

Pure Resolutions LLC

An Independent Review Organization

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Notice of Independent Review Decision

Case Number:

Date of Notice: 09/03/2015

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:

Nuvigil 250mg

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 patient is a female who was originally injured on xx/xx/xx. The patient has been followed for chronic pain and was receiving intrathecal Sufentanil as well as taking oral Norco and Baclofen. The patient was being followed by for ongoing chronic pain. The patient did report developing daytime somnolence due to other medications. The 07/23/15 clinical report did note that a trial of Nuvigil was effective for daytime somnolence. Currently the patient was receiving intrathecal Sufentanil at 27mcg per day in addition to 10mg of Hydrocodone every 8 hours orally. It is noted that titration of medications had failed to eliminate daytime somnolence and had also increased her overall levels of pain. The patient was recommended to continue with Sufentanil intrathecally as well as Nuvigil to avoid daytime somnolence.

The requested Nuvigil 250mg was denied by utilization review as this medication is not indicated to counteract somnolence from narcotics use. The current FDA indications for Nuvigil include shift work sleep disorder and narcolepsy. As these indications were not present, the use of Nuvigil was not recommended as medically necessary.

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

The patient has developed daytime somnolence due to narcotics use to include Sufentanil intrathecally and oral medications such as Norco. Nuvigil is commonly utilized on an off label basis to address excessive daytime somnolence due to narcotics use. The patient does not have any current FDA indications for the use of Nuvigil. It is noted in the records that the patient's narcotics regimen has been reduced but has been unsuccessful in eliminating daytime somnolence. The patient did response to an initial trial of Nuvigil. In this case, the provider did not indicate the rationale for increasing Nuvigil from 150mg as was given during her trial to 250mg. Given the off label use and lack of indications for this medication, it is this reviewer's opinion that medical necessity has not been established. As such, the prior denials remain 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)