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NOTICE OF INDEPENDENT REVIEW DECISION

DATE NOTICE SENT TO ALL PARTIES: Jan/27/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Compound cream T dermal TD6 to include Ketamine, fluribiprofen, bupivacaine, cyclobenzaprine, lipoderm active max

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: M.D., 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:

[X] 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 <u>each</u> health care service in dispute. It is this reviewer's opinion that medical necessity for Compound cream T dermal TD6 to include Ketamine, fluribiprofen, bupivacaine, cyclobenzaprine, lipoderm active max in this case is not established

INFORMATION PROVIDED TO THE IRO FOR REVIEW:
ODG - Official Disability Guidelines & Treatment Guidelines
Radiographs of the right foot dated 10/31/13
Clinical report dated 11/01/13
Clinical report dated 11/01/13
Psychological evaluation
CT scan of the right foot dated 11/18/13
Handwritten clinical report dated 11/20/13
Handwritten clinical report dated 12/18/13
Utilization review reports dated 11/11/13 & 12/13/13

PATIENT CLINICAL HISTORY [SUMMARY]: The patient is a female who sustained an injury to the right foot. The patient's right foot was struck. Initial radiographs showed an incomplete faint lunar lucency in the medial base of the 5th metatarsal suspicious for a non-displaced fracture. The patient was initially placed on anti-inflammatories and Tramadol for pain. Physical examination did show ecchymosis in the medial and lateral aspect of the tarsal bones in the right foot. The patient was also recommended for psychological treatment in October of 2013. Further CT studies of the right foot from 11/18/13 ruled out any fractures. The patient was seen through 12/18/13. The clinical reports were handwritten and difficult to interpret due to handwriting and copy quality. It did appear that Naproxen was causing nausea. The patient continued to have edema and a Tinel's sign in the right foot. There appeared to be possible concerns regarding nerve entrapment.

The requested compounded dermal cream to include Ketamine, Flurbiprofen, Bupivocaine, Cyclobenzaprine, and Lidoderm was non-certified by utilization review on 11/11/13 as there

was no evidence to support a failure of approved medications and compounded creams were not recommended as 1st line therapy.

The topical medication was again non-certified on 12/13/13 as there was no denoted trial regarding other medications or evidence of risk factors to prevent short term use of oral medications.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION: The patient sustained a crush trauma to the right foot that resulted in ecchymosis. Any severe fractures were ruled out by imaging. The most recent clinical report did detail the patient having nausea with the use of anti-inflammatories such as Naproxen. Based on the clinical documentation, there is no evidence to support that the patient was reasonably intolerant or had failed trials of oral medications to include muscle relaxers. Additionally, medications including Ketamine, Flurbiprofen, and Cyclobenzaprine are not FDA approved for transdermal use. Given the limited evidence in the clinical literature substantiating the use of topical medications without indications of failure or intolerance to other standard oral medications, it is this reviewer's opinion that medical necessity for Compound cream T dermal TD6 to include Ketamine, fluribiprofen, bupivacaine, cyclobenzaprine, lipoderm active max in this case 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

[X] MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

[ ] MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

[ ] MILLIMAN CARE GUIDELINES

[X] 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)