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Notice of Independent Review Decision

**May 28, 2014**

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

URGENT (KCBDGOT) Cream #1 x4 refills

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

Physical Medicine and Rehabilitation Physician

**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.

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a female who on xx/xx/xx, was injured. She felt a tear in her low back and started with pain.

**2008:** On June 8, 2008, performed a peer review and noted that the patient had placement of a permanent spinal cord stimulator (SCS) on December 3, 2004. The patient then had removal of an implanted spinal cord lead with removal of a spinal cord lead generator and revision of a SCS lead with a revision of a SCS generator with a restored generator on June 10, 2005. The patient had the SCS lead removed on October 16, 2006. She was evaluated from August 9, 2007, through March 20, 2008, and was provided prescription medications for management of subjective pain complaints to include Effexor, Celebrex,

Gabapentin, Hydrocodone, Colace, Trazodone, Duragesic Patch and Darvocet N-100. opined that the patient had failed back syndrome and ODG would support an expectation that there should be access provided to prescription medications on a long-term basis, provided that there is documentation that utilization of prescription medications help to decrease pain symptoms and enhance functional capabilities.

On August 1, 2008, performed a peer review and opined that it was unknown whether the treatment was related to the related injury due to ambiguous documentation of the issue and lack of documented evidence that all current treatment was related to an occupational injury.

**2009:** On March 5, 2009, evaluated the patient for low back pain and right buttock pain radiating to right lower extremity. diagnosed lumbar post-laminectomy syndrome and nerve root irritation and recommended CT myelogram of lumbar spine. Methadone, Provigil and Lyrica were refilled.

On April 28, 2009, myelogram of the lumbar spine showed no significant extradural defects at any lumbar level except for post-operative changes. A post-myelogram CT scan of the lumbar spine showed satisfactory postoperative appearance at L5-S1 following anterior and interbody fusion and posterolateral fusion with bony masses and an inter-pedicular screw on the left.

**2010:** Urine drug screen dated April 1, 2010, was positive for Fentanyl.

On June 27, 2010, performed a peer review and noted the following treatment history: *In 2000, the patient was initially treated who referred her to neurosurgeon for low back pain despite physical therapy (PT) and medications to include Valium, Soma and Vioxx. Lumbar MRI dated April 4, 2000 showed degenerative changes at L5-S1 with a disc bulge but no S1 nerve root displacement. treated her with Vicoprofen and Zanaflex. She was treated with a caudal injection and L4 injection on July 18, 1999, and piriformis injection on August 22, 2000. Care also continued and she was on medications including Zydone, Zanaflex, Protonix and Elavil. Discogram/CT in October found L5-S1 annular disruption. On November 21, 2000 opined that the patient had definite evidence of discogenic disruption at L5-S1. Based on discogram and decreasing effectiveness of medications, he recommended IDET vs. laser discectomy. He also noted that she was unable to take Elavil as it caused excitation and insomnia. On August 23, 2001, a second surgical opinion was performed who agreed with the diagnosis of discogenic back pain at L5-S1, with either IDET or fusion indicated for treatment, although a repeat discogram was recommended as well as preoperative psych evaluation. She continued with Darvocet. Psych evaluation found symptoms of depression related to the work injury and psychiatric consultation with psychotherapy was recommended. On November 9, 2001, performed L5-S1 global fusion. In 2002, the patient continued on Vicodin and Darvocet along with PT. Celexa and alprazolam were started for depression. The narcotics were stopped. The electrodiagnostic studies were unremarkable. The patient did not do well in work conditioning, with ongoing complaints of severe pain. It was opined that there*

was a need to address psychological issues for rehab to be effective. on September 11, 2002, recommended psychological treatment and added Neurontin and muscle stimulator to the management. On November 20, 2002, the patient reported no change complaints of pain and by December 2002, she was having increased leg pain. had her on Flexeril and Neurontin and added Duragesic 25 mcg with a referral to PT (60 mg of oral morphine equivalents a day). In 2003, the patient's medications included Remeron, Duragesic, Effexor and Neurontin. felt SCS might be helpful. The patient was receiving active psychological treatment by January 22, 2003. Her recent RACZ procedure provided 50% relief in back pain. Complaints of ankle pain began after the back injection. A functional capacity evaluation (FCE) was performed on March 20, 2003. On June 26, 2003, Duragesic was increased and the medication list as of August 20, 2003, included Duragesic, Ambien and Neurontin. Neurontin was stopped the following month and changed to Trazodone. A psych assessment was done on September 25, 2003. Some progress was noted with psychotherapy and added Lexapro and tapered her off Effexor in November, but she did not tolerate the change and Effexor was resumed the next month. She continued to use Duragesic, Neurontin, Protonix and Trazodone. In 2004, a trial of SCS was done on September 17, 2004. The patient reported 50-60% relief of pain with the trial along with improved function and decreased use of meds. recommended permanent placement of SCS that was done on December 3, 2004 with Pisces Quad stimulator. Her medication list no longer included bupropion or Triavil. on December 14, 2004, found her with increased back and leg pain, along with nausea and abdominal pain. Opioid medication dose was unchanged. In 2005, medications included Duragesic, Effexor, Trazodone, Celebrex, phenergan, Neurontin and Colace. Lidoderm was added on March 10, 2005. In October 2005, the patient complained with increased numbness in hands with positive Tinel's. Neurontin and Duragesic were increased. Wellbutrin was added with tapering down of Effexor. She also had Plavix and papaverine from an unknown doctor. In 2006, per July 13, 2006, the patient complained of bilateral hip pain. There was addition of Ultram to the regimen. The patient was referred who recommended removal of the non-functioning SCS. The patient was utilizing Neurontin, Celebrex, Trazodone, promethazine, Colace, Effexor, Wellbutrin, Ultram, papaverine, Plavix, mirtazapine and Triavil. increased Ultram and Prevacid and Effexor was discontinued, but otherwise things were unchanged. The patient was on penicillin from another doctor in December. changed her from Trazodone to Ambien for sleep and increased Ultram. In 2007, the situation was unchanged over the first part of 2007, but by April the patient complained of severe pain. increased her Celebrex dose and changed her from Ultram to Darvocet. Follow up continued. The situation was stable and medications were refilled, and in June 2007, the patient was given information on morphine pump. Low back pain increased and Duragesic patch every 48 hours and Darvocet. Her VAS score was unchanged with this increase. She was not interested in the morphine pump. Prevacid, promethazine and Ambien were denied on peer review, which was upheld per IRO decision. continued her regular medications and ordered labs. In 2008, the patient noted mood swings and anger outburst and was given Effexor and Aciphex. The pain increased despite the medication in March 2008. Darvocet was changed to Norco and Effexor was increased that

helped. Labs were normal. In a peer review in August 2008, found that ongoing treatment was not medically necessary and felt a pain pump might be effective alternative to escalating use of other medications such as transdermal fentanyl, but only if psychological evaluation found her an appropriate candidate. The patient continued to see on a regular basis for refills. Norco was stopped in November 2008 and she continued on Duragesic. In 2009, the patient continued with right buttock pain radiating down the right leg. The patient was overall stable in April. A CT myelogram was requested. In August 2008, the patient complained of increased leg pain and weakness and she was Nuvigil. A urine drug screen dated March 5, 2009, was positive for oxazepam (she was prescribed temazepam on February 19, 2009). The patient remained under the care. A drug screening dated November 11, 2009, was positive for nortriptyline, otherwise negative. note for December 1, 2009, did not discuss the drug screen. The patient reported increased pain related to cold weather. Her medications were refilled unchanged. In 2010, the patient reported increased pain on March 4, 2010. refilled her medications. A Lidoderm patch was provided on April 1, 2010. On May 4, 2010, the patient received Lyrica, Effexor XR, Trazodone, Celebrex, Nuvigil and Doc-Q-Lace. noted that the use of opioids at this high of a dose and under current circumstances in which diagnosis (particularly psychiatric) was unknown and the evidence of misuse was inappropriate. Methadone has variable conversion, but this was her total dose of oral morphine equivalents from both opioids was approximately 400 to 500 mg a day. The methadone dose alone was at least 200 mg of oral morphine equivalents. This was a huge dose of opioid to take on a p.r.n. basis, which could be the case as she appears to miss doses. If she were to begin to take methadone again as currently prescribed after a prolonged gap (at least 14 days), she ran the risk of death due to late onset respiratory depression. In addition if she stops it abruptly, she runs the risk of withdrawal.

From August 26, 2010, through March 10, 2011, the patient was under care for ongoing issues of low back pain. refilled the medications and recommended laboratory workup. On March 10, 2011, Dilaudid and Lyrica was increased.

**2011:** On April 7, 2011, urine drug screening was positive for opiates and fentanyl.

From April 7, 2011, through July 28, 2011, the patient continued care for ongoing complaints of low back pain and mid back pain. Her medications were refilled.

On August 22, 2011, performed a peer review on the patient and continued to opine that the use of opioid at high dose and under current circumstances of diagnosis (particularly psychiatric) was unknown and there were strong risk factors for substance dependence was inappropriate. The guidelines also offer many addiction screening tests. It does not appear that anyone involved with opioid prescribing had taken into account the possibility of her high risk for dependence/misuse due to her history of sexual abuse or evaluated for indicators of possible misuse. recommended the patient be seen by an addiction specialist with a background in psych immediately. There was a strong likelihood that the claimant would continue to receive some sort of opioid from the physician. If the

patient did not wish to be involved with this type of treatment, weaning was recommended. The patient chose to forgo the evaluation (as recommended per the ODG) and weaning was suggested from this class of meds. A weaning schedule was attached.

From August 25, 2011, through November 17, 2011, the patient was under care for continued care for lower back pain and leg pain. Throughout, the patient's medications were refilled and she was referred for an IT opiate pump trial which she was still to forgo.

On December 13, 2011, evaluated the patient for low back pain and bilateral lower extremity pain. The patient rated the pain at 4-7/10. She was on continued conservative management with medications to include Lyrica, hydromorphone, Trazodone, Nuvigil and Duragesic. She was referred for a possible IT opiate pump implantation. The patient was also currently utilizing Dilaudid, Lyrica, Effexor XR, Senna and Lansoprazole. On examination, the patient had a mildly antalgic gait. She had spasms in muscle tone. The lumbar range of motion (ROM) was restricted in all planes. The facet joints were tender on palpation. There was positive provocation. Squish test and Rocking test was positive. There was a long lumbar scar. The DCS generator was located in the left buttock. Motor examination showed 4/5 in left plantar flexion and bilateral dorsiflexion. diagnosed failed back surgery syndrome, opiate tolerance and depression. The patients SOAPP-14 score was 4. recommended psychological evaluation and possible IT pump opiate trial.

Urine drug screen dated December 15, 2011, was positive for Fentanyl, Norfentanyl, Benzodiazepines and Pregabalin.

On December 15, 2011, evaluated the patient for lower back pain/leg pain and ankle/foot pain. There was associated tingling in the right leg. She rated the pain at 7/10 on pain scale. recommended follow up with IT pump and refilled medications.

**2012:** From January 12, 2012, through December 11, 2012, the patient was seen for lower back and legs complaints. The patient had moderate pain described as aching and burning and radiating to the left leg. The patient had bilateral lower extremity pain along with constant low back pain. The patient was maintained on Lyrica, hydromorphone, trazodone, Nuvigil and Duragesic. later discontinued Dilaudid and Colace. The patient also underwent gall bladder surgery in May. recommended IT pump trial and clearance for it.

On April 3, 2012, a urine drug screen was negative.

On October 6, 2012, performed a peer review and rendered the following opinions: (1) The patient's underlying medical pathology was unknown. Therefore, the lack of information documented in terms of underlying medical condition and drugs required did not allow for the safe use of any medication the patient was taking. (2) Medical documentation did not support a casual

relationship between the accident and/or injury and the injuries affected by the patient. The omission of pertinent information indicated there was other underlying medical disease that was contributing to the patient's medical problem. (3) It appears that there were pre-existing conditions that were undocumented that contributed to the patient's medical presentation. (4) The patient could have a cancer that was that cause of symptoms. (5) Medical services, treatments and diagnostics were not medically necessary and related to the injury based on the limited documentation provided. (6) The current treatment in all medical probability placed the patient at risk of early death. The use of high doses of opioids could mask symptoms of chronic disease and/or cancer, resulting in inappropriate treatment. (7) The patient was a very poor candidate for the use of scheduled drugs due to her history which included abuse and underlying psychiatric illness. The patient should undergo an evaluation with an independent addiction specialist as soon as possible. She would require some sort of opioid analgesic in low doses. (8) Nuvigil use was inappropriate and should be discontinued. Trazodone needed to be stopped due to risk of GI bleed with Plavix. Effexor was not appropriate as it was used for treatment of a pre-existing condition. Lyrica was appropriate. Lansoprazole use was not medically related as the patient was not on nonsteroidal anti-inflammatory drugs (NSAIDs).

**2013:** From February 5, 2013, through September 17, 2013, the patient was seen on a regular basis for ongoing moderate, sharp and burning low back and leg pain. The patient was not interested in IT pump trial. She received regular medication refills. The patient had memory loss, confusion and insomnia.

On April 2, 2013, urine drug screen was positive for fentanyl and norfentanyl which was consistent and also positive for nortriptyline which was inconsistent.

On July 23, 2013, urine drug screen was positive for fentanyl and norfentanyl which was consistent and also positive for nortriptyline which was inconsistent

On September 20, 2013, performed another peer review and rendered the following opinions: (1) The patient's medications included trazodone, venlafaxine, Tegaderm, Duragesic, Lyrica, senna and lansoprazole. (2) Drug screens are recommended two to three times a year. Benzodiazepines and possibly barbiturates screening was also recommended. Fentanyl screen was also recommended. Complete drug list should be documented. The patient had no evidence of improvement in function with high dose opioids. She needs to undergo an addiction screen.

From September 26, 2013, through December 5, 2013, the patient had regular follow-ups for lower back and leg pain. decreased dose of Duragesic and recommended stopping trazodone. The patient was not sleeping well. Duragesic was being weaned. The patient was utilizing Duragesic, Lyrica and other medication. Clonidine was prescribed. Handwritten reports are illegible.

On October 10, 2013, the patient underwent manual muscle testing and ROM exam.

On December 8, 2013, performed another peer review and opined the manual muscle testing was not related to the original work injury.

**2014:** The patient was seen in January and February lower back and right leg as well as mid back. The patient was utilizing clonidine, Lyrica, Senna-S. Duragesic, Tegaderm and clonidine were stopped in February and tramadol and Restoril were started.

On February 6, 2014, urine drug screen was negative.

On February 20, 2014, evaluated the patient for ongoing lower back/legs pain that was sharp and severe in nature. The back pain radiated to the right hip/buttock/leg. Pain level was 8/10. The patient was utilizing temazepam. Tramadol, Lyrica and Senna-S. The patient was doing better on Restoril and tramadol. increased dose of tramadol and refilled Restoril, Lyrica and Senokot.

In letter of medical necessity dated February 24, 2014, stated that the patient had exhausted all conservative measures in treatment of her chronic medical condition. She had been weaned off Duragesic and transitioned to tramadol. She was utilizing Restoril for chronic insomnia, Lyrica for chronic lower extremity neuropathic pain caused by nerve damage secondary to lumbar chronic pain syndrome. Senokot used for chronic constipation secondary to long term chronic narcotic medication use. The patient's functional capabilities were much improved with the ongoing medications regimen and without them she had difficulty performing activities of daily living (ADL) and had to spend most of her time in the bed. The patient also mentioned suicidal ideation if she did not have her medications because of her baseline pain level was unbearable and her subsequent lifestyle unacceptable. These medications were medically necessary and important to alleviate her pain and suffering and taking her off them was not recommended.

Per utilization review dated March 3, 2014, the request for Restoril and Lyrica was denied.

On March 19, 2014, evaluated the patient for lower back/leg pain moderate and aching in nature. The patient reported increased low back pain and decrease in sleep due to low back pain. She was utilizing tramadol, Lyrica and temazepam. refilled medication and recommended low back exercises.

On March 20, 2014, prescribed compound cream for myofascial pain with neuropathic components (KBCDGOT) Ketamine10% Baclofen2% Cyclobenzaprine2% Diclofenac3% Gabapentin6% Orphenadrine5% Tetracaine 2%.

On April 15, 2014, the patient reported lower back/leg pain that was moderate and aching in nature and experienced most in the evening or night. Sitting and bending aggravated her pain where as lying down; medications and heat relived

her pain. The pain level was 7/10. She was utilizing temazepam, tramadol and Lyrica. The patient had loss of balance, mood swings, bowel changes, abdominal pain, memory loss, depression, joint pain and swelling in feet. Diagnoses were facet syndrome arthropathy, nerve root irritation, postlaminectomy syndrome and opiate dependency. refilled medications and recommended continuing exercises.

Per utilization review dated April 23, 2014, the request for URGENT (KCBDGOT) Cream #1 x4 refills was denied with the following rationale: *“The clinical information submitted for review fails to meet the evidence-based guidelines for the requested service. The mechanism of injury information is not provided in the medical record. The patient's medication regimen includes tramadol 150 mg three times daily; Lyrica 150 mg three times daily, and temazepam 30 mg, one tablet at bedtime. Surgical history information is not provided in the medical record. Diagnostic studies information is not provided in the medical record. Other therapies include medication management and activity modification. The patient is a female who reported an injury xx/xx/xx. A review of the medical record reveals the patient's diagnosis is post-laminectomy syndrome of the lumbar region, ICD9 code 722.83. Clinical note dated April 15, 2014 reports the patient continues to have significant complaints of lower back pain, and posterior leg pain which he rates as moderate and describes the pain as aching. The patient denies any numbness or tingling. She states that pain is aggravated with sitting and bending. The pain is relieved with lying down, medications, and heat application. She rates her pain 7/10 on the pain scale. The patient was not working. She did complain of a loss of balance, mood swings, bowel changes, abdominal pain, memory loss, depression, joint pain, weakness and swelling in the feet. The requested service is for urgent KCBDGOT cream #1 x4 refills. Per Official Disability Guidelines, it is stated that topical analgesics are largely experimental in use with few randomized control trials to determine the efficacy or safety of its use; and it is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. It is also noted that any compound medication that includes at least 1 drug or drug class that is not recommended is not recommended. The requested medication contains ketamine 10%, baclofen 2%, cyclobenzaprine 2%, diclofenac 2%, gabapentin 6%, and tetracaine 2%. The only recommended topical form of diclofenac is 1% gel, and the request contains 2 %. Per Official Disability Guidelines, baclofen is not recommended as a topical analgesic. Muscle relaxants are not recommended, as there is no evidence for use of any muscle relaxant as a topical analgesic product. Gabapentin is not recommended as a topical analgesic, as there is no peer-reviewed literature to support its use. As there is no documentation of any failed use of antidepressants or anticonvulsants to treat the patient's condition, and the requested medication contains four medications that are not recommended as topical analgesics, the medical necessity for continued use of the medication cannot be determined.”*

Per reconsideration review dated May 5, 2014, the appeal for URGENT (KCBDGOT) Cream #1 x4 refills was denied with the following rationale: “The request for URGENT (KCBDGOT) Cream #1 x4 refills, the compounded topical medication containing ketamine, baclofen, cyclobenzaprine, diclofenac,

gabapentin, Orphenadrine and Tetracaine is not supported as medically necessary. *The patient is a female who reported an injury xx/xx/xx due to undisclosed mechanism of injury. Current diagnoses included lumbar post-laminectomy syndrome and nerve root irritation. Previous surgical interventions are unknown per clinical documentation. It is documented that the patient has been weaned from Duragesic 100 mcg patch and all schedule II narcotics with current medications including tramadol 50 mg QID, Restoril 15 mg one-two tablets QHS, and Lyrica 150 mg. Clinical documentation indicated the patient continued to have significant complaints low back pain and posterior leg pain described as moderate and aching. The patient rated her pain at 7/10 in severity. Physical examination was not provided. Per the United States FDA and Official Disability Guidelines, the safety MD efficacy of compounded medications has not been established through rigorous clinical trials. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. It is noted in the clinical documentation that the patient is currently utilizing Lyrica as part of her medication regimen. Further, both the FDA and Official Disability Guidelines require that all components of a compounded topical medication be approved for transdermal use. This compound contains multiple components which have not been approved for transdermal use. In addition, there is no evidence within the medical records submitted substantiating the necessity of transdermal versus oral route of administration. Therefore, URGENT (KBCDGOT) Cream #1 x4 refills cannot be recommended as medically necessary.*

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

Based on the medical records received URGENT KBCDGOT Cream is a compound drug and contain ketamine, baclofen, cyclobenzaprine, diclofenac, gabapentin, Orphenadrine and Tetracaine. According to ODG “many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\gamma$  agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.

Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen.

Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product.

Gabapentin: Not recommended. There is no peer-reviewed literature to support use.

Other antiepilepsy drugs: There is no evidence for use of any other antiepilepsy drug as a topical product.

*Ketamine*: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined.”

Since any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended the decision is upheld and the medication requested is not approved.

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

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