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IRO CASE #:

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:** Amantadine 8%, Amitriptyline 2%, Baclofen 4%, Gabapentin 5%, Ketoprofen 10% in Versatile Base AWP cream 240 grams with five refills

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

Fellow American Academy of Physical Medicine and Rehabilitation

**REVIEW OUTCOME:**

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

X Upheld (Agree)

Medical documentation does not support the medical necessity of the health care services in dispute.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a female who was injured on XX/XX/XX, while rolling a heavy pipe weighing approximately 97 pounds and felt a pop in her low back at work.

On XX/XX/XX, the patient was evaluated for the complaint of low back pain. The pain radiated to the right anterior thigh. It was characterized as constant and moderate in intensity. Examination showed palpation at L3-L4 and L4-L5. The patient was diagnosed with low back pain and prescribed Norco, Robaxin and Celebrex. The patient was referred to physical therapy (PT) and was placed off work through XX/XX/XX.

On XX/XX/XX, x-rays of the lumbar spine revealed degenerative changes at L4-L5 with retrolisthesis, degenerative disc disease and facet hypertrophy. There was abnormal appearance to the facets at this level, which might be due to underlying pars defect.

On XX/XX/XX, the patient was seen and recommended therapy three times a week for four weeks consisting of hot/cold packs, therapeutic exercises, electrical stimulation, ultrasound and home exercise program (HEP).

On XX/XX/XX, the patient was evaluated for a follow-up visit for low back pain. She started PT two days ago. Physical examination remained unchanged. Medications were refilled and the patient was advised to continue PT.

On XX/XX/XX, XX prescribed a lumbar brace for the diagnosis of lumbar radiculopathy and low back pain.

On XX/XX/XX, the patient reported her symptoms had been worse since the previous visit. XX prescribed a Medrol Dosepak and recommended magnetic resonance imaging (MRI). The patient was unable to work at that time.

On XX/XX/XX, an MRI of the lumbar spine without contrast performed and revealed grade 2 anterolisthesis of L4 on L5 due to defect in the pars of L4 bilaterally. Postsurgical changes were also noted at the L5-S1 level with a wide decompressive laminectomy defect without recurrent disc herniation or central canal stenosis. There was a wide thecal sac at the level of L5-S1 in the thecal sac region, raising the possibility of early meningocele. There was no acute disc extrusion and compression fracture of the vertebral bodies.

On XX/XX/XX, XX prescribed Lyrica and referred the patient to XX.

On XX/XX/XX, XX evaluated the patient for follow-up. The patient was status post physical therapy without improvement in her symptomatology. She rated her pain as a 10/10. On exam, the patient had difficulty with heel walk and toe walk. Straight leg raise was positive. Lumbar range of motion (ROM) was decreased in forward flexion secondary to pain. Sensory exam revealed a hypoesthetic region over the L4 and L5 distributions on the right to pinprick and light touch. XX reviewed MRI of the lumbar spine and diagnosed recurrent lumbar radiculitis, to rule out pseudoarthrosis and adjacent level disease. The patient was recommended CT myelogram of the lumbar spine and x-ray of the lumbar spine.

On XX/XX/XX, the patient reported she saw XX and requested a steroid injection. XX refilled Norco, Lyrica, Celebrex and Robaxin.

On XX/XX/XX, XX performed a peer review and opined: The mechanism of work-related, XX/XX/XX, event of pushing a pipe produced a lumbar strain in all medical probability. The ODG identifies that pushing or pulling does not produce new acute structural damage to the lumbar spine in all medical probability. The patient had symptoms down the right leg to the knee, the opposite side of the postsurgical and longstanding findings on the lumbar MRI that were to the left. The office notes from the treating provider identified no abnormal neurological exam findings. Thus, the work event did not aggravate the pre-existing disease of life findings in the lumbar spine. Any diagnoses other than a lumbar strain were not produced, accelerated or aggravated by the work-related event on XX/XX/XX.

On XX/XX/XX, in a follow-up visit, the patient noted the current medication regimen was not controlling pain. She was scheduled for a designated doctor examination (DDE) on XX/XX/XX, and prescribed Lidoderm patches.

On XX/XX/XX, a peer clinical record review was completed. The provider request for Lidoderm 5% Adhesive Patch was certified.

On XX/XX/XX, XX diagnosed the patient with lumbar radiculopathy and refilled the medications. The patient was unable to work.

On XX/XX/XX, a myelogram with post-myelogram CT scan of the lumbar spine was completed. The study revealed degenerative disc disease at the L4-L5 level with bilateral laminectomies. There were bilateral

extradural defects at L4-L5 on the left side. There was osteophyte formation from the medial aspect of the facet joint complex at the left L4-L5 level with bilateral lateral and posterior fusion at the L4-L5 level. There was anterolisthesis of the L4 vertebral body with reference to L5.

On XX/XX/XX, the patient reported pain to the entire right lower extremity. XX advised to continue ongoing treatment plan.

On XX/XX/XX, the patient was evaluated for low back pain and lumbar radicular symptoms. XX prescribed Lidocaine ointment and recommended epidural steroid injection (ESI).

On XX/XX/XX, per DWC-73 work status report, the patient was placed on restricted work with no lifting/carrying.

On XX/XX/XX, the patient returned reporting no improvement in her symptoms. The low back pain radiated into the right lower extremity laterally to the knee with associated numbness and tingling in a similar distribution. The pain was rated at a 10/10. Examination showed decreased lumbar ROM. The diagnoses were lumbar spondylolisthesis at L4-L5, grade I with instability recurrent lumbar radiculopathy, herniated nucleus pulposus at L4-L5 and lumbago. XX recommended evaluation for ESI and lumbar fusion at L4-L5.

On XX/XX/XX, per utilization review, the request for outpatient caudal ESI was denied.

From XX/XX/XX, through XX/XX/XX, XX evaluated the patient for follow-up of low back pain and refilled Lyrica, Norco, Celebrex, and Robaxin. The patient had an injection that did not help. It was noted that the patient reached maximum medical improvement (MMI) on XX/XX/XX, with 5% whole body impairment (WPI). On XX/XX/XX, XX prescribed a lumbar support brace.

Per utilization review dated XX/XX/XX, the request for the lumbar orthotics was certified.

On XX/XX/XX, the patient was seen and advised to continue ongoing treatment regimen.

Per utilization review dated XX/XX/XX, anterior lumbar interbody fusion at L4-L5 with posterior lumbar decompression was certified.

From XX/XX/XX- XX/XX/XX, the patient had monthly follow-up visits for follow-up of low back pain. Examination showed tenderness to the right paraspinal muscles of the thoracic and lumbar spine. The patient was in a distressed mood. The plan was to continue current treatment plan.

On XX/XX/XX, in a follow-up visit the patient reported wheezing and weakness in the bilateral lower extremities and numbness in the right lower extremity. The patient was diagnosed with prolapsed lumbar intervertebral disc and asthma and prescribed Ventolin. XX prescribed transdermal compound cream consisting of amantadine 8%, baclofen 4%, gabapentin 5%, amitriptyline 2%, ketoprofen 10% and penetrating cream base.

On XX/XX/XX, XX evaluated the patient for follow-up of low back pain. She reported continued pain to the left anterior and posterior thigh. On exam, there was decreased sensation of the lower thigh and tenderness to the right paraspinal muscles of the thoracic and lumbar spine. The patient was diagnosed with prolapsed lumbar intervertebral disc.

Per utilization review dated XX/XX/XX, XX denied the request for amantadine 8%, baclofen 4%, gabapentin 5%, amitriptyline 2%, ketoprofen 10% in versatile base AWP Cream 240 gm with five refills. Rationale: "The order for compounded cream was not recommended. The cream is not mentioned in the documentation provided. It is not clear why this medication is being prescribed or what the directions are. It contains multiple ingredients not recommended by guidelines and some ingredients that are not addressed in guideline for topical use. One of the ingredients, ketoprofen is not approved for topical use. There is no demonstrated medical necessity for this prescription."

On XX/XX/XX, XX denied the reconsideration appeal of adverse determination for the compound cream amantadine 8%, baclofen 4%, gabapentin 5%, amitriptyline 2%, ketoprofen 10% in versatile base AWP Cream 240 gm with five refills based on the following rationale: "Prior utilization review was non-certified on XX/XX/XX. It was denied as it contains multiple ingredients not recommended by guidelines and some ingredients that are not addressed in the guidelines for topical use. The 1 ingredient ketoprofen is not approved for topical use. Clinical note from XX/XX/XX, the patient is in for follow up for low back pain with lumbar radiculopathy. She has had previous injections which did not help, previous physical therapy which did not help. She continues to have pain to the mid back and low back right side with pain to the entire right lower extremity. The patient also reports continued pain to the left anterior and posterior thigh. On physical examination, the patient is in moderate distress. She had a slow stooped gait. Is limping to the right lower extremity. Reflexes are symmetric in the patella's sensation on the right is decreased, sensation on the left lower thigh in the L5 distribution. There is tenderness to right paraspinal muscles of thoracic and lumbar. Strength in the knee extension on the right is rated 4/5, knee extension on the left is rated 4/5. Dorsalis ankle dorsiflexion and rihialis anterior bilaterally are rated 4/5. The appeal request for amantadine 8%, baclofen 4%, gabapentin 5%, amitriptyline 2%, ketoprofen 10% in versatile base AWP Cream 240 gm with five refills is not medically request. The Official Disability Guidelines and USFDA do not recommend the use of compounded medications as these medications are noted to be largely experimental use with few randomized controlled trials to determine efficacy or safety. Further, the FDA requires all components of a transdermal compound medication he approved for transdermal use. This compound contains gabapentin, ketoprofen, baclofen, amitriptyline and amantadine which have not been approved by the FDA for transdermal use. Any compounded product that contains at least 1 drug that is not recommended and therefore, not medically necessary. The determination and appeals were relayed to the provider's office. Based on the clinical information submitted for this review and using the evidence-based peer-reviewed guidelines referenced above, this request is non-certified. Any compounded product that contains at least 1 drug (or drug class) that is not recommended and therefore, not medically necessary."

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

Topical compounds are generally not recommended unless there are oral contraindications. In addition, "The Official Disability Guidelines and USFDA do not recommend the use of compounded medications as these medications are noted to be largely experimental use with few randomized controlled trials to determine efficacy or safety. Further, the FDA requires all components of a transdermal compound medication he approved for transdermal use. This compound contains gabapentin, ketoprofen, baclofen, amitriptyline and amantadine which have not been approved by the FDA for transdermal use. Any compounded product that contains at least 1 drug that is not recommended is therefore not medically necessary". Therefore the decision should be upheld.

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

**ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**