

US Decisions Inc.

An Independent Review Organization
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DATE AMENDED NOTICE SENT TO ALL PARTIES: Feb/19/2016

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: MED Cymbalta 60mg #60, Gabapentin 800mg #90, Nucynta ER 100mg #60 and Nucynta IR 50mg #60

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: MD, Board Certified Anesthesiology and Board Certified 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 the opinion of this reviewer that the request for Nucynta ER 100mg #60 is not medically necessary

PATIENT CLINICAL HISTORY [SUMMARY]: The patient is a female with apparent complaints of pain. On XX/XX/XX, a letter was submitted stating the patient had pain starting in XXXX after an injury at work. The patient had severe burning of the left upper extremity with pain rated at 7/10. The provider stated that since her syndrome was known to be more than neuropathic pain, with diagnosis of CRPS, Nucynta was an excellent choice and she needed the ER for baseline pain and the IR for pain spikes throughout the day. Gabapentin was also described as a good medicine and it was noted she had been on Cymbalta for a long time which was known to help with her neuropathic pain and she needed to continue that medication as well. On XX/XX/XX, a letter was submitted, again noting that Nucynta was an excellent choice for the syndrome known to be more than neuropathic pain with CRPS.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION: On XX/XX/XX, a peer review report indicated that Nucynta 100 mg was not medically necessary and due to the nature of the drug weaning was recommended. It was noted the patient had been on the drug for a long time without real indication of functional benefit and pain had been rated at 7/10 not indicative of good therapeutic benefit for the medication.

On XX/XX/XX a peer review report noted that Nucynta was not medically necessary, as the patient had pain rated at 9/10 worse with activity, and the patient had been on the medications for an unstated length of time and with pain rated at 9/10, continued use of the drug was not supported.

A study by Afilalo, Marc, and Bart Morlion, titled "Efficacy of tapentadol ER for managing moderate to severe chronic pain" reported "Tapentadol ER (100 - 250 mg bid) is effective for moderate to severe osteoarthritis pain, low back pain, and pain related to DPN and provides efficacy similar to that of oxycodone HCl CR (20 - 50 mg bid) for patients with osteoarthritis and low back pain. Tapentadol ER treatment has been associated with better gastrointestinal tolerability and compliance with therapy than oxycodone CR, which suggests that tapentadol

ER may be a better option for the long-term management of chronic pain.”

Without documented efficacy, continued use of the drug, Nucynta ER 100mg is not supported.

It is the opinion of this reviewer that the request for Nucynta ER 100mg #60 is not medically necessary 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)

SCHUKRO, REGINA P., ET AL. "EFFICACY OF DULOXETINE IN CHRONIC LOW BACK PAIN WITH A NEUROPATHIC COMPONENTA RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CROSSOVER TRIAL." THE JOURNAL OF THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS 124.1 (2016): 150-158.

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)