



**MEDICAL EVALUATORS
OF TEXAS** ASO, LLC.

2211 West 34th St. • Houston, TX 77018
800-845-8982 FAX: 713-583-5943

Notice of Independent Review Decision

DATE OF REVIEW: September 2, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Lidoderm patches 5%

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

This case was reviewed by a physician who holds a board certification in Anesthesiology with sub-certification in Pain Medicine. The reviewer is currently licensed and practicing in the state of Texas.

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

CLINICAL HISTORY [SUMMARY]:

The claimant is a female who sustained injury on 01/21/2015 when she fell out of the shower/tub causing injury to her left side lower back, left wrist, and ribs. She was diagnosed with left lumbar intervertebral disc disorder with myelopathy, sprain of left ribs, and enthesopathy of left wrist and carpus. The claimant was treated with physical therapy and medications including Ibuprofen and Flexeril. The claimant has not had surgery for this injury.

The claimant had MRI of the lumbar spine performed 03/04/2015 which revealed no segmental instability or spondylosis, L5-S1 focal 4mm left subarticular disc herniation noted with tear in outer annulus compression of left S1 nerve root, and no foraminal encroachment. EMG/NCS of lower extremities performed on 03/11/2015 showed no electrodiagnostic evidence of lumbar radiculopathy, sacral plexopathy, focal peroneal or tibial neuropathies, lateral plantar neuropathies. EMG/NCS of upper extremities performed on 04/15/2015 showed no electrodiagnostic evidence of cervical radiculopathy, brachial plexopathy, focal medial, radial or ulnar neuropathies in elbow or wrist segments, upper limbs large fiber polyneuropathy, neuromuscular transmission defects or myopathy.



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Office visit dated 07/17/2015 indicates the claimant reported pain level of 8/10. The claimant overall lumbar spine symptoms and radiating pain have remained the same. The claimant reported radiating pain in her bilateral hips/buttocks/thigh and from left lower flank upwards of the left shoulder blade. The claimant reported numbness and tingling as well as lower extremity weakness. The claimant denied loss of bowel or bladder control. The claimant also reported left hand tingling/numbness and left rib pain. The claimant reported that overall the symptoms have increased worsening of left upper extremity strength and numbness and range of motion decreased. Physical exam of the lumbar spine showed no obvious deformity. Range of motion decreased in all planes. Muscle spasm along the paraspinal muscles and tenderness. Lower extremity exam showed deep tendon reflexes hypoactive, sensation decreased on left L4, L5 and S1 nerve root distribution persists. Muscle strength decreased slightly, suspected due to pain in lower back. Special testing sitting SLR negative left and right. Gait was normal. There was decreased sensation in left C5, C6, C7, C8 distal distribution. Reflexes 1+ right bicep, 0+ left bicep. The claimant was recommended Gabapentin, Tramadol, Lidoderm patches, and Flexeril.

An initial authorization review dated 07/29/2015 indicates the patient has used ibuprofen and Flexeril with no indication that the patient has tried and failed antiepileptic drugs or antidepressants to qualify for the off-label use of Lidoderm as per ODG criteria. Therefore, the request for Lidocaine pad 5%, qty 90, is neither medically necessary nor appropriate.

First level appeal review dated 08/10/2015 indicates the current treatment plan included starting AED (Gabapentin); however, it is unclear if that has been started as of yet and the efficacy of treatment cannot be determined. Therefore, the requested Lidocaine Pad 5% Qty 90, D/S 30 is not medically necessary or appropriate.

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

This claimant suffered a fall in the shower/tub on 01/21/2015 and sustained injuries including left wrist contusion, head contusion, left thigh contusion, left rib sprain, lumbar strain, and thoracic contusion. The insurance company has disputed the cervical injuries and lumbar injuries beyond strain. EMG nerve conduction studies were performed for the lower extremities on 03/10/2015 and for the upper extremities on 04/15/2015 and neither supported findings of radiculopathy or neuropathy.

According to ODG updated 07/15/2015, the Lidoderm patches are recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. In this case, although the claimant did present with neurological complaints in the lower extremities and neurological changes on physical examination (07/17/2015), the EMG nerve conduction studies were not supportive of neuropathic pain. Additionally, the other ODG requirement of a trial of tricyclics or SNRI antidepressants such as gabapentin or Lyrica prior to the use of Lidocaine patch. This claimant's medical record indicates this



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claimant was prescribed Gabapentin on 07/17/2015, however, it does not state that she has tried and failed these medications.

For the above reasons, the request for Lidocaine patch 5% does not satisfy the ODG recommendations. Therefore, the medical necessity has not been established and is not appropriate at this time.

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

ODG - Pain (Chronic) – assessed online on 09/01/2015

Topical analgesics

Lidocaine: Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. See Criteria for use below. Topical lidocaine, in the formulation of a dermal patch (Lidoderm®) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended.

Indications: Recommended for localized pain that is consistent with a neuropathic etiology after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). Topical lidocaine patches are generally not recommended for non-neuropathic pain (including osteoarthritis or myofascial pain/trigger points). See Criteria for use below. Most studies have utilized the Neuropathic Pain Scale (NPS) as measure of neuropathy when there are questions of whether this is the cause of pain. There is limited information as to long-term efficacy and continued information as to outcomes should be provided to allow for on-going use. (Argoff, 2004) (Galer, 2004) (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) (Fishbain, 2006) (Affaitati, 2009) (Burch, 2004) (Gimbel, 2005) (Dworkin, 2003) (Finnerup, 2005) (O'Connor, 2009) Discussion about specific details of these studies are given in detail with references. Second-line drugs such as capsaicin 8% patches had moderate to low effect sizes, but only low quality



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evidence was available for lidocaine patches and the NNT could not be calculated. (Finnerup, 2015)

Trigger points & myofascial pain: Not recommended. (Affaitati, 2009) (Dalpaiz, 2004)

Osteoarthritis of the knee: Not generally recommended unless a component of neuropathy is indicated using measures such as the Neuropathic Pain Scale. All current available studies were sponsored by the manufacturer of lidocaine patches and are non-controlled, and of short-term in duration. (Burch, 2004) (Kivitz, 2008)

Axial back pain (including osteoarthritis): Not recommended unless neuropathy is suggested. Current studies as to use of Lidoderm patches for non-neuropathic low back pain are non-controlled, may or may not evaluate for the presence of neuropathic quality, have included multiple stages of pain (from acute to chronic), have included multiple diagnoses, show limited results in pain reduction, and are generally sponsored by the manufacturer. Acute groups have had better results than chronic pain patients, which may be attributed to natural recovery. (Gimbel, 2005) (Galer, 2004) (Argoff, 2004)

The FDA has approved a lidocaine/ tetracaine cream (Pliaglis®) for local analgesia. This is only indicated for superficial aesthetic procedures, such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal. (FDA, 2013)

Criteria for use of Lidoderm patches:

- (a) Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology.
- (b) There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica).
- (c) This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points.
- (d) An attempt to determine a neuropathic component of pain should be made if the plan is to apply this medication to areas of pain that are generally secondary to non-neuropathic mechanisms (such as the knee or isolated axial low back pain). One recognized method of testing is the use of the Neuropathic Pain Scale.
- (e) The area for treatment should be designated as well as number of planned patches and duration for use (number of hours per day).
- (f) A Trial of patch treatment is recommended for a short-term period (no more than four weeks).
- (g) It is generally recommended that no other medication changes be made during the trial period.
- (h) Outcomes should be reported at the end of the trial including improvements in pain and function, and decrease in the use of other medications. If improvements cannot be determined, the medication should be discontinued.
- (i) Continued outcomes should be intermittently measured and if improvement does not continue, lidocaine patches should be discontinued.