# I-Resolutions Inc.

**An Independent Review Organization**
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03/14/18 Amended Letter 06/21/18

***Description of the service or services in dispute:***
XXXX spray and XXXX patches

***Description of the qualifications for each physician or other health care provider who reviewed the decision:***
Board Certified Anesthesiology

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

Overturned (Disagree)

☑ Upheld (Agree)

☐ Partially Overturned (Agree in part / Disagree in part)

***Patient Clinical History (Summary)***
XXXX who was diagnosed with sprain of ligaments of lumbar spine, initial encounter (847.2).

On XXXX, the patient was evaluated by XXXX for the chief complaint of low back pain. XXXX was injured on XXXX. XXXX had continued low back pain radiating into XXXX right lower extremity. The pain was constantly aching and aggravated by standing and sitting. It was rated at 6-10/10. On examination, there was decreased lumbar lordosis and spasm of the bilateral paraspinals. Lumbar spine range of motion was limited in extension and bilateral axial loading. Facet tenderness was positive at the right L3-L4, L4-L5 and L5-S1 levels. Facet loading was positive bilaterally. There was positive FABER test. Positive bilateral sacroiliac joint tenderness was also noted. Sensation was decreased in the right L4 dermatome.

Treatment to date consisted of medications (including XXXX), right radiofrequency ablation, lumbar medial branch block at L4-L5, lumbar epidural steroid injection and TENS unit.

An MRI of the lumbar spine dated XXXX, revealed transitional lumbosacral vertebra with sacralization of L5; disc bulges and ligamentum flavum/facet hypertrophy at L3-L4 and L4-L5; and mild left neural foraminal narrowing at the L4-L5 level.

Per a utilization review determination letter dated XXXX, the request for XXXX spray and XXXX patches was denied. It was determined that a peer-to-peer discussion was unsuccessful despite a call to the doctor's office. The records submitted were minimal and only included previous peer reviews. There were no recent clinical reports submitted for review discussing the patient's current condition or the indications for the use of XXXX patches.

Per a Notice of Adverse Determination dated XXXX, the clinical basis for denying the request was that XXXX did not perform peer-to-peer discussion regarding medications. The submitted documentation indicated that the patient had been prescribed XXXX patches. XXXX was requested in conjunction with the patches. However, the submitted documentation did not provide a specific quantifiable reduction in pain score as a result of the prior use of XXXX. Additionally, although the patient had been consistent with urine drug testing, the documentation did not provide evidence of functional improvement as a result of prior use. As such, the necessity of XXXX patches was not established. Regarding the XXXX spray, this had been requested in order to apply prior to application of the XXXX patches. However, continuation with XXXX was not determined to be consistent with guidelines. Furthermore, there was no description of an allergy or irritation regarding XXXX to support the use of XXXX. Finally, it was considered an off-label use of XXXX spray, and as such, XXXX was noncertified.

Per a Notice of Adverse Determination dated XXXX, the reconsideration request was not approved. Rationale: "The clinical basis for denying these services or treatment: A peer to peer discussion was unsuccessful despite calls to the doctor's office. This request is for XXXX patches to hold patches on the skin and stop irritation. The records do not indicate that there is any skin irritation noted, as the record indicates skin lesions were not present. This is to hold on the XXXX patch; however, the patient has at least 1 drug screen apparently abhorrent for XXXX, and XXXX continues to use other opioids with the XXXX, which is not supported by the Guidelines. While this request is not for XXXX, it is for medical supplies to hold XXXX to the body, which there is no further need for XXXX. There is no indication for continued XXXX patches at this time. The request is non-certified."

***Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.***
The request for XXXX is approved. Given the documentation available, the requested service(s) is considered medically necessary.

Not in question is the issue of whether XXXX patch is necessary or approved. Not in question is the issues of prior inconsistent drug screens.

XXXX is a non-allergic skin adhesive that is frequently used for skin site bio-occlusion. It is popular because it is easily applied and waterproof. However, when worn for several days, skin irritation occurs – this is not an allergic response, but a form of dermatitis. The XXXX spray contains a steroid and when applied to the skin, ameliorates the dermatitis, thereby allowing the XXXX to be applied over the patch.

This is covered under the doctrine of res ipsa loquitur. Under United States common law, res ipsa loquitur has the following requirements:

1. The event does not normally occur unless someone has acted negligently;

2. The evidence rules out the possibility that the actions of the plaintiff or a third party caused the injury; and

3. The type of negligence in question falls within the scope of the defendant's duty to the plaintiff.

A reaction to the XXXX, which is highly probable, would require pre-treatment with XXXX, under this doctrine.

***A description and the source of the screening criteria or other clinical basis used to make the decision:***

☐ ACOEM-America College of Occupational and Environmental Medicine um knowledgebase
☐ AHRQ-Agency for Healthcare Research and Quality Guidelines DWC-Division of Workers

☐ Compensation Policies and Guidelines European Guidelines for Management of Chronic Low Back Pain

☐ Interqual Criteria

☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards
☐ Mercy Center Consensus Conference Guidelines
☐ Milliman Care Guidelines
☑ ODG-Official Disability Guidelines and Treatment Guidelines

*XXXX use and XXXX use are not directly addressed in ODG.

Pain (Chronic) (Updated 02/15/18) XXXX

*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 XXXX is off-label. Due to complexity of induction and treatment the drug should be reserved for use by clinicians with experience.*

*Drug description: XXXX 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 XXXX 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 XXXX formulations other than XXXX (such as XXXX) 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 XXXX to precipitate withdrawal in opioid-experienced patients.*

*Available formulations:*

*XXXX hydrochloride injection (XXXX®; generics available).*

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

*XXXX hydrochloride and XXXXhydrochloride sublingual film (XXXX®; no generics): Available as a film in doses of XXXX/ XXXXof 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 XXXX sublingual tablets is to occur on XXXX, being replaced by the sublingual film described above.*

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

*XXXX for opioid dependence*

*Recommended for selected patients for treatment of opioid dependence.*

*The use of XXXX 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 XXXX 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 (XXXX 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) XXXX (XXXX and naloxone) inside the cheek buccal film was FDA approved for the maintenance treatment of opioid dependence. (FDA, 2014) The results of this RCT suggest that initiation of XXXX 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)*

- ☐ Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and 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)