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Notice of Independent Review Decision

Case Number:

Date of Notice: 09/29/2015

Review Outcome:

A description of the qualifications for each physician or other health care provider who reviewed the decision:

Anesthesiology

Description of the service or services in dispute:

Sufentanil 50mg, refill intrathecal pain pump

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)

Patient Clinical History (Summary)

Patient is a female. On xxxxx, she was seen in clinic. She was there for follow up and refill of her intrathecal pain pump. She was on Sufentanil at 35mcg per day. She reported continued some therapeutic response with her oral Hydrocodone and she was taking that medication every 6 hours. Her pump was interrogated, and 3mL was obtained. Sufentanil 50mcg per cc was utilized to refill her pain pump and 19 ccs were placed in the pump with 1 cc discarded and the pump was reprogrammed. On 03/19/15, the patient returned to clinic. Her pain pump was interrogated and refilled at that time. On 08/17/15, the patient returned to clinic. She was using the Sufentanil at 35mcg per day, and continued to report benefit. She denied adverse effects. Her pain pump was refilled without a change in medication. On 09/09/15, the patient returned to clinic. It was noted she was doing reasonably well with her current medication regimen, and her pain pump was interrogated and refilled with Sufentanil 50mcg per cc with a current rate at 35mcg per day.

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

On 08/14/15, a notification of adverse determination was submitted for the requested intrathecal pain pump refill with Sufentanil, and it was noted that Sufentanil is not FDA approved for use in intrathecal pumps as there was little research associated with its use, and the patient's response to the recent pain pump refill with Sufentanil in the form of objective functional improvement was not documented to warrant continued treatment. Therefore the request was non-certified. On 09/08/15, a notification of adverse determination was submitted in which it was noted there was a lack of documentation of failure of all lesser measures for the individual, and there was a lack of documented efficacy of the drug. Pain was not objectively documented per the record and therefore the request was non-certified. The records submitted for this review also fail to objectively document pain relief over time with the use of this medication. Sufentanil has been used for intrathecal chronic non-malignant pain but is non-FDA approved and there was little research associated with its use. Therefore, it is the opinion of this reviewer that the request for Sufentanil 50mg refill for an intrathecal pain pump 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 and Environmental Medicine um
- knowledgebase AHCPR-Agency for Healthcare Research and Quality Guidelines
- DWC-Division of Workers Compensation Policies and
- Guidelines European Guidelines for Management of Chronic
- Low Back Pain Interqual Criteria
- Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical
- standards Mercy Center Consensus Conference Guidelines
- Milliman Care Guidelines
- ODG-Official Disability Guidelines and Treatment
- Guidelines Pressley Reed, the Medical Disability Advisor
- Texas Guidelines for Chiropractic Quality Assurance and Practice
- Parameters Texas TACADA Guidelines
- TMF Screening Criteria Manual
- Peer Reviewed Nationally Accepted Médical Literature (Provide a description)
- Other evidence based, scientifically valid, outcome focused guidelines (Provide a description)