



Specialty Independent Review Organization

**Date notice sent to all parties:** 3/6/2016

**IRO CASE #:**

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

The item in dispute is the prospective medical necessity of Duragesic patch 12 mcg, apply q48h #15.

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

The reviewer is a Medical Doctor who is board certified in Anesthesiology.

**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)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of Duragesic patch 12 mcg, apply q48h #15.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is status post back injury on XX/XX/XX. The mechanism of injury was lifting a 5 gallon water tank. Claimant has a history of surgery in XXXX, XXXX and XXXX with revision. The patient reports low back pain radiating to bilateral lower extremities. She has tried physical therapy, chiropractor, injections, baclofen and fentanyl, imitrex, and miranol with effect. On XX/XX/XX, the patient complained of back pain rated 6/10 at rest and eight 8/10 with movements. A review of systems noted the patient was positive for abdominal pain, nausea, vomiting and heartburn. The patient denied dysuria or blood in the urine. The patient also denied difficulty swallowing or loss of bowel or bladder control. The physical examination of the lumbar spine revealed decreased range of motion to all planes. There were decreased reflexes on examination. Motor strength was noted to be normal. The treatment plan included a chronic pain management referral.

On XX/XX/XX, the patient presented for a pain management assessment. It was also noted the patient has tried different medications. The patient reported low

back pain, bilateral hip pain, bilateral legs and bilateral feet pain rated 6/10. The physical examination revealed tenderness over the lower lumbar levels that radiated to the lower extremities. There was noted mild weakness in the right leg over the left and decreased sensitivity in bilateral feet. A urine drug screen was performed in house. The treatment plan included prescriptions for Duragesic patch and baclofen, and diagnostic x-rays upon follow-up. The patient's diagnoses include post laminectomy syndrome.

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

The Official Disability Guidelines, topical analgesics are recommended for patients with failed antidepressants and anticonvulsant therapy. Moreover, the guidelines state that Duragesic is not considered a first-line therapy as it is a long-acting opioid. However, it may be indicated for the management of chronic pain for patients who require continuous opioid analgesia for pain that cannot be managed by other means. The patient was noted to have been utilizing Duragesic/fentanyl patch for an unspecified duration of time as her date of injury was from 1999. However, there was lack of clinical documentation outlining details that her chronic pain was not managed by other means or lower levels of conservative treatment. Moreover, there was lack of clinical documentation indicating that the patient had objective positive efficacy with a reduction in pain and improving function with Duragesic use. Based on the above, the request is not supported at this time. As such, the request is non-certified.

Official Disability Guidelines (ODG):

Treatment Index, 14th Edition (web), 2016, Pain (updated 01/12/2016), Duragesic (fentanyl transdermal system)

Endeared it as a first-line therapy. Duragesic is a long-acting opioid. See opioids, long-acting. The FDA-approved product labeling state that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for patients that cannot be managed by other means.

Topical analgesics.

Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended.

**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)**