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Notice of Independent Review Decision

Date: November 27, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Revision of pain pump 62362

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Diplomate, American Board of Physical Medicine and Rehabilitation and Pain Medicine

REVIEW OUTCOME:

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

☒ Upheld (Agree)

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

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

TDI:

- Office visits (09/24/12 - 10/02/12)
- Utilization reviews (09/27/12, 10/08/12, 10/24/12, 11/06/12)

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- Office visits (09/24/12, 10/02/12)
- Review (04/27/09)
- Office visits (05/01/07 – 10/31/12)
- Utilization reviews (09/27/12, 10/08/12, 10/24/12, 11/06/12)

ODG criteria has been utilized for the denials

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a female who on xx/xx/xx slipped onto the floor landing. She injured her back.

1991 – 2006: No records are available.

2007: On May 1, 2007, evaluated the patient for a follow-up visit for IT pump placement. It was noted that the patient was seen in the emergency room (ER) for urinary retention following pump placement and she was sent home with a Foley catheter which she discontinued on her own. She reported diffuse swelling since the implant. She had lumbar spinal stenosis. The pain was primarily in the lower lumbar spine radiating to the left more than right buttock, perineum, lateral thigh(s) left more than right, and lateral lower leg(s) left more than right. The pain was constant, moderate, severe and chronic in nature. Associated symptoms included numbness in the lateral thigh(s), left more than right, lateral lower leg(s) left more than right lower leg(s) and foot (feet) left more than right laterally. She reported some pain relief with stretching and worsening with back flexion and sitting. She had a history of herniated disc, back surgery, obesity and poor back conditioning. She had undergone treatment including transcutaneous electrical nerve stimulation (TENS) unit with no relief, physical therapy (PT) with some relief, pain interventions, ESI and a trial of spinal cord stimulator (SCS) that did not provide adequate pain relief. assessed lumbar spinal stenosis. The intrathecal pump was reprogrammed to run at a rate of 0.2200 mg per day. recommended increasing the intrathecal pump by 10% and follow-up before alarm date.

2008: No records are available.

2009: On April 27, 2009, performed a review and rendered the following opinions: (1) The ongoing treatment regimen overall was appropriate for evidence-based medicine. The patient underwent a successful intrathecal trial as indicated by ODG and subsequent placement of intrathecal pain pump. Titration was reasonable and necessary if the patient continued to have proof of limited narcotic use by mouth with subsequent intrathecal infusion. The current dose of Dilaudid 1.1212 mg a day was reasonable. Both and should not manage the patient's pain medications at the same time. The psychiatrist did not need to be involved unless the depression was unrelated to the pain syndrome. If the patient was taking antidepressants, in particular Xanax, trazodone, and Cymbalta for chronic pain-related depression, then this regimen should be managed by the same provider that was managing the other adjuvant pain medications. However, if the patient was on this regimen for either a pre-existent condition of depression or depression non-related to chronic pain syndrome, then it should be managed by a psychiatrist that was not related to this particular case. Otherwise, for chronic pain-related depression and anxiety, the regimen of trazodone, Cymbalta, and Xanax was reasonable and necessary. Ongoing medications including Zanaflex, Phenergan, Tegretol, trazodone, Cymbalta and Xanax were reasonable.
The following treatment history is noted: *The patient was a female who unfortunately suffered a work-related injury on xx/xx/xx, when she slipped onto the floor. The patient sustained a low back injury and was initially evaluated on September 9, 1991. She underwent several low back surgeries including, on October 15, 1991, a laminectomy and discectomy at L4-L5 on the left followed by a mass fusion at L4-L5 on March 17, 1992, The patient went on to undergo a*

repeat spinal fusion at L4-L5 for nonunion. On January 5, 1993, performed a posterior interbody fusion with radical discectomy at L4-L5 and a lateral mass fusion at L4-L5 with instrumentation at L4-L5 and screw placement/ decompression of the L5 nerve roots bilaterally. On September 29, 1993, performed an L4-L5 arthrodesis with lateral cage and BMP and lateral plate on September 29, 2003. Per "on February 20, 1996, that the patient also had another operation, 360, possibly at two levels, L4-L5 and L5-S1, anterior posterior fusion and then had had the posterior stabilization material removed. Still has the anterior"

The patient was under the care of a psychiatrist and was therefore on Paxil and Xanax. According to the clinic note on February 29, 1996, , the patient was on opioid therapy with OxyContin and adjuvant therapy with Neurontin and Ultram. At that time, the pain was in the low back and posterior aspect of her legs bilaterally. On April 18, 1997, she was taking Voltaren, Tegretol, Ultram, and OxyContin, and on May 21, 1995, indicated that she was also taking Xanax and morphine. In addition, the patient wanted the titration of her medications at this clinic visit. On April 2, 2000, changed her morphine to Darvocet and on October 26, 2000, she was admitted for intrathecal morphine and bupivacaine trial. On January 18, 2001, she underwent dorsal root blocks and again on January 26, 2001, as well as pulse radiofrequency rhizotomy on the left at L3 and L4 nerve roots. This was again repeated on October 24, 2002. The patient was seen on September 2, 2003, by another pain management physician essentially with the same complaints of low back pain radiating into her legs bilaterally. She was found to be taking morphine extended release in addition to Tegretol and Zanaflex, all prescribed in addition to Xanax and Paxil everyday and Wellbutrin twice a day by the psychiatrist.

On April 15, 2004, she was seen in a PM&R pain group who the patient was seeing to this date. She continued to undergo other interventional modalities including a diagnostic medial branch block on the right L2 through L5 levels on December 15, 2005. On September 21, 2006, notes reflect that she would no longer prescribe morphine by mouth and so, the patient began seeing On October 11, 2006, the doctor noted that she had pain in the lower spine radiating to buttock, perineum, lateral thigh, and lateral lower leg, left worse than right. The patient also had some accompanying numbness and on physical exam, had a positive straight leg raise and limited lumbar range of motion (ROM). On March 21, 2007, an intrathecal trial was done, and following this, an intrathecal SynchroMed infusion pump was placed on April 25, 2007. The patient was then seen every two weeks for programming of the pump and titration. She had regular refills and titration until her most recent evidence of pump amount 1.1212 mg of Dilaudid per day as documented on her February 9, 2009, visit with. She continued to take non-narcotic medications as of February 5, 2009, Nexium 40 mg everyday, Zanaflex 4 mg three times a day, Phenergan 25 mg three times a day, and Tegretol 200 mg three times a day. In addition, the psychiatrist was prescribing trazodone 100 mg as well as Cymbalta and Xanax 1 mg.

2012: On September 24, 2012, noted that the patient was able to complete activities of daily living (ADL) without any assistance. She had pain located in the lower lumbar spine and radiating to the right buttock, lateral thigh(s) and lateral

lower leg(s). The pain was constant, chronic, and moderate-to-severe in nature. assessed chronic pain syndrome, lumbar spinal stenosis and low back pain. It was noted that the patient had reported that she had noticed an increase in pain for about eight days. She felt her intrathecal pump was flipping. After looking at the intrathecal pump under fluoroscopy, the catheter was noted to be twisted and bunched up. recommended replacing the intrathecal pump and catheter due to it being kinked and the pump being over five years old. The patient was to take bedrest for more than four days and follow-up before intrathecal pump alarm date.

Per utilization review dated September 24, 2012, negotiated approval was provided for implantation revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medications administration via an external pump or implantable reservoir/infusion pump without laminectomy.

On October 2, 2012, evaluated the patient for revision of a pain pump. The patient had abdominal pain while bending over. She reported nausea/vomiting associated with having withdrawals from the Dilaudid in her pump. Review of systems (ROS) was positive for fatigue, headaches, shortness of breath with walking or lying flat, swelling of extremities, loss of appetite, change in bowel habits, nausea/vomiting, diarrhea and painful bowel movements/ constipation, incontinence, joint pain, stiffness/swelling, weakness of muscle or joints, muscle pain or cramps, back pain, cold extremities and difficulty in walking, frequent/recurring headaches, numbness/tingling sensation and tremors, memory loss or confusion, nervousness, depression, and insomnia, diabetes and heat or cold intolerance. Diagnosis was lumbar spine stenosis with neuroclaudication and recommended laboratory tests, x-rays of the chest and electrocardiography (EKG) and spine infusion implant. The patient was to be scheduled for pain pump revision with assistance.

Per utilization review dated October 8, 2012, the request for pain pump revision was denied with the following rationale: *"The prior review by me done a few weeks ago indicated had tested the pump and the battery had 17 months of life left. Until a computer printout showing end of life is supplied to corroborate the pump battery is dying, the request for pump replacement is not supported. There is no indication why the battery would show 17 months left a few weeks ago and now be dying."*

A second appeal was made for revision on pain pump.

Per reconsideration review dated October 24, 2012, the request for pain pump revision was denied with the following rationale: *"The appeal request for pain pump revision is not recommended as medically necessary. It appears that the patient has been authorized to undergo pump catheter replacement, but not entire pump replacement. On previous review it was noticed that another M.D., is claiming the patient is having withdrawal with N/V and pain and she wants to replace the entire pump with the M.D. involving in the prior review. It was noted that interrogation of the pump revealed end of life in 17 months. As such, there is no need for pain pump replacement."*

Per utilization review dated November 6, 2012, the request for pain pump revision was denied with the following rationale: *"This preauthorization request has been previously reviewed by a physician advisor and an adverse determination was issued. Pursuant to TDI Division of Workers' Compensation Rules, 28 TAC §134.600(o) (5) a request for preauthorization for the same healthcare shall only be resubmitted when the requestor provides objective clinical documentation demonstrating that the injured employee has met clinical prerequisites for the requested healthcare that had not been met before the previous request was submitted or a substantial change in the employee's medical condition. A physician advisor has previously reviewed all clinical information submitted either on initial or appeal review and this request cannot be considered at this time for additional prospective review as no substantial objective change in the injured employee's condition is noted or clinical prerequisites have not been met."*

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
The initial request for revision of the intrathecal catheter was approved and is medically necessary at this time. The pain pump is noted to have 17 months remaining and would require replacement at that time. This request is not medically necessary at this time.

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

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