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Notice of Independent Review Decision

DATE OF AMENDED REVIEW: 12/21/07

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Vicodin ES, Cymbalta, Neurontin, Buspar and Lunesta

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

Texas License
Board Certified Orthopedic Surgeon

REVIEW OUTCOME

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

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. Clinical notes from, M.D., dated 01/29/99.
2. Clinical notes from, M.D., dated 02/16/99 thru 03/03/99.
3. MRI dated 02/23/99 & 03/15/99.
4. Clinical notes from, M.D., dated 03/11/99 thru 08/13/99.
5. Clinical notes from Care, Inc. dated 03/24/99.
6. EMG/NCV of bilateral lower extremities by xxxxx. dated 04/20/99.
7. Functional capacity evaluations by Systems dated 05/19/99, 07/01/99, 07/23/99.
8. Functional restoration program notes by Systems, Inc. dated 05/19/99.
9. Biofeedback notes from, Ph.D., M.S.S.W, LMFT, LMSW-ACP dated 06/07/99, 09/09/99, 10/26/99, 05/22/00.
10. M.D. dated 07/08/99 to 12/03/99.
11. Clinical note from Clinic, xxxxxx dated 08/23/99.
12. Clinical notes and surgical note from, M.D. Care dated 09/17/99, 10/11/99, 12/17/99, 02/24/00, 05/03/00.
13. xxxxxxxx dated 10/07/99 & 12/14/99.

14. Clinical note from, M.D. at xxxxxx dated 11/09/99.
15. Report of medical evaluation by, M.D. at xxxxxx dated 12/10/99.
16. M.D., dated 12/22/99.
17. Clinical notes from, M.D. at Pain Group dated 12/23/99.
18. Clinical notes from, M.D., dated 01/25/00 to 05/08/00.
19. Operative report dated 02/10/00.
20. M.D., dated 03/03/00.
21. Notes from P.T., dated 02/10/00.
22. Clinical notes from, M.D. at xxxxxxxx dated 04/26/00 to 11/06/07.
23. EMG/NCV of the bilateral lower extremities by, M.D. at xxxxxxxx, P.A., dated 05/04/00.
24. Clinical note from, M.D., dated 06/14/00.
25. M.D., dated 08/08/00.
26. Operative report from Hospital dated 08/09/00.
27. M.D., dated 08/29/00.
28. Notes from Physical Therapy dated 09/26/00.
29. Clinical notes from, Ph.D. clinical psychologist dated 10/05/00, 07/07/00, 05/07/01, 09/13/04.
30. EMG/NCV by, M.D., dated 12/06/00.
31. Ph.D., dated 02/15/01 & 06/07/01.
32. Functional capacity evaluation by Physical Therapy and Medicine dated 09/18/01.
33. Clinical notes from, M.D., dated 09/15/04 thru 11/10/04.
34. Peer reviews by, M.D. at Confirm dated 02/18/06, 05/02/06, 07/03/07.
35. M.D., dated 03/04/06.
36. Peer review by, M.D., dated 08/08/06.
37. Notifications of determinations from dated 10/26/07.
38. Radiographic studies and procedures to include bone scan with spect imaging, MRI of the lumbar spine, lumbar discogram, and MRI of the cervical spine.
39. ***Official Disability Guidelines.***

PATIENT CLINICAL HISTORY [SUMMARY]:

The employee was xx years old when she reported an injury while at work on xx/xx/xx.

The employee was first seen by, M.D., on xx/xx/xx at which time the employee stated she fell from a ladder at work and struck her buttocks area and had low back pain and a bruise in the inner aspect of the right thigh. The employee was diagnosed with low back contusion and told to continue present nonsteroidal anti-inflammatory medications and was given and a prescription for Vicodin ES for her pain symptoms.

On 02/23/99, the employee underwent a bone scan with spect imaging. This revealed increased tracer accumulation within the left facet joint at L4-L5 either posttraumatic or degenerative in nature.

The employee followed up with her primary care physician, Dr., who read the bone scan as not showing any evidence of fracture in the area of the sacrum.

On 03/11/99, the employee had an initial evaluation with, M.D. At that time, the employee was taking Flexeril, Diflunisal, and Ultram for her injury. The employee was experiencing pain in her low back while standing for prolonged periods of time and when sitting down. The employee was assessed as having a contusion to the sacrum with possible fracture including possible fracture to the L4-L5 facet joint area.

The employee underwent an MRI of the lumbar spine on 03/15/99 which revealed a 2 mm posterior central disc protrusion at L4-L5 with an acute partial thickness tear through the posterior central fibers of the annulus fibrosis. It also revealed disc desiccation at the L4-L5 and L5-S1 and transitional S1 vertebral body.

On follow-up with Dr., the employee was diagnosed with ongoing herniated nucleus pulposus of the lumbar spine, myofascitis and facet joint arthrosis of the lumbar areas and coccydynia. The employee was given a refill of Ultram, Xanax, and Diflunisal and was continuing physical therapy.

The employee continued to follow-up with Dr. at Health Systems, Inc. for follow-up for her pain symptoms and for physical therapy. The employee was later noted to have increased bowel sounds probably due to unrelated gastrointestinal problems and was given an antispasmodic.

On follow-up with Dr. in April of 1999, the employee was continuing to have low back pain and was diagnosed with lumbosacral strain with acute L4-L5 central disc protrusion with partial thickness annular tear and was also diagnosed at that time with reactive depression. The employee continued with her current medications and was also given a prescription for Prozac. At that time, the employee was also taking Soma, Xanax, Diflunisal, and Ultram for her injury.

On 04/09/99, the employee was noted on examination with Dr. to have headache which had lasted approximately four days and was continuing to have gastrointestinal distress. The employee was noted not to be taking her medications due to history of hepatitis and the severe gastrointestinal distress that she had been undergoing. The employee was also complaining of radicular symptoms bilaterally with associated right knee pain with positive swelling to the knee. The employee had tenderness to palpation with positive trigger point to the cervical and lumbar regions. She was also noted to have positive swelling to the right knee with positive crepitus to the knee. She was diagnosed on that date with cervical and lumbar myofascitis, facet arthrosis, possible herniated lumbar disc, post concussion syndrome and tension type headaches, and gastrointestinal distress. The employee was to continue physical therapy and hold off on her medications and follow-up with Dr. in two weeks. It appears later

on the same day the employee was told to continue her current medications of Prozac, Diflunisal, Ultram, Xanax and Soma and was also given a prescription for Celebrex and advised to take with fluid and Maalox. The employee was also found to have a microcytic anemia and was advised to follow-up on this lab result.

On 04/21/99, the employee underwent a lower extremity nerve conduction velocity and needle EMG study. The employee's findings suggested an S1 radiculopathy on the left and an L5 radiculopathy on the right.

On 05/06/99, on follow-up with Dr., the employee was referred to Dr. for psychosocial therapy along with assistance in pain management through biofeedback and counseling to help her control her pain level with less amounts of narcotics.

On 05/10/99, the employee underwent a Functional Capacity Evaluation (FCE) at Health Systems. The employee was found to perform in the sedentary work category.

On 05/27/99, the employee underwent an epidural steroid injection in the L3-L4 region.

On 06/03/99, the employee underwent a second epidural steroid injection in the L3-L4 disc space.

On 06/07/99, the employee underwent an initial evaluation with, Ph.D. and was diagnosed with reactive depression, reactive anxiety, and acute pain syndrome.

In June of 1999, the employee continued to follow-up with Dr. and to continue with her physical therapy. During this time the employee's medications were changed several times due to continuing gastric upset secondary to nonsteroidal anti-inflammatory medication intolerance. The employee was stopped on her medications including a time where she was to hold off on medications for the weekend except for vitamins and hormones. The employee was given prescriptions for Phenergan, Ambien for sleep and was also given Prilosec for her gastric upset. The employee was also changed from Vicodin to Darvocet N-100 for her pain symptoms.

In July of 1999, the employee was referred by Dr. to a spinal surgeon for further evaluation and treatment.

On 08/23/99, the employee was evaluated by Sports Medicine. Upon examination on that date, the employee had full range of motion of the lumbar spine. The employee had generalized tenderness along the coccygeal region but without specific trigger points. Deep tendon reflexes were 2+ at the knees, 1+ at the right ankle, and 2+ at the left ankle. The employee had 5/5 strength of bilateral lower extremities and manual examination of the spine shows her to be

diffusely tender. On this date, the employee was diagnosed with coccydynia and lumbar radicular syndrome, and it was recommended at that time that the surgeon did not feel that the employee had a surgical lesion and that it was suspected that her injury was to the soft tissue and would get better with time.

In September, 1999, the employee was referred by Dr. to Dr.. The employee underwent an initial evaluation with Dr. on 09/17/99. The employee was found to have gait within normal limits and lumbar spine had restricted range of motion in all planes with pain. The employee was tender from L3 to S1 without spasm or trigger points. Manual examination of the pelvis including SI joints was negative. Straight leg raising produced low back pain. Motors were 5/5 and symmetric of the bilateral lower extremities and reflexes were present and symmetric without clonus. The employee was felt to have discogenic mechanical low back pain and leg pain secondary to radiculitis from inflammatory changes around the disc. It was recommended that the employee undergo a lumbar discogram. The employee underwent a three level discogram on 10/07/99 which showed normal L3-L4. The employee had midline posterior and left posterior oblique fissures with posterior annular opacification and bilateral facet spondylosis at L4-L5 and midline anterior and posterior fissure with diffuse annular opacification and mild left facet spondylosis at L5-S1.

On follow-up with Dr. on 10/11/99, it was discussed with the employee that they could either do nothing or surgery with an anterior lumbar interbody fusion with a BAK cage at L5-S1 versus intradiscal electrothermal therapy was suggested to the employee. All these procedures were discussed with the employee, and she was given information to consider at home.

On follow-up with Dr. on 10/25/99. it shows that the employee chose not to undergo surgery at that time and that she continued to take Soma, Vicodin, Valium, Xanax, and Prozac. Also during this time, the employee continued to follow-up with for psychotherapy.

On 11/09/99, the employee underwent a neurosurgical second opinion for her back pain. It was noted that they concurred with Dr. recommendation for possible anterior lumbosacral interbody fusion.

On 12/10/99, the employee underwent a report of medical evaluation by Dr. at Evaluation Centers. The employee was found to not have reached Maximum Medical Improvement (MMI)

On 12/14/99, the employee underwent another MRI of the lumbar spine. This revealed early degenerative disc disease with a 1 mm central disc bulge and posterior horizontal fissure at L4-L5 and degenerative disc disease with a 2 mm central disc bulge and posterior horizontal fissure at L5-S1.

On 12/17/99, it was noted that during a follow-up with Dr. that the employee was to be sent to pain management to detoxify her from the narcotics she was taking

prior to surgery and that they were trying to deal with her addictions to the pain group.

On 12/20/99, the employee had an initial visit with Dr. at Pain Group. The employee's Xanax, Cytotec, and Soma were discontinued, and the employee was to continue Vicodin two to three times a day, Prozac, and Doxepin was given for sleeplessness.

On 02/10/00, the employee underwent a total anterior discectomy at L5-S1, an anterior interbody fusion at L5-S1 with back instrumentation at this level, and a left iliac crest bone graft for the procedure. It was noted that the employee tolerated the procedure well and there were no complications.

On follow-up with Dr. on 03/21/00, the employee underwent a steroid injection into the trochanteric region on the right side. During this time, the employee was continuing to complain of pain in her low back with symptoms down both legs.

It was noted that the employee moved from to and had an initial evaluation with, M.D., at xxxxxxx of. On this initial evaluation on 04/26/00, the employee was continuing to complain of pain in the low back and bilateral lower extremity numbness and tingling. The employee was taking Advil, Vicodin, Zantac, natural colostrum, calcium, Synthroid, Lipitor, and Premarin. Upon examination, the employee had a very minimal limp. She could toe walk but had difficulty heel walking due to pain. There was no midline thoracolumbar tenderness or paraspinal muscle tenderness, but there was tenderness directly over the sacrum and sciatic notches bilaterally. The employee was assessed as status post anterior lumbar discectomy and interbody fusion with internal fixation with BAK titanium fusion cages and left iliac crest bone grafting, persistent postoperative mechanical back pain, and lower extremity radiculitis. The employee was told to add Vioxx to her pain medications and was also instructed to take Prilosec due to her gastric problems with anti-inflammatory medications. The employee was also started on Neurontin for her postoperative neuropathic leg discomfort.

On follow-up with Dr. on 05/03/00, it was recommended that the employee undergo an EMG/NCV due to her continued pain symptoms.

The employee underwent this study at xxxxxxx of on 05/04/00. The employee was found to have diffuse sensory and motor neuropathy, mainly axonal that is mild to mild plus. It was also noted that there was no evidence on this examination of peroneal entrapment at the knee, tibial neuropathy, plexopathy, or L3-S1 radiculopathy.

After this study, the employee continued to follow-up with Dr. in. The employee continued to experience pain in her low back and down her legs during this time, and Dr. referred the employee to another doctor in for biofeedback and also to Dr. for a neurology consultation.

On follow-up with Dr. on 06/21/00, the employee began complaining of pain in her neck and right shoulder and brought a copy of her TWCC-41 form which shows original injury listed areas of rectum, both legs, neck, and left shoulder. The employee was recommended to have a cervical spine MRI performed in order to evaluate this new problem.

The employee underwent an MRI of the cervical spine on 07/03/00 which revealed mild abutment of the ventral aspect of the thecal sac without evidence for neural compression at C5-C6.

The employee began seeing, Ph.D., on 07/07/00 for continued psychotherapy due to her continued pain symptoms. During this time, the employee was continuing with her postoperative physical therapy.

In June, 2000, the employee was seen by, M.D. at xxxxxx. It was noted that the employee had an elevated TSH and the employee had admitted that she was taking her Synthroid on an infrequent basis. The employee was to continue to follow-up with Dr. to monitor her TSH, and it was also noted by Dr. that the employee's repeat liver functions were improved and that she had a history of hepatitis of some type in her teens.

On 08/09/00, the employee underwent a right sacroiliac joint block by Dr..

On follow-up with Dr. on 08/23/00, the employee was shown to have a positive response to bilateral sacroiliac joint injection, but within a few hours after the procedure appeared to have a flare-up and a substantial increase in her pain. Dr. planned to have the employee undergo a CT scan to evaluate her fusion and to follow-up with his office after the CT scan was completed.

The employee underwent a high resolution helicolumbar spine CT scan with and without contrast on 08/29/00. This revealed a previous laminectomy and interbody spinal fusion at L5-S1 with good bony fusion and excellent bone response to the interbody fusion. There was good alignment of the vertebral bodies noted. At L5-S1, there was minimal posterior central epidural scarring without evidence of nerve entrapment, and there was no evidence of new or recurrent herniated disc.

On follow-up examination with Dr. on 09/13/00, he reviewed the employee's CT results which showed a solid interbody fusion at L5, and felt at that time the employee was ready for a more vigorous postoperative rehabilitation program. Dr. also stated that this should be done in conjunction with continued treatment with Dr. and that he would send the employee to Physical Therapy.

On follow-up with Dr. on 10/20/00, it was noted that the employee had a fall with straddling injury, and that the employee may have damaged the support

ligamented structures around the sacroiliac joint causing injury to her lumbar disc and has been the basis for persistent pain syndrome with concomitant neuropathic basis.

The employee was referred to OB/GYN physician, Dr. for evaluation of her pelvis and pelvic floor supportive structures to decide whether there might have been some injury which could require surgical corrective treatment.

The employee underwent a repeat EMG/NCV of the bilateral lower extremities with, M.D. on 12/06/00. This study revealed bilateral lower extremity sensory peripheral neuropathies with no sensory potentials obtainable. It also revealed bilateral tibial motor peripheral neuropathies of at least moderate severity with demyelination noted by slowed nerve conduction velocities. There was a mild right L5 radiculopathy and some bilateral lower lumbar paraspinal denervation noted.

The employee underwent a laparotomy with adhesiolysis and bilateral salpingoophorectomy due to pelvic adhesions, uterosacral vault suspension, paravaginal defect repair, birch procedure and posterior colporaphy with Dr. on 01/18/01.

On 02/13/01, the employee's treating physician, Dr., stated the employee had reached MMI on 02/13/01 and was given a whole body impairment rating of 15%.

The employee continued to follow-up on a monthly to bimonthly basis with Dr. from this point up until 06/24/04 for her low back pain symptoms. The employee continued to be prescribed medications such as Daypro, Celexa, Vicodin ES, Neurontin and Buspar.

In July, 2003, the employee was prescribed Actiq lollipops for her pain symptoms.

In February, 2004, the employee was prescribed Duragesic Patches for her pain symptoms with the Actiq lollipops for breakthrough pain. The employee also continued to follow up with Dr. during this time for her psychotherapy.

On 06/24/04, the employee was referred to, M.D. The employee had an initial evaluation with Dr. on 08/09/04. The employee was diagnosed with chronic intractable pain and was given prescriptions for Neurontin, Buspar, Lexapro, Zanaflex, and Vicodin ES. The employee continued to follow up with Dr. and Dr. until 11/10/04, at which time the employee was dismissed by Dr. on the grounds "she was disrespectful to me and my employees." It was also noted that the employee was a week early on her prescription for medication and that it was noted that she was abusing the medication and taking more than what she was prescribed.

At this point, the employee continued to follow-up with Dr. for her pain management.

A peer review was done by, M.D. on 02/18/06. It was noted in this review that the employee would benefit most from home exercise program without supervision, and that she should be under the care of a pain management specialist to oversee pain medication management and assist in weaning off narcotics which “would be the most appropriate pharmacological treatment option at this time in my opinion.” The employee was noted to be taking Neurontin, Zanaflex, and Vicodin for her pain symptoms. These medications were found to be reasonable and medically necessary with the exception of the Vicodin which was found to be not appropriate for the long-term in the doctor’s opinion. It was suggested that alternative medications such as Darvocet and Ultram be used for the employee’s pain symptoms. It was also noted that the use of Lexapro and Buspar was necessary for depression but were, in the opinion of the doctor, not related to the compensable injury at that time. It was also noted that Nexium was a medication for reflux and was not related to the compensable injury at that time.

The employee underwent another MRI of the lumbar spine on 03/04/06, which revealed four lumbar type vertebra with previous L4-S1 discectomy with intervertebral metallic cages at L4-S1. There was no evidence of disc herniation, spinal canal or intervertebral neural foraminal stenosis noted. There was mild bilateral degenerative changes of the facets at L3-L4 and L4-S1 levels.

Another peer review was performed by, M.D., on 08/08/06. Dr. reviewed the medical records and spoke with Dr. concerning

this employee. Dr. summarized that he would discontinue the employee’s Zanaflex and would recommend employee undergo psychiatric evaluation along with chronic pain management program evaluation.

The employee continued to follow-up with Dr. for her pain symptoms and to receive her prescriptions from him. It appeared on 08/18/06 he tried to refer the employee to Rehab for chronic pain management, but it was unclear why the employee did not follow-up with this clinic.

In 2007, it was noted the employee was taking Lunesta, Buspar, Vicodin ES, Neurontin, Nexium and Cymbalta for her rigorous compensable injury from xx/xx/xx. It was noted that during this time the employee seemed to have very few examinations, and there was no mention of the employee’s pain levels using a pain scale during her follow-ups in 2007.

The employee’s medications, which included Vicodin ES, Cymbalta, Neurontin, Buspar, and Lunesta were reviewed by the insurance company and found to be not reasonable or necessary at the time. This was disputed by the employee’s

treating physician, Dr.. The claim was again denied by the employee's insurance carrier.

In review of the documentation, it was found that the requesting doctor was requesting that all medications be brand names, and that in one of the notes in one of the requests, the doctor stated that the employee had reaction to generic medications. In review of the medical records, I did not see any documentation of these reactions.

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

Based on the materials that have been reviewed and prior denials by the insurance carrier, I would have to concur with the two previous denials and state that the Vicodin ES, Cymbalta, Neurontin, Buspar, and Lunesta are not medically necessary or indicated at this time. Per **Official Disability Guidelines** under the criteria for use of opioids for long-term users, it is stated that employees pain symptoms should be followed and employees should provide a pain diary or evaluation of additional need for supplemental medication. The employee's recent follow-ups have not included an evaluation of the employee's pain symptoms from baseline or stating if the employee is improving or able to function on the current dose. According to the **Official Disability Guidelines**, Neurontin may be used in combination with employee's pain medication to help lower the dosage of both the medications in order that the employee would have a better analgesia with lower doses of each of the medications. Again, both these medications should be monitored, and employee's pain symptoms should be evaluated regularly in order to maximize the employee's dosing of these medications.

Since this type of follow-up does not seem to be seen in the last couple of years, that is why I am determining that this medication as well as the other medications are not medically necessary or clinically warranted at this time. It was recommended in 2006 and 2007 that the employee be referred to follow-up with chronic pain management specialist and psychiatrist for the employee's symptoms, but since this time the employee has not had a follow-up with any of these specialties.

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

1. ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES