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Notice of Independent Review Decision

DATE OF REVIEW: 12/28/10

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of the medication Nitiobid patch 0.027 percent prn.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

The reviewer is a Medical Doctor who is board certified in Internal Medicine. This reviewer has been practicing for greater than 10 years.

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)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of the medication Nitiobid patch 0.027 percent prn.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source):

Records reviewed from: A letter – 12/13/10; Drug list – undated; Denial Letters – 10/28/10 & 12/3/10; Office Notes – 10/13/10; Bowel Program Note – undated; MD Office Visit Note – 4/15/10; MD Clinic Note – 10/19/09.

Records reviewed from: fax note – 12/10/10; Home Health Certification and Plan of Care and Addendum; and Pharmacy Nitro-Bid Prescription History – 3/11/04-1/6/10.

A copy of the ODG was not provided by the Carrier/URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who suffered an injury on xx/xx/xx which resulted in a quadriplegia and neurogenic bladder and bowel, despite posterolateral fusion with iliac bone graft for C5 and C6 subluxation. He has undergone augmentation cystoplasty and takes Bactrim to prevent urinary tract infections. He undergoes daily digital stimulation due to autonomic dysreflexia. The provider has ordered nitrobid patch to treat elevated blood pressures (above 160 systolic or 110 diastolic) which sometimes occur during this maneuver. Prescriptions for Viagra were filled on 5/11/10, and 10/27/10.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

Nitrobid patch has FDA approval only for angina, heart failure due to myocardial infarction, and perioperative hypertension. It does not have an FDA-labeled indication for treatment of hypertension or as needed treatment of hypertension not in the perioperative period. In addition, nitrobid patch is contraindicated when used concurrently with phosphodiesterase inhibitors such as sildenafil or vardenafil, due to the increased hypotensive effect of the combination. The claimant takes Viagra. It would be appropriate for the claimant to be treated with another as needed agent for elevated blood pressures during digital stimulation, such as clonidine which would not be contraindicated and has FDA approval for treatment of hypertension. Thus, nitrobid 0.027% is not medically necessary.

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

- ACOEM- AMERICAN 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) PDR, 2010 Edition**

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