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An Independent Review Organization

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NOTICE OF INDEPENDENT REVIEW DECISION

DATE NOTICE SENT TO ALL PARTIES: Apr/21/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: 3/6/2014 and 5/5/2014
Polyethylene glycol 3350 NF powder 527gm; 90 promethazine 25mg; 90 trazodone 50 mg;
90 persantine 50mg

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: M.D., Board Certified Physical Medicine and Rehabilitation and 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 this reviewers opinion that medical necessity for Polyethylene glycol 3350 NF powder 527gm; 90 promethazine 25mg; 90 trazodone 50 mg; and 90 persantine 50mg between 3/6/2014 and 5/5/2014 has not been established.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]: Claimant is a male who reportedly was injured in a fall on xx/xx/xx. He suffered a closed head injury with loss of consciousness and he sustained a spinal cord injury including T12 fracture requiring T10-L2 PSF with decompression. He also sustained right-sided pneumothorax and multiple fractures. While hospitalized, he developed septic shock with anoxic encephalopathy and was in a coma for two months requiring tracheostomy and percutaneous endoscopic gastrostomy. He was left with partial paraplegia of lower extremities and some cognitive dysfunction. He subsequently underwent extensive rehabilitation and he was reported to have been able to progress to the point of standing and walking with a walker with some assistance. He is noted to have a history of deep vein thrombosis status post inferior vena cava filter placement and status post right total hip replacement on 02/06/12 due to avascular necrosis.

The request for Polyethylene glycol 32350 NF powder 537 gm 3/6/14 – 5/5/14, 90 promethazine 25 mg 3/6/14 – 5/5/14, 90 trazodone 50 mg 3/6/14 – 5/5/14 and 90 persantine 50 mg 3/6/14 – 5/5/14 was previously denied . According to the utilization review letter dated 03/11/14, the polyethylene glycol powder was denied because evidence based guidelines support the use of polyethylene glycol powder for up to 6 months only. The documentation provided did not indicate how long claimant had been taking the polyethylene glycol or how the patient responded to the medication. The promethazine was denied based on evidence based guidelines that promethazine is recommended for use as a sedative and antiemetic in pre-operative and post-operative situation and there was no evidence to suggest that the

claimant was in a pre or post-operative period. The trazodone was denied based on ODG guidelines that trazodone was recommended for insomnia only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. The persantine was denied based on lack of clinical rationale for continued use of Persantine, and also due to evidence based guidelines indicating that prolonged use of anticoagulant therapy was associated with a definite incidents of bleeding complications and recommendations do not support long term prophylaxis in patients with retained lower extremity motor function after spinal cord injury. Additionally, research recommends that oral short-acting Persantine should be avoided in older adults.

The denial was supported on appeal. In the appeal review letter dated 03/25/14, the propylene glycol denial was based on the original determination; the documentation failed to reveal how long the patient had been prescribed the medication for treatment of constipation, and it was unclear if the patient was benefiting from it's use. An effort to contact was made and a fax response was supposed to be sent via fax transmission, however, no additional medical report was received by the time of the due date. The denial of the promethazine was also upheld. In a letter requesting reconsideration dated 03/17/14, stated the promethazine was being used as an adjunct for post-traumatic endolymphatic hydrops. The denial was upheld because there was no documentation of benefit from the medication in the context of functional benefit. The trazodone denial was upheld because guidelines indicate that evidence for off-label use of trazodone for treatment of insomnia is weak. In addition, the submitted documentation did not provide evidence of improvement in the patient's insomnia complaints as a result of the use of this medication, in the context of functional benefits. The Persantine denial was upheld because research failed to provide recommendations for the use of Persantine to enhance cerebral perfusion (which was the reason for use of Persantine for this claimant in his letter of 03/17/14), however guidelines do state that dipyridamole (Persantine) is a potentially inappropriate medication for use in older adults due to risk of orthostatic hypotension and bleeding, and recommend that it be avoided as there are more effective alternatives available.

There is another request for reconsideration letter dated 03/24/14 that appears was not available for review by the time of the previous appeal review determination. In this letter, stated that the claimant has responded well to propylene glycol with ongoing improvement and continues with functional benefits from the treatment, however there is no mention of what specific benefits have been achieved, and there is no mention of how long the claimant has been on this medication. He noted that the claimant has had continuous nausea related to his post-traumatic endolymphatic hydrops and promethazine has helped mediate the nausea. He further noted that claimant has been on promethazine and this medications "has continued to optimize his function from his endolymphatic hydrops", however there is no specific mention of what functional improvements he has benefitted from by the use of this medication on a daily basis. stated that trazodone is used in patients who were status post traumatic brain injury for insomnia as a sleep aide and claimant has responded well to this medication in reference to his post-traumatic insomnia. However, he did not identify specific functional benefits that the claimant had achieved from use of this medication.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION: Because there was no additional information submitted that defines the specific benefits the claimant has received from the use of propylene glycol, or how long the claimant has been taking this medication, the continued use of the polyethylene glycol powder between 3/6/14 – 5/5/14 cannot be recommended as medically reasonable or necessary. Evidence based guidelines recommend that safety and efficacy of polyethylene glycol has been established when used for constipation only up to six months. FDA approval of this medication is for treatment of occasional constipation ((use <2 weeks). The documentation provided does not identify functional benefits from use of this medication or how long the claimant has been taking this medication. As such, it is this reviewer's opinion that the medical necessity of polyethylene glycol powder 3350 NF powder, 537 gm, used between 3/5/14 and 5/5/14 has not been established and the prior denials are upheld.

As for the promethazine, clarified in his letter of 03/24/14 that the claimant has been taking this medication for the continuous nausea that he has from his post-traumatic endolymphatic hydrops. He further stated that claimant has had improvement in his nausea from this medication. Review of evidence based guidelines does support that antiemetics such as promethazine may be used for acute treatment of severe nausea and vomiting associated with acute episodes of vertigo related to endolymphatic hydrops. However there are no evidence based guidelines found that support the continued ongoing use of promethazine on a daily basis for chronic long-term management of endolymphatic hydrops. As per letter of 03/24/14, this claimant has been on this medication. As such, it is this reviewer's opinion that the medical necessity of the promethazine 25 mg #90 used between 3/5/14 and 5/5/14 has not been established and the prior denials are upheld.

Because there was no additional information submitted regarding the use of Persantine, the continued use of this medication is not recommended. Evidence based guidelines state that this medication is potentially inappropriate for use in older adults and there are more effective alternative available. It was noted in the appeal review determination letter of 03/25/14, that when office was contacted to discuss this medication, it was stated that was going to withdraw the request for Persantine at that time. As such, it is this reviewer's opinion that the medical necessity of the Persantine has not been established and the prior denials are upheld.

As for the trazodone, there was no additional documentation submitted mentioning specific functional benefits claimant had received from use of trazodone. Official Disability Guidelines indicate that the use of trazodone is an option for insomnia, but only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. In request for reconsideration letter of 03/17/14, he states that the trazodone is not being used for depression in this case, but for insomnia. Therefore, because evidence for the off-label use of trazodone for treatment of insomnia is weak and submitted documentation did not provide evidence of specific benefits in the context of functional benefits, it is this reviewer's opinion that the medical necessity of trazodone 50 mg #90, used between 3/5/14 and 5/5/14 has not been established 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)

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

Polyethylene glycol powder: Am J Gastroenterol. 2007 Jul;102(7):1436-41. Epub 2007 Mar 31.

A randomized, multicenter, placebo-controlled trial of polyethylene glycol laxative for chronic treatment of chronic constipation.

Dipalma JA1, Cleveland MV, McGowan J, Herrera JL.

Phenergan: <http://scholar.google.com/Meniere'sdisease>

EA Dinces, S Rauch, DG Deschler, P Eamranond - 2010 - gearslutz.com

Persantine: American geriatrics society 2012 beers criteria update expert panel. American geriatrics society updated beers criteria for potentially inappropriate medication use in older adults. J am geriatr soc. 2012 apr; 60(4):616-31 (35 references) pubmed external web stie policy Table. 2012 American Geriatric Society (AGS) Beers criteria for potentially inappropriate medication use in older adults. Dipyridamole, oral short acting*

(does not apply to extended release combination with aspirin); May cause orthostatic hypotension; more-effective alternatives available; intravenous form acceptable for use in cardiac stress testing; avoid.