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Notice of Independent Review Decision

DATE OF REVIEW: DECEMBER 10, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Medical necessity of proposed medication Kadian 30mg, #60 (E1399)

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

This case was reviewed by a Medical Doctor licensed by the Texas State Board of Medical Examiners. The reviewer specializes in Physical Medicine and Rehabilitation and is engaged in the full time practice of medicine.

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)

| Primary Diagnosis | Service being Denied | Billing Modifier | Type of Review | Units | Date(s) of Service | Amount Billed | Date of Injury | DWC Claim# | IRO Decision |
|-------------------|--------------------------|------------------|----------------|-------|--------------------|---------------|----------------|------------|--------------|
| 307.89, 722.4 | Kadian 30mg, #60 (E1399) | | Prosp | 1 | | | Xx/xx/xx | xxxxx | Upheld |

INFORMATION PROVIDED TO THE IRO FOR REVIEW

TDI-HWCN-Request for an IRO-19 pages

Respondent records- a total of 1668 pages of records received to include but not limited to: Letter 11.25.13; records 12.11.03-7.16.13; MedToxicology Labs report 9.17.13; Peer Review reports 7.17.12, 9.23.13; letter 9.24.13, 10.17.13; Combined Individual Claimant Activity report; MMI report 6.20.1996; records, 7.22.2004; MRI Rt Knee; IME report 2.21.06, 4.18.11, 5.19.11 addendum; Peer Review , 2.16.07, 5.7.08, 4.30.09; 10.11.07; Peer Review, 3.3.08; report; report 9.11.08-9.13.12; letter 9.11.08; DDE report 11.3.08; Assess reports 6.12.12, 11.27.12; report 5.15.12, 6.12.12; RME report 9.4.12; Compliance Toxicology report 11.27.12; Diagnostics report 11.14.12; Peer Review 8.7.09; WC Services report 10.27.09; Diagnostics report 3.22.11; Spine

records 6.28.11-1.12.12; Diagnostics report 6.25.13; ODG guidelines Low Back, Lumbar and Thoracic; ODG Pain

Requestor records- a total of 0 pages of records received to include but not limited to:
First request sent 11.20.13; Second request sent 12.4.13, no records received

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured employee is a gentleman who reported a work-related injury on xx/xx/xx. On this date, the injured employee reported he had a non-specific auto-immune condition associated with chemical exposure.

The injured employee was evaluated on xx/xx/xx. had seen the injured employee multiple times and had corrected some minor medical problems, such as a low thyroid. At this point in time, in the evaluator's best medical judgment, the injured employee had a non-specific auto immune condition associated with chemical exposure. As a result of this, the injured employee had a connective tissue disorder classified as possibly early scleroderma and associated with Raynaud's phenomena, especially involving the feet. The injured employee continued to have stiffness, thickening of the skin, and dryness of the skin that had not improved at all. In addition, there were some paresthesias of the distal lower extremities and somewhat less in the hands. This was suggestive of a peripheral neuropathy which was associated with chemical exposure. Another problem the injured employee had was shortness of breath. The evaluator believed he had an irritation of the airways associated with chemical inhalation. The fourth problem for the injured employee was anxiety and depression associated with all the above.

An x-ray of the chest on March 15, 1995, showed the appearance of increased interstitial pattern raising the question of chronic inflammatory disease. There were pleural effusions in the right costophrenic sulcus. The appearance of the chest was unchanged since 1992.

performed a Designated Doctor Evaluation on April 23, 1998, and stated the injured employee had reached Maximum Medical Improvement on June 17, 1996. The injured employee was given a 56% whole person impairment rating.

On May 18, 2000, performed a Treating Doctor Evaluation that stated the injured employee had reached Maximum Medical Improvement on May 18, 2000. The injured employee was given a 0% whole person impairment rating.

On June 7, 2005, an evaluation revealed the injured employee was following in regards to his Sjögren's syndrome, neuropathy, and interstitial pulmonary disease. There was periodic nausea and he was prescribed Phenergan. The assessment was Sjögren's syndrome, interstitial pulmonary disease, and neuropathy. The refills were for medications of Maxair, Skelaxin, Nasocort, Lasix, hydrocodone, a nasal spray, Phenergan, Nexium, Tessalon Perles, enalapril, terazosin, and Synthroid. Because of the neuropathy, the injured employee was given Neurontin. The injured employee continued to follow with the treating physician for medical care and medications.

On February 21, 2006, performed an independent medical evaluation. It was his opinion, according to the injured employee's information that they provided to the evaluator that were not in the medical records, that the Appeals Court had decided the pulmonary aspects, dry eye syndrome, or Sjögren's syndrome were compensable. Through the adjudicated process, the scleroderma was compensable, which was affiliated with aches and pains, arthritic manifestations, cutaneous changes, and swallowing problems. The hypertension, diabetes, and hyperlipidemia were not compensable.

On a follow-up on March 7, 2006, the injured employee recently had an independent medical evaluation, which they agree with his current plan of care, including all of his medications. The assessment was Sjögren's syndrome, Raynaud's syndrome, scleroderma,

pulmonary fibrosis, and dry eye syndrome. The injured employee underwent two steroid injections into both sacroiliac joints.

On March 4, 2006, in a statement of accepted facts, it stated the carrier disputed the injured employee's compensable injury, including the lumbar radiculopathy. There was no medical evidence to support the lumbar complaints were related to any of the compensable diagnosis or related to the chemical inhalation claim.

On a follow-up on August 8, 2006, there was continued swelling of the lower extremities. The recommendation was to refill the current medications.

On evaluation on April 12, 2007, the injured employee was there for follow-up and his primary scleroderma. The injured employee was fairly stable at this time. The recommendation was for tramadol, hydrocodone, and Kenalog for the skin. The injured employee continued to follow with the treating physician for medications and medical care.

on March 23, 2008, performed a Peer Review and stated Maxair would be considered reasonable, necessary, and related to the pulmonary disorders as well as Nasocort. Genoptix eye drops would be considered reasonable, necessary, and related to the compensable injuries. Synthroid for thyroid supplementation would be reasonable, necessary, and related to the autoimmune hypothyroid condition. Phenergan, which was a nausea medication, which may be considered in part related to the esophageal condition described above. Other medications listed, including terazosin which was used as an anti-hypertensive was not reasonable and not directly related to the compensable injury. The pain medications currently being prescribed for chronic low back pain which would not be considered related included Kadian, Ultram, Norco, and Skelaxin. Lyrica was a reasonable medication for neuropathy. It was not clear if this was due to diabetic peripheral neuropathy, which was unrelated or for a neuropathy due to the systemic auto-immune condition, which had been accepted as compensable. Chantix was a smoking sensation agent and would not be related to the compensable injury.

The injured employee followed up on May 5, 2008, for chronic pain syndrome. The injured employee was being followed up for a circumscribed scleroderma. There were arthralgias and finger swelling. The assessment was circumscribed scleroderma, primary, and chronic pain syndrome. The recommendation was to continue the current medications.

On a follow-up on April 17, 2009, the injured employee was being treated for chronic pain syndrome. The pain was located in the head, left forearm, left neck, right forearm, and right neck. There was also pain in the left lower leg and right lower leg. There was pain in the back. The clinical assessment was chronic pain syndrome. The recommendation was to refill Kadian and Genoptix. The injured employee continued to follow with the treating physician for medications and medical care.

On a follow-up on January 5, 2010, the injured employee was there for his pain medications and a follow-up visit. The injured employee had been stable recently. The severity of pain was 4/10. Overall, the pain was very well controlled. There were no medication side effects. The recommendation was to continue the current medications, which included Restasis, Lyrica, Genoptix, Nasocort, Synthroid, Ultram, Nexium, Phenergan, Norco, Symbicort, Spiriva, hydrochlorothiazide, Lasix, terazosin, Chantix, and Maxair.

On April 21, 2010, the injured employee underwent a cataract extraction with posterior chamber implant, left eye. The injured employee continued to follow-up on a monthly basis for medical care and medications. On a follow-up on August 3, 2010, there were subjective complaints of left ankle, left knee, left lower leg, left thigh, right ankle, right knee, right lower leg, and right thigh pain. On examination, there was pain with movement of the neck and back. The recommendation was to continue with Kadian, Prevacid, Norco, Uloric, Phenergan, and Synthroid.

On a follow-up with the treating physician on March 22, 2011, the injured employee followed up for his chronic pain syndrome. The pain was constant, but relatively well controlled. The injured employee reported improved sleep and increased physical activities. The clinical assessment was keratoconjunctivitis sicca, Sjögren's disease, calcinosis, and circumscribed scleroderma. The recommendation was to continue the current medications. The injured employee continued to follow with the treating physician for medications and medical care.

A urine drug screen on June 15, 2012, was positive for Kadian, Norco, and tramadol. Carisoprodol was detected, but could not be matched to any of the reported prescriptions.

On a follow-up visit on October 4, 2012, the recommendation was to continue with the current medications.

On May 28, 2013, a follow-up reported the injured employee was there for medication refills. The assessment was scleroderma. The recommendation was Kadian. The injured employee continued to follow with the treating physician monthly for medications and medical care. A pharmacy log on September 3, 2013, reported the current medications were Nexium, Voltaren, Lactulose, Restasis, Amitiza, tramadol, and Kadian.

performed a Peer Review on September 23, 2013. stated the medications reflected the injured employee had a toxic exposure in xxxx and developed scleroderma, chronic pain, obstructive pulmonary disease, and complications secondary to this disease process. Based on the medical records provided, there was nothing else to offer this injured employee other than maintenance care and office visits quarterly for medication management. The injured employee was now on Kadian and tramadol. The injured employee was stable. The injured employee did not appear to be abusing or misusing his medications. The urine drug screen was consistent. There were no effects of aberrant behavior. The use of morphine was a main medication and tramadol for breakthrough pain was appropriate. The injured employee met the Official Disability Guidelines criteria for these medications. stated that based on the injuries that had been accepted, this was going to be a lifelong injury and the effects were not likely to resolve.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION. IF THERE WAS ANY DIVERGENCE FROM DWC'S POLICIES/GUIDLEINES OR THE NETWORK'S TREATMENT GUIDELINES, THEN INDICATE BELOW WITH EXPLANATION.

RATIONALE:

Based on the medical records available for review, the Official Disability Guidelines Workmens' Compensation Drug Formulary, and the Official Disability Guidelines Pain Chapter, in my medical opinion, the continued use of the proposed medication, Kadian 30 mg #60 would not be medically supported for the compensable injury. Kadian is an N-drug on the Official Disability Guidelines Workmens' Compensation Drug Formulary and its continued use would not be supported. The Official Disability Guidelines Pain Chapter reports that Kadian is recommended for a trial after failure of non-opioid analgesics, short-acting opioid analgesics, and after a trial of generic extended release morphine equivalent to MS Contin. Kadian is not recommended as a first-line option.

According to the FDA approved prescribing information, the use of Kadian is a first opioid analgesic. There has been an evaluation that Kadian is an initial opioid analgesic in the management of pain, as it would be more difficult to titrate a patient to adequate analgesia, and it is unadvisable to begin treatment using an immediate release morphine formulation. Research has shown no significant difference between Kadian in 24 and 12-hour dosing durations as compared to MS Contin treatment of cancer pain in terms for safety. There is no documentation the injured employee has failed generic extended release morphine equivalent to MS Contin. Official Disability Guidelines state routine and long-term opioid therapy is not recommended and Official Disability Guidelines recommends consideration of a one-month limit on opioids for new, chronic, non-malignant pain patients in most cases as there is little research to support its use.

The research available does not support overall general effectiveness and indicates numerous side effects with long-term use. The latter includes the risk of ongoing psychological and difficulty weaning. Opioids have been suggested for neuropathic pain that does not respond to first line recommendations, antidepressants, or anticonvulsants. There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic pain with resultant neuropathy.

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

XX DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

XX MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

XX ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES