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Notice of Independent Review Decision

MEDICAL RECORD REVIEW:

DATE OF REVIEW: 08/17/2010

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified) Doctor, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Retrospective: Reimbursement for medications of Flexeril and Tranxene DOS 03-99-10 to 05-18-10

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o 03-03-09 IME report from Dr.
- o 06-23-09 Medical report from Dr.
- o 07-24-09 Letter from Dr. to continue medications
- o 01-20-10 Psychiatric Evaluation from Dr.
- o 06-04-10 Request for IRO from the Claimant
- o 06-14-10 Request fro Reimbursement letter from the claimant
- o 06-14-10 Pharmacy Patient Prescription Record 6-4-08 through 5-18-10 -11 pages from
- o 06-30-10 Adverse determination letter denying reimbursement from,
- o 07-07-10 Fax notice of improper request for IRO from
- o 07-14-10 Request for IRO from the Claimant
- o 07-14-10 Confirmation of Receipt of Request for IRO from TDI
- o 07-16-10 Notice to P&S of Case Assignment from TDI
- o 07-16-10 Letter of explanation regarding RIO assignment from TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient who sustained an industrial injury to the neck and back on when carrying a file box. She is status post surgery for thoracic outlet syndrome in 2001 and is followed for continuing back pain secondary to her injury and degenerative spinal discs. She smokes one pack of cigarettes daily. She had a malignant melanoma diagnosed in 2003 and has had hypertension since 2007 as well as chronic anxiety and depression. She has an addiction or dependence on Fentanyl patches and has gone through detox.

An IME was conducted on March 3, 2009. She twisted her neck and back when carrying a file box. Thereafter, she had complaints

of pain in her back, neck and left upper extremity. MRI of 1999 showed a minimal lumbar disc bulge; otherwise, normal MRI. Cervical MRI of 1999 showed mild disc bulges at C4-5 and C5-6, otherwise normal MRI. Thoracic MRI of 1999 was normal. Lumbar and cervical CT scans of 2000 did not reveal any new significant findings. She was given a diagnosis of thoracic outlet syndrome, although no nerve studies have been found. In October 2001 she underwent a left scalenotomy and left brachiocephalic neurolysis. She has not worked since the injury. She is using Tranxene (a benzodiazepine for anxiety), Trazadone, Cymbalta, Fleceril and Lyrica. She has some very mild lumbar spasm, but mainly a tightness of the extensor muscles. She would flex to 60 degrees. The rest of the motions were (voluntarily limited) to 10 degrees. Left shoulder exam showed some areas of questionable mild trigger points in the trapezial and rhomboid regions. She may have a possible neurogenic thoracic outlet syndrome. There is no objective factual evidence of any cervical disc pathology or rotator cuff pathology or thoracic or lumbar disc pathology. She might benefit from trigger point injections in the posterior shoulder. If a single Lidocaine injection is helpful, then perhaps even Botox injections might be appropriate to give longer-term management. There is no evidence-based support for use of Flexeril, or any other muscle relaxant, in this chronic situation (per cited ODG guidelines). There is minimal evidence to support ongoing use of Lyrica. Evidence-based literature would not support continued use of a benzodiazepine such as Tranxene which should be weaned. Most guidelines limit use of benzodiazepines to 4 weeks. A tapering schedule is noted. A psyche eval would be needed to determine if other psychotropic medications remain related in relationship to the effects of the central injury. The most appropriate medications for this patient would be one, or perhaps two, antidepressants. She would benefit from a home exercise program. No additional diagnostics, PT or chiropractic treatment is needed. An office visits every 3-6 months would be reasonable. An independent psyche review is needed. The only additional orthopedic treatment might be trigger point injections to the posterior shoulder girdle area.

The patient was seen in follow up by her neurosurgical provider on June 23, 2009 for recurring posterior neck and occipital pain with associated headaches and tingling/numbness sensations into the left and now right upper extremities. She currently smokes one pack a day. She is using Cymbalta, Flexeril, Lyrica, Tranxene-T and Trazadone HCL. She has a normal neurologic examination, although stocking glove hypoesthesia is noted in the left wrist/hand. Tinel's test is negative. Assessment is degeneration of cervical intervertebral disc - primary and occipital neuralgia. She presents with neck and scapular pain. However the majority of the pain involves a complaint of neck spasms, which produce a headache consistent with an occipital neuralgia. She notes the IME has recommended Botox injections, which she feels is not a standard treatment for neck pain. This treatment could be reasonable if done by someone well trained and experienced. She had a problem with narcotics in the past and went through Detox. A nerve stimulator was also discussed as a possible treatment.

Psychiatric Evaluation was conducted on January 20, 2010 for panic and anxiety attacks secondary to chronic pain. She had attempted to overdose with Elavil. She was treated with medication and psychotherapy, which improved her anxiety and depression by 50%. She uses Clorazepate 7.5 mg TID, Cymbalta 30 mg TID, Cyclobenzadrine 10 mg TID and Trazadone 150 mg at night for sleep. The patient was previously hospitalized in a general hospital because she had severe anxiety and wanted to slap one of her children; she does not remember how long or what medications were used. She mentioned that she took Xanax in 1983 for a few years before the incident. She was not taking Xanax at the time of the incident. She received psychotherapy by a social worker and medication management by her family physician which helped her symptoms. She is upset because the carrier is no longer covering the medications, which have been helping her. She mentioned that when the insurance company stopped paying for her medication she began drinking so much that she would have black outs. She got her medications and quit drinking in December of 2009. She was tearful. Diagnosis is Major Depression disorder and panic disorder with agoraphobia. Cervical surgery, cervical injury, lumbar injury. She sustained major depression and panic attacks as a result of her chronic medical condition and should continue on her medication.

Request was made for An IRO on June 4, 2010.

On June 7, 2010 the claimant was notified that an IRO was not appropriate at this time as a request for reimbursement had not been submitted.

On June 14, 2010 the claimant requested reimbursement for medications per attached pharmacy records. Per the claimant both her treating MD and the psychologist have recommended she continue all four of her medications. Per the pharmacy, discontinuing medications can be dangerous.

On June 30, 2010 the claimant was informed that continues use of Flexeril and Tranxene is not supported, per RME review of March 3, 2010.

Per the provider on July 24, 2010 the patient needs to continue her medications.

Request for reimbursement for out-of-pocket expenses paid for medications Flexeril and Tranxens was considered in review on June 30, 2010 with recommendation for non-certification as, per the RME examination of March 3, 2009 they are not supported for chronic conditions per the evidence-based literature.

Request for reconsideration - was considered in review on - with recommendation for non-certification -

Request was made for an IRO.

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

Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by

Ortho McNeil Pharmaceutical. ODG supports brief use of cyclobenzaprine: Treatment should be brief. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. The addition of cyclobenzaprine to other agents is not recommended. Drowsiness and dizziness are common side effects.

Clorazepate is used to treat anxiety, acute alcohol withdrawal, and seizures. This medication belongs to a class of drugs called benzodiazepines which act on the brain and nerves (central nervous system) to produce a calming effect. It works by enhancing the effects of a certain natural chemical in the body (GABA). Side effects include headaches. Per ODG, benzodiazepines are not recommended for long-term use unless the patient is being seen by a psychiatrist. Benzodiazepines: Effective for acute treatment. Long-term use is problematic as few patients achieve and sustain remission with monotherapy. These agents are used primarily as an adjunct for stabilization during initiation of an SSRI or SNRI. The disadvantage of use is the risk of abuse and physiological dependence with long-term use. These drugs also have no anti-depressant effect.

The provider has noted, she presents with neck and scapular pain. However the majority of the pain involves a complaint of neck spasms, which produce a headache consistent with an occipital neuralgia. However, the provider has also concurred with IME opinions that Botox may be a useful treatment for occipital headaches. Other than mild trigger points in the posterior shoulder regions, the IME examination did not note any true muscle spasms. It is noted that a common side effect of clorazepate is headaches. Smoking is also a risk factor for vascular related headaches.

The two medications under consideration are not supported for long-term use and a recommended weaning schedule has been outlined by the IME for safe, low risk weaning of clorazepate. Flexeril can also be safely weaned. There are not objective clinical findings to support muscle spasms 11 years post injury and evidence-based guidelines do not support chronic use of these medications.

Therefore, my recommendation is to agree with the prior non-certification for Retrospective: Reimbursement for medications of Flexeril and Tranxene.

The IRO's decision is consistent with the following guidelines:

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

X 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

The Official Disability Guidelines 07-27-2010 Cyclobenzaprine (Flexeril):

Recommended as an option, using a short course of therapy. See Medications for subacute & chronic pain for other preferred options. Cyclobenzaprine (Flexeril®) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by Ortho McNeil Pharmaceutical. See also Muscle relaxants (for pain).

ODG TWC 07-27-2010 Pain Chapter - Anxiety Medications in Chronic Pain: Recommend diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Benzodiazepines are not recommended for long-term use unless the patient is being seen by a psychiatrist. Definition of anxiety disorders: Anxiety disorders for this entry include (1) generalized anxiety disorder (GAD); (2) panic disorder (PD); (3) post-traumatic stress disorder (PTSD); (4) social anxiety disorder (SAD); & (5) obsessive-compulsive disorder (OCD). Descriptions of each are included below

(1) GENERALIZED ANXIETY DISORDER (GAD): GAD is characterized by anxiety/tension, excessive worry, restlessness, fatigability, poor concentration, irritability, muscle tension and poor sleep. Treatment for GAD is patient specific and the following serves only as a guide in providing pharmacotherapy. Some patients may require adjunctive psychotherapy, such as cognitive behavioral therapy (CBT) or may prefer psychotherapy, instead of pharmacotherapy. (Zwanzger, 2008) SSRIs or SNRIs are typically first line agents for GAD. TCAs such as imipramine have been shown to be somewhat effective, but are not recommended as first-line agents due to side effects in particular. Outcomes are measured with tests such as the Hamilton Rating Scale for Anxiety (HAM-A), the Clinical Global Impression Improvement (CGI-I) scale and Clinical Global Impression Severity (CGI-S) scale.

(2) (d) Benzodiazepines: Effective for acute treatment. Long-term use is problematic as few patients achieve and sustain remission with monotherapy. These agents are used primarily as an adjunct for stabilization during initiation of an SSRI or SNRI. The disadvantage of use is the risk of abuse and physiological dependence with long-term use. These drugs also have no anti-depressant effect. Diazepam (Valium®, generic available): Dosing information: 5-15 mg daily. Clonazepam (Klonopin®, generic available): Dosing information: 1-2 mg up to TID.

(e) TCAs (Tricyclic antidepressants): This class of medications is an effective treatment for GAD but few studies have investigated their use for DSM-IV defined GAD. Their use is limited by poorer tolerability.

(f) Other medications that may be useful: Hydroxyzine (Atarax®, generic available): Dosing information: 50 mg/day. Pregabalin (Lyrica®, generic available): Non-FDA approved indication. Dosing information: 50-200mg three times daily (with a general range of 200-450 mg a day) Atypical antipsychotics: Olanzapine (Zyprexa®) and Risperidone (generic available): used as an adjunct agent.

Clorazepate is used to treat anxiety, acute alcohol withdrawal, and seizures. This medication belongs to a class of drugs called benzodiazepines which act on the brain and nerves (central nervous system) to produce a calming effect. It works by enhancing the effects of a certain natural chemical in the body (GABA). Side effects include headaches.

[<http://www.medicinenet.com/clorazepate-oral/article.htm>]