

# C-IRO Inc.

An Independent Review Organization

1108 Lavaca, Suite 110-485

Austin, TX 78701

Phone: (512) 772-4390

Fax: (512) 519-7098

Email: resolutions.manager@ciro-site.com

## NOTICE OF INDEPENDENT REVIEW DECISION

DATE NOTICE SENT TO ALL PARTIES: Aug/04/2014

IRO CASE #:

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:** pharmacy purchase of compound cream containing ketamine 10%, baclofen 2%, cyclobenzaprine 2%, diclofenac 3%, gabapentin 6 %, orphenadrine 5%, tetracaine 2%, 240 gm with three refills

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:** D.O., Board Certified Physical Medicine and Rehabilitation and Pain Medicine

**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)

**Provide a description of the review outcome that clearly states whether medical necessity exists for each health care service in dispute.** It is this reviewer's opinion that medical necessity for the requested pharmacy purchase of compound cream containing ketamine 10%, baclofen 2%, cyclobenzaprine 2%, diclofenac 3%, gabapentin 6 %, orphenadrine 5%, tetracaine 2%, 240 gm with three refills is not established

**PATIENT CLINICAL HISTORY [SUMMARY]:** The patient is a female who sustained an injury in xxxx. The patient had been followed for ongoing complaints of chronic pain following a revision spinal fusion procedure at L4-5 and L5-S1 performed in 2005. The patient was being followed by an unknown provider through 2014. Recent medications for the patient per the 04/17/14 clinical report included intrathecal Morphine. The patient was utilizing oral medications; however, it is unclear what this medication was due to the notes handwriting and copy quality. The patient's pain scores ranged from 4-10/10 on the VAS. The patient did report significant relief with intrathecal medications. Pain scores at this evaluation were elevated to 10/10 on the VAS. The patient did have the intrathecal pump refilled at this evaluation.

The requested compounded topical medication was denied by utilization reviews dated 06/25/14 and 07/11/14 as the components of the requested topical medication were not supported by current evidence based guidelines.

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION:** The patient has been followed for ongoing complaints of chronic low back pain radiating to the lower extremities following previous lumbar fusion procedures in 2005. The patient has been utilizing intrathecal medications with reported good relief. The patient's most recent pain scores were severe, 10/10 on the VAS. In regards to the request for the compounded topical medication to include Ketamine, Baclofen, Cyclobenzaprine, Diclofenac, Gabapentin, Orphenadrine, and Tetracaine, the clinical documentation submitted for review would not support this

compounded medication as medically necessary. The ODG and US FDA note that the efficacy of compounded medications has not been established through rigorous clinical trials. The FDA requires that all components of compounded topical medication be approved for transdermal use. This compound contains Ketamine, Baclofen, Cyclobenzaprine, Diclofenac, Gabapentin, and Orphenadrine which are not approved for transdermal use. The clinical documentation provided did not discuss the claimant's prior oral medication use and did not indicate that there were any substantial side effects with the oral version of the requested medication components. Furthermore, there was no rationale regarding the efficacy of the compounded medication to support multiple refills. Therefore, it is this reviewer's opinion that medical necessity for the requested pharmacy purchase of compound cream containing ketamine 10%, baclofen 2%, cyclobenzaprine 2%, diclofenac 3%, gabapentin 6 %, orphenadrine 5%, tetracaine 2%, 240 gm with three refills is not established and the prior denials are upheld.

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

ACOEM-AMERICA 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)