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Notice of Independent Medical Review Decision

Reviewer's Report

DATE OF REVIEW: January 14, 2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Placement of permanent baclofen pump.

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

M.D., Board Certified in Neurology.

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 requested service, placement of permanent baclofen pump, is not medically necessary for treatment of the patient's medical condition.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. Request for a Review by an Independent Review Organization dated 12/10/10.
2. Confirmation of Receipt of a Request for a Review by an Independent Review Organization (IRO) dated 12/14/10.
3. TDI Notice to IRO of Case Assignment dated 12/15/10.

4. Medical records from MD dated 11/16/10.
5. ITB Screening Test dated 10/19/10.
6. CT Brain Without Contrast dated 7/13/10.
7. Physician Progress Notes from Center dated 12/10/10, 10/21/10, 10/19/10 and 10/14/10.
8. Admission History & Physical Examination from Center.
9. Denial documentation.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who sustained a head injury while working on an when he was struck in the head by a large pipe on xx/xx/xx. A traumatic brain injury was diagnosed. The patient had a depressed skull fracture, orbital fractures and an intracerebral hemorrhage. He also had a cardiopulmonary arrest and possible anoxic brain injury. Eventually, he underwent a tracheostomy and insertion of a gastric feeding tube. Neurologic progress was documented. He became conscious and was able to answer yes and no questions. The feeding tube was found to be malpositioned and this was corrected. He was then transferred to a rehabilitation hospital. The patient appears to have developed significant spasticity. On 12/14/09, a neurology progress note indicated the patient was on “max doses of several oral anti-spasticity agents and pain meds.” He then received a 100 microgram intrathecal dose of baclofen and “his spasticity decreased by two points in several muscle groups. Following the pump trial, he was able to tolerate standing flexion @ 80 degrees and his upper extremities moved much easier.” The intrathecal baclofen trial was determined to be successful. An intrathecal baclofen screening test report dated 10/19/10 indicates “the patient had significant improvement in tone reduction and improved ROM. This was also evidenced by patient’s ability to tolerate full stance in the standing frame approximately 10° short of full knee extension whereas previous attempts have been lacking approximately 40° of knee extension...” The provider has recommended permanent placement of a baclofen pump.

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

The requested service, placement of permanent baclofen pump, is not medically necessary for this patient. Official Disability Guidelines (ODG) for implantable drug-delivery systems requires documentation that strong opioids or other analgesics in adequate doses have been tried without relief of pain or evidence of intolerable side effects to systemic opioids or other analgesics. The records state the patient was maximized on several oral anti-spasticity agents and pain medications but the records are unclear as to the specific medications tried and failed as well as their dosing and frequency. Further, there is no documentation of a trial and response to oral baclofen. Additionally, prescribing information for the intrathecal baclofen pump indicates that patients with spasticity due to traumatic brain injury should wait at least one year after the injury before consideration of long-term intrathecal baclofen therapy. Therefore, the patient does not meet the approved clinical indications for the prescribed treatment. All told, the requested service is not medically necessary for treatment of the patient’s medical condition.

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)
- MANUFACTURER'S PRESCRIBING INFORMATION.