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Notice of Independent Review Decision

DATE OF REVIEW: 8-12-2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of Fluoxetine HCL 20 milligrams, #60 with one refill.

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 Physical Medicine and Rehabilitation. 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 disagrees with the previous adverse determination regarding the Fluoxetine HCL 20 milligrams, #60 with one refill.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties: D.O. and Insurance Company via.

These records consist of the following:

- 2/24/2010: Initial Pain Evaluation D.O.
- Follow-up Note:, D.O.: 11/15/2010, 12/09/2010.
- Follow-up Notes in 2011:, D.O.: 4/04, 4/25, 5/09, 6/06, 6/20, 7/11.
- 12/08/2010: Independent Medical Evaluation: M.D.
- 1/11/2011: Anesthesia Note.
- 7/12/2011, 7/15/2011: Pre-Authorization Form, Requesting Fluoxetine HCL 20 mg capsule, with annotation "Appeal 7-15-11".
- 7/18/2011: Notice of Review Outcome: Initial Adverse Determination/Denial.
- 7/21/2011: Prior Authorization Request Form.
- 7/21/2011: Notice of Review Outcome: Adverse Determination upheld on appeal.
- 7/28/2011: Letter from of, with enclosures.
- Drug Screen Report, Solutions, LLC.: 5/09/2011.
- Procedure Note: Cervical Epidural Steroid Injection: 12/07/2010, 1/11/2011.

A copy of the ODG was provided by the Carrier/URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant sustained a work related injury on xx/xx/xx while employed by , Inc. The claimant's neck pain did not respond to conservative care including cervical ESI in June 2005. He went to surgery January 11, 2006 for anterior cervical discectomy and fusion. After surgery, the claimant's neck pain persisted.

Dr. saw the worker in consultation February 24, 2010 for consideration of facet injection therapy. At that time, the listed current medications were Nexium, hydrocodone, and tizanidine. Dr. diagnosed post cervical laminectomy pain syndrome following a work-related injury, cervicogenic headache consistent with cervical facet dysfunction bilaterally, and myofascial pain syndrome of the cervical and upper thoracic regions. Dr. recommended injection therapy and active range of motion exercise. He prescribed Cymbalta 60 mg q.a.m. and Klonopin 1 mg at night.

The claimant did not return to see Dr. until November 15, 2010. He was no longer taking the Cymbalta which did help him. Dr. resumed Cymbalta 60 mg daily. He proposed cervical ESI pending insurance authorization. Cervical ESI was performed on 12/07/2010 and 01/11/2011.

Dr. M.D. saw the claimant for an independent medical evaluation on December 8, 2010, diagnosing neck pain after a fall from standing height, cervical degenerative disease treated surgically and accepted as a portion of the injury, and chronic neck pain, etiology undetermined. In response to questions he affirmed that due to the fusion that was performed, it is likely that the examinee will continue to have pain on an ongoing basis into the future, and will require further treatment. Furthermore he stated that further medical care is reasonable and necessary...the examinee should be seen once every four to six months

for maintenance of his medications, as required by Texas State Law and recommended by the O.D.G.

On April 4, 2011 the claimant complained of continued depression, anxiety, and sleep disorder. Dr. explained that the worker “must see us on a regular basis in order to find those medications which will help him with his pain, his activity levels, and his function”. Cymbalta left him somewhat dizzy. Dr. wanted to see the worker on a regular basis in order to find the right medications for his pain hoping to get it down to an acceptable level, after which “we will consider further intervention”.

On April 25, 2011 Dr. emphasized that it is “imperative that a behavioral chronic pain approach which is to include serotonin uptake inhibitor medication such as Celexa or Lexapro which I have here in my office be started. As a result, we are going to give him samples. It is important that Lexapro or other serotonin uptake inhibitors highly efficacious in reactive depression and myofascial pain syndrome be instituted at once. It is this behavioral, rehabilitative, and persistent myofascial pain which must be treated in order to afford a satisfactory outcome”. On May 9, 2011 Dr. reported that the worker was making gains already following institution of Celexa just two weeks out. He added Lyrica 75 mg t.i.d. to his hydrocodone.

On June 6, 2011 Celexa was increased to 40 mg q.a.m. He was taking Restoril 30 mg at night and was sleeping better. Neuropathic pain particularly in his shoulder and arm continued at a moderate grade. At this point, having failed surgical, rehabilitative, and medical treatment options, Dr. considered a trial of spinal cord stimulation and requested referral for psychological clearance to rule out major depression, anxiety, or personality disorder which would preclude a satisfactory outcome.

On June 20, 2011 Dr. noted that the claimant’s affect had already improved with SSRI agents such as Celexa or Lexapro.

“Unfortunately, his carrier is not giving these medicines in a timely manner. We will, therefore, try Prozac 20 mg q .a.m. to be increased to 40 mg q.a.m. This medication and management alone has helped him deal with his pain, become more functional and more active. He is no longer going in and out of hospitals. He is no longer seeking other medical treatment other than from this office only...we are going to recommend spinal cord stimulation. We will continue him on a combination of neuropathic and antidepressant support in the meantime, and we will schedule him for cervical spinal cord stimulation as an outpatient pending insurance authorization.

On July 11, 2011 Dr. was awaiting psychological clearance. He reiterated that in the meantime, it was imperative that the Prozac, an SSRI agent with analgesic properties and mood elevation properties particularly helpful in chronic pain states be given in a timely manner.

“It is not uncommon to use SSRIs or mixed norepinephrine/serotonin agents in chronic pain. In the meantime, he is requiring a combination of Norco and Lyrica. We will give him these on

a steady basis. His last urinalysis was consistent with these agents, and we will schedule him for follow-up in one month's time. Once appropriate psychological treatment and clearance has been obtained, spinal cord stimulation will be considered”.

On July 18, 2011 the request for Prozac was denied, partially on the grounds that no data was submitted regarding neuropsychological test results, partially on the grounds that the use of an SSRI along with Lyrica is redundant for treatment of neuropathic pain. However, Dr. note of July 11 documented that he was anticipating the timely administration of Prozac but in the meantime was using Lyrica instead of Prozac to treat the chronic pain while awaiting psychological clearance for the proposed spinal cord stimulation. The adverse determination was upheld on appeal July 21. 2011

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

Based on the records submitted for review, the requested procedure is recommended at this time. The treatments proposed by Dr., including the use of antidepressants, fall within the ODG guidelines and the MDguidelines for management of chronic pain. The specific drug Fluoxetine (Prozac) was not Dr. first choice, but other antidepressant drugs were poorly tolerated or non-authorized for use. The quantity of Fluoxetine requested would be sufficient for a therapeutic trial of the medication.

From the ODG Treatment Integrated Treatment/Disability Duration Guidelines Pain (Chronic) (updated 08/05/11) pertaining to antidepressants for chronic pain:

- Antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks.
- In a large RCT the benefits of improved depression care (antidepressant medications and/or psychotherapy) extended beyond reduced depressive symptoms and included decreased pain as well as improved functional status.
- Chronic pain may harm the brain, based on using functional magnetic resonance imaging (fMRI), whereby investigators found individuals with chronic back pain (CBP) had alterations in the functional connectivity of their cortical regions - areas of the brain that are unrelated to pain - compared with healthy controls. Conditions such as depression, anxiety, sleep disturbances, and decision-making difficulties, which affect the quality of life of chronic pain patients as much as the pain itself, may be directly related to altered brain function as a result of chronic pain.

Pertaining to selective serotonin reuptake inhibitors (SSRIs)

- They are controversial based on controlled trials. It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain. [Note: the cited references were published in 2005].
- Side Effects: Bleeding: An association has been found between the use of SSRI antidepressants and gastrointestinal bleeding. A treatment option for those at risk for bleeding includes switching to an antidepressant with a lower degree of inhibition of serotonin reuptake (Intermediate reuptake: venlafaxine, amitriptyline, imipramine, citalopram; Low reuptake: desipramine, doxepin, trazodone, bupropion, mirtazapine). SSRIs with the highest degree of inhibition of serotonin reuptake include paroxetine, sertraline, and fluoxetine. According to the FDA prescribing information for fluoxetine (Prozac): Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding.

According to the MD guidelines pertaining to chronic pain: effective management is based upon rehabilitation, behavior modification and therapy. Therapeutic measures for chronic pain can include physical therapy, occupational therapy, recreational therapy, interventional treatments (such as nerve blocks, nerve ablations, spinal surgeries and stimulation), psychological therapy, biofeedback, cognitive behavioral therapies, and medications including analgesics, antidepressants, anticonvulsants, and nonsteroidal anti-inflammatory drugs.

In conclusion, Dr. proposed appropriate treatment in accordance with the ODG Guidelines. He attempted to try more than one antidepressant medication for chronic pain management but the initial choices were poorly tolerated or non-authorized. The risk-benefit profile of Prozac for chronic pain management appears to be less satisfactory than the profile for Celexa, but that medication was poorly tolerated. Redundant treatment with Lyrica did not occur, as the Lyrica was used instead of Prozac “in the meantime” while awaiting authorization for the Prozac.

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)**