Recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). *Suggested populations:* (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. Use for pain with formulations other than Butrans is off-label. Due to complexity of induction and treatment the drug should be reserved for use by clinicians with experience.

Drug description: Buprenorphine is a schedule-III controlled substance. Its mechanism of action is complex, involving four different opioid receptors at central and peripheral sites. It is primarily classified as a partial mu-agonist and kappa antagonist. It blocks effects of subsequently administered opioid agonists.

Proposed advantages of treatment: (1) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor); (2) Ability to suppress opioid withdrawal; (3) Indications of safety for use in patients with renal impairment. There appears to be a ceiling effect for respiratory depression. ([Johnson, 2005](#)) ([Koppert, 2005](#)) ([Pergolizzi, 2008](#)) ([Malinoff, 2005](#)) ([Landau, 2007](#)) ([Kress, 2008](#)) ([Heit, 2008](#)) ([Helm, 2008](#)) ([Silverman, 2009](#)) ([Pergolizzi, 2010](#)) ([Lee, 2011](#)) ([Rosenblum, 2012](#)) ([Daitch, 2012](#)) ([Colson, 2012](#)) See also [Opioid hyperalgesia](#).

Treatment of chronic pain: A waiver is not required for the off-label use of sublingual buprenorphine for the treatment of pain. An "X" should NOT be put before the DEA number. It is recommended that the words, "Chronic Pain Patient" and "Off-Label Use" be written on the prescription. The most common use of buprenorphine formulations other than Butrans (such as Suboxone) for the treatment of chronic pain is for individuals who have a history of opioid addiction.

Use in opioid-experienced patient: There is the potential for buprenorphine to precipitate withdrawal in opioid-experienced patients.

Available formulations:

Buprenorphine hydrochloride injection (Buprenex®; generics available).

Buprenorphine hydrochloride sublingual tablets (Subutex® [innovator brand is off market]; generics available): 2 mg and 8 mg.

Buprenorphine hydrochloride and naloxone hydrochloride sublingual film (Suboxone®; no generics): Available as a film in doses of buprenorphine/ naloxone of 2mg/0.5mg, 4mg/1 mg, 8mg/2 mg and 12mg/3 mg. Tablet formulations are available as 2mg/0.5mg and 8mg/2mgs. Discontinuation of branded Suboxone sublingual tablets is to occur on 3/18/13, being replaced by the sublingual film described above.

Buprenorphine transdermal system (Butrans®; no generics): FDA-approved for moderate to severe chronic pain. Available as transdermal patches at 5mcg/hr, 10mcg/hr and 20mcg/hr.

See also [Buprenorphine for treatment of opioid dependence](#).

Recommended for selected patients for treatment of opioid dependence. The use of buprenorphine maintenance therapy was introduced in 2002. This drug can be prescribed in a physician office setting for this indication by certified physicians. Original studies investigate the use of buprenorphine for treatment of heroin addiction and research is still ongoing for use in populations with prescription drug abuse, or with comorbid dependency and chronic pain.

Drug characteristics in terms of dependence and addiction treatment: The drug is a semi-synthetic mu opioid partial agonist and a kappa receptor antagonist. The medication as used for this indication is available in sublingual tablet or film

formulations. Current literature indicates many of the drug's effects plateau at 16 mg, although doses of 32 mg are used clinically. Most patients stabilize at doses between 16 and 24 mg given in a once daily dose. The intensity of the rewarding effect is milder and plateaus at higher doses, and these characteristics are thought to limit abuse potential. ([Alford, 2011](#)) ([Clark, 2011](#)) ([Weiss, 2011](#)) ([Bart, 2012](#)) ([Ducharme, 2012](#)) ([Mark, 2012](#)) ([Colson, 2012](#)) Zubsolv (buprenorphine and naloxone), a recently FDA-approved medication for maintenance treatment of opioid dependence, is a once-daily sublingual tablet that offers higher bioavailability that allows patients to use lower strength and reduce the amount of available drug for potential misuse and diversion. ([FDA, 2013](#)) Bunavail (buprenorphine and naloxone) inside the cheek buccal film was FDA approved for the maintenance treatment of opioid dependence. ([FDA, 2014](#)) See also [Buprenorphine for treatment of chronic pain](#); & [Weaning, opioids](#) (specific guidelines). The results of this RCT suggest that initiation of buprenorphine treatment in the emergency department with referral to a hospital-based primary care clinic may increase patient engagement in treatment and decrease self-reported opioid use within 30 days. ([D'Onofrio, 2015](#))

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)