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Notice of Independent Review Decision

[Date notice sent to all parties]:

05/31/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: pharmacy 5/02/2013

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

Board Certified Anesthesiology

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

[X] Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Drug screen report dated 01/25/13

Clinical reports dated 04/08/13 & 05/14/13

Letter of medical necessity dated 05/01/13

Prior reviews dated 04/25/13 & 05/07/13

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who initially sustained an injury to the neck on xx/xx/xx when she slipped and fell. The clinical report on 04/08/13 stated the patient continued to have neck pain radiating to the interscapular area as well as the front areas of the neck. The patient reported worsening symptoms with physical therapy. MRI studies were stated to show disc

herniations at C4-5; however, no imaging studies were submitted for review. The patient was unable to tolerate Tramadol secondary to sedation side effects. The patient was also noted to have a gastric bypass and oral anti-inflammatories were not recommended. The patient did report some benefits from muscle relaxers. As of 04/08/13, the patient was utilizing Voltaren gel that was applied 4 times per day. Physical examination demonstrated decreased range of motion in the cervical spine with paraspinal muscular spasms present. Follow up on 05/14/13 indicated the patient did have resolution of recent radicular symptoms. The patient reported continued benefits from muscle relaxers. The patient was continuing to use Voltaren gel. Physical examination was relatively unchanged from the prior evaluation. The patient was recommended to continue with Voltaren gel.

The use of Voltaren gel was denied by a utilization review on 04/25/13 as there was no indication of failure of other first line medications or anti-inflammatories.

The request was again denied by a utilization review on 05/07/13 as there was no indication of any significant functional improvements that were gained with the use of Voltaren gel.

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

The patient has had ongoing chronic neck pain stemming from a prior cervical fusion at C2-3. The patient is noted to have had a gastric bypass and oral anti-inflammatories are contraindicated. The clinical notes report good effect with muscle relaxers; however, the clinical documentation does not show definitive improvements with the use of Voltaren gel only. Given the significant risk profiles for topical Voltaren gel and the lack of clinical documentation which establishes the efficacy of this medication, it is this reviewer's opinion that medical necessity for ongoing use of Voltaren gel is not established.

IRO REVIEWER REPORT TEMPLATE -WC

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

[X] MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

[X] ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Official Disability Guidelines, Online Version, Pain Chapter

Voltaren® Gel (diclofenac)

Not recommended as a first-line treatment. See Diclofenac Sodium (Voltaren®), where Voltaren Gel is recommended for osteoarthritis after failure of an oral NSAID, or contraindications to oral NSAIDs, or for patients who cannot swallow solid oral dosage forms, and after considering the increased risk profile with diclofenac, including topical formulations. According to FDA MedWatch, postmarketing surveillance of Voltaren Gel has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. (FDA, 2011) For more details see Topical analgesics, Non-steroidal antinflammatory agents (NSAIDs), and the diclofenac topical listing.