

# AccuReview

An Independent Review Organization

569 TM West Parkway

West, TX 76691

Phone (254) 640-1738

Fax (888) 492-8305

Notice of Independent Review Decision

**[Date notice sent to all parties]:** December 1, 2013

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Suboxone 2/0.5mg Film 1 sublingual q 4-6 hours prn for pain #150 3 refills

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:**

This physician is Board Certified in Anesthesiology with over 11 years of experience.

**REVIEW OUTCOME:**

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

Upheld (Agree)

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

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

01-31-12: Visit Note

01-31-12: Drug Screen Panel

03-15-12: MRI Wrist without Contrast – Right

04-04-12: Visit Note

09-11-12: Visit Note

11-13-12: Visit Note

11-16-12: Drug Screen Panel

12-05-12: Visit Note

01-03-13: Visit Note

02-20-13: Visit Note

03-21-13: Visit Note

04-03-13: Drug Screen Panel

05-16-13: Visit Note

06-13-13: Visit Note

07-11-13: Visit Note  
07-31-13: Letter of Medical Necessity  
07-31-13: Letter of Medical Necessity  
07-31-13: Request for Authorization  
08-13-13: Visit Note  
08-20-13: Drug Screen Panel  
09-12-13: Visit Note  
10-09-13: Visit Note  
10-09-13: Pre-Authorization Request  
10-14-13: UR performed  
10-23-13: Request for Reconsideration Request  
11-06-13: UR performed  
11-07-13: Visit Note dictated

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a female who sustained a work related injury on xx/xx/xx. There is no information of type of injury or mechanism of injury noted in the medical records or documentation provided.

01-31-12: Visit Note. Current medications: Suboxone 2mg SL, Requip 0.5mg QHS, Elavil 25mg QHS, Lexapro 20mg QD, Tekloma 150mg QAM, potassium 10mg BID, Lasix 40mg QAM, HCTZ 40mg QAM, Fenofibrate ?mg QAM, Celexa. Chief complaint: Claimant woke up last several days with increased pain in right wrist. She was seen yesterday and diagnosed with possible tendonitis. Given Medrol dose pack and Celebrex x 9days then RT. Stated feels better with splint and also related to increased swelling, having RLS. PCP has not refilled Requip. Pain in wrist is sharp and burning. PE: Claimant appears anxious and complained of depression. Right wrist in thumb spica splint, noted decreased ROM. Diagnosis: CRPS II right wrist, R/O tendonitis. Plan: finish treatment initiated and continue Suboxone, follow up in 2 months.

01-31-12: Drug Screen Panel. Claimant tested positive for Amitriptyline.

03-15-12: MRI Wrist without Contrast – Right: Extensive postsurgical and degenerative changes are noted at the carpal first metacarpal articulation on the radial side of (Record incomplete, unable to obtain complete copy).

04-04-12: Visit Note. Chief complaint: claimant stated no relief with ibuprofen/Suboxone and stated “can’t deal with it”. Noted lymphoma to bilateral LE. PE: Ortho: tender to palpation at 1 and 2 metacarpal base, right wrist brace. Diagnosis: DJD R wrist, CRPS R wrist, opioid abuse, Substance dependent. Plan: increase Amitriptyline to 100 mg PO QHS x 1 wk, 125mg x 1 wk then 150mg QHS, renew medications and follow up in 2 months.

09-11-12: Visit Note. Claimant complained of right wrist pain, revision 4/12, stated feels worse and Suboxone takes the edge off. Claimant stated no benefit with heat/ice. She complained of occasional hallucinations. Claimant has been out of Suboxone for 2 weeks. PE: Ortho: incision well healed with no

thermal/mechanical allodynia. Diagnosis: chronic pain, CRP UE (nerve pain, not CRPS), drug dependent, unspecified, opioid abuse. Plan: changed Amitriptyline to 50mg TID, Neurontin 300mg TID (start 1 HS x 1 wk, 1 HS ++ 1 at 1800 x 1 wk, then TID) and Micardis 80mg QD. Follow up in 2 months.

11-13-12: Visit Note. Claimant complained of increased pain R wrist and noted benefit with Amitriptyline, Suboxone benefit, no use with meds, and complained of increased BP with ADL/activity. Diagnosis: chronic pain, CRPS vs. nerve pain, drug dependent, unspecified, opioid abuse. Plan: increase Gabapentin 300mg QID, review medications, hot bath and melatonin one hour before bedtime, d/c tobacco next month, PLO gel QID, follow up in 4 weeks.

11-16-12: Drug Screen Panel. Claimant tested positive for Amitriptyline and Suboxone.

12-05-12: Visit Note. Claimant presented with need for new splint. Stated increased Gabapentin has helped, melatonin showed benefit, hot bath 1 hr at HS no benefit. Diagnosis: CRPS – UE, chronic pain, drug dependency. Plan: Lidocaine patch for R wrist, refill meds, wrist splint, benzocaine creme OTC.

01-03-13: Visit Note. Current problems/complaint: Suboxone 2mg (#30), fatigued-flat today. Home stress: going to sell truck instead of CC buying. No new brace. Claimant stated that the Suboxone keeps her awake but stabilizes the pain. Diagnosis: CRPS – UE, chronic pain, drug dependency. Plan: status of the new brace, Gabapentin increased to 300mg TID and 600mg QHS, renew meds, and follow up in 4 weeks.

02-20-13: Visit Note. Claimant complained of being out of her medications since Saturday. Quit tobacco. R UE: jerks started last Thursday keeping her awake, like dystonia. Without benefit with UE with Requip and benefit with LE with Requip only at night with increased pain the next day. Complained of decreased benefit with Suboxone secondary to stress at home. She stated the Gabapentin has helped. PE: Neuro: no dystonia noted during exam. Diagnosis: CRPS-UE, chronic pain, drug dependency. Plan: review meds, try topical with benzocaine. Follow up in 4 weeks.

03-21-13: Visit Note. Claimant stated medications are okay with benefit from Suboxone. Diagnosis: CRPS-UE, chronic pain. Plan: Follow up in dental school for tooth ache, needs ibuprofen. Follow up in 2 weeks.

04-03-13: Drug Screen Panel. Claimant tested positive for Amitriptyline.

05-16-13: Visit Note. Claimant presented with increased R wrist pain. She has gained 40 lbs and stopped tobacco. She still needs a new brace. PE: Neuro: decreased LT nerve distal incision, increased pain with light touch, skin lightly darkened on R, + edema RUE. Diagnosis: CRPS/UE, chronic pain. Plan: needs letter for thumb spica splint, old one is worn out, renew meds, Mg 500-1500mg PRN constipation. Follow up in 4 weeks.

06-13-13: Visit Note. Claimant complained of increased pain for 4 days without over worsening, increased restlessness causing decreased sleep due to increased arm pain. She complained of dry mouth with Suboxone. PE: no brace. Diagnosis: CRPS/UE, chronic pain. Plan: review meds, pull letter for new brace, Vistaril 25 mg PO Q4hr, Inderal 20mg PO Q8hr, follow up in 4 weeks.

07-31-13: Letter of Medical Necessity. Medication Requested: Lidoderm Patch Apply 1 to the affected area (12 hours on, 12 hours off) #10. Clinical: The claimant is under care for chronic intractable pain. The Lidoderm patch is a transdermal anesthetic analgesic agent that is being used to reduce the claimant's level of pain and increase the level of function. The claimant has tried other co-analgesics, which were ineffective. The duration of use will likely be long-term.

07-31-13: Letter of Medical Necessity. Medication Requested: Lexapro 10mg 2 tabs daily #60. Clinical: Claimant is under care for chronic intractable pain and as a part of treatment for this condition, she has developed a secondary reactive depressive mood disorder that further aggravates her levels of pain and decreases her function levels. Lexapro is an antidepressant which works synergistically with the other medications, and is being used to reduce the claimant's level of pain and increase her level of function.

07-31-13: Request for Authorization. Requested Medication: 1. Suboxone Film 2/0.5mg one SL Q4-6 hours for pain #150/month supply, 2. Lidoderm Patch #10 patches month supply, 3. Lexapro 10mg 2 QD #60 month supply. Please authorize 6 month supply. Diagnosis: R wrist Ph 719.43. The request for Suboxone is due to the following: 1. Claimant with a hyperalgesic component to pain, 2. Claimant with centrally mediated pain, 3. Claimant with neuropathic pain, 4. Claimant at high-risk of non-adherence or abuse with standard opioid maintenance, 5. For analgesia in claimants who have previously been detoxified from high-dose opioid abuse.

08-13-13: Visit Note. Claimant presented with increased depression and increased R wrist pain secondary to stress that decreases with medication. Diagnosis: CRPS/UE, chronic pain. Plan: review of meds, look into church.

08-20-13: Drug Screen Panel. Claimant tested positive for Amitriptyline and Suboxone.

09-12-13: Visit Note. Claimant complained of increased R wrist pain causing decreased sleep due to the pain. PE: Neuro: grossly intact, hyperalgesia with R RAD wrist. Diagnosis: CRPS/UE, chronic pain. Plan: review meds.

10-09-13: Visit Note. Claimant complained of increased forearm/wrist pain and increased stress. PE: Ortho: increased edema/swelling dorsal aspect distal wrist, trophic changes of skin color (onion skin), noted to be tender with medium pressure. Diagnosis: CRPS/UE, chronic pain. Plan: review meds, aggravation of pain due to increased stress, needs more away from care taking.

10-14-13: UR performed. Reason for denial: According to the records provided for this review, the claimant sustained an injury on xx/xx/xx. The details of the injury are not documented with this request. The claimant now has complaints of forearm/wrist pain that increased increased fatigue and soreness. On exam, the claimant has increased edema at the dorsal aspect of the distal wrist; the claimant had erythema and was tender with medium pressure. There is inadequate objective information submitted with this request to recommend approval of the requested medication. There is no documentation of the claimant's pain level or physical exam findings consistent with the need fro treatment with the requested medication. Unable to clarify the need for this medication with the AP. Therefore, the recommendation is for non-certification of this request.

11-06-13: UR performed. Reason for denial: There was mention of the claimant being on multiple medications for pain beside the Suboxone and not clear as to what specific overall functional benefit has been achieved with the Suboxone as opposed to functionally without it. It is also not clear whether there is any plan to wean or discontinue any of the other medications while on the Suboxone. Therefore, the request is not medically reasonable or necessary.

11-07-13: Visit Note. Claimant presented complaining of being homeless, increased arm pain x 5 days secondary to stress. She is trying to stay positive, but depression in increasing. She stated Suboxone was providing 60% relief of pain. Diagnosis: R wrist pain 719.43. Plan: review meds via other insurance, claimant to file IRO.

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

Previous adverse determinations are upheld and agreed upon. The claimant sustained a wrist injury of unclear etiology in xxxx. Claimant now complains of right wrist and forearm pain with increased soreness and fatigue. MRI results are unclear. Claimant is on several pain medications and while the claimant reports 60% relief with the Suboxone it is unclear what the level of relief is without the medication. There must be demonstrable evidence that other opioid medications have failed and that there exists a plan to wean other medications in conjunction with the Suboxone use. Therefore, after review of the medical records and documentation provided, the request for Suboxone 2/0.5mg Film 1 sublingual q 4-6 hours prn for pain #150 3 refills is not medically reasonable or necessary and furthermore denied.

Per ODG:

Buprenorphine for chronic pain	Recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). <i>Suggested populations:</i> (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. <i>Drug description:</i> Buprenorphine is a schedule-III controlled substance. Its
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<p>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.</p> <p><i>Proposed advantages of treatment:</i> (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. (<a href="#">Johnson, 2005</a>) (<a href="#">Koppert, 2005</a>) (<a href="#">Pergolizzi, 2008</a>) (<a href="#">Malinoff, 2005</a>) (<a href="#">Landau, 2007</a>) (<a href="#">Kress, 2008</a>) (<a href="#">Heit, 2008</a>) (<a href="#">Helm, 2008</a>) (<a href="#">Silverman, 2009</a>) (<a href="#">Pergolizzi, 2010</a>) (<a href="#">Lee, 2011</a>) (<a href="#">Rosenblum, 2012</a>) (<a href="#">Daitch, 2012</a>) (<a href="#">Colson, 2012</a>) See also <a href="#">Opioid hyperalgesia</a>.</p> <p><i>Treatment of chronic pain:</i> 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.</p> <p><i>Use in opioid-experienced patient:</i> There is the potential for buprenorphine to precipitate withdrawal in opioid-experienced patients.</p> <p><b><u>Available formulations:</u></b></p> <p><i><u>Buprenorphine hydrochloride injection</u></i> (<i>Buprenex®; generics available</i>).</p> <p><i><u>Buprenorphine hydrochloride sublingual tablets</u></i> (<i>Subutex® [innovator brand is off market]; generics available</i>): 2 mg and 8 mg.</p> <p><i><u>Buprenorphine hydrochloride and naloxone hydrochloride sublingual film</u></i> (<i>Suboxone®; no generics</i>): 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.</p> <p><i><u>Buprenorphine transdermal system</u></i> (<i>Butrans®; no generics</i>): FDA-approved for moderate to severe chronic pain. Available as transdermal patches at 5mcg/hr, 10mcg/hr and 20mcg/hr.</p> <p>See also <a href="#">Buprenorphine for treatment of opioid dependence</a>.</p>
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**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)**