AccuReview
An Independent Review Organization
569 TM West Parkway
West, TX 76691
Phone (254) 640-1738
Fax (888) 492-8305

January 17, 2018

IRO CASE #: XXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Hydro-Apap 15/200 mg Qty: 180 Patient takes 1 cap every 4 hrs prn pain With 3 refills, 2. Duragesic Patch 100 mcg Qty: 15 Patient applies 1 patch every 48 hrs with 3 refills

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

This physician is Board certified in Anesthesiology with over 15 years of experience.

REVIEW OUTCOME:

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

☒ Overturned (Disagree)

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

PATIENT CLINICAL HISTORY [SUMMARY]:

XXXX: Follow up dictated by XXXX. CC: chronic low back, left foot and left leg pain, s/p L5-S1 PLIF with posterior instrumentation on XXXX. Patient continues to have moderate to severe pain, left is worse than right. Patient developed symptoms of complex regional pain syndrome in the left foot with edema, hypersensitivity, allodynia, etc. Patient gets cold and numb and very sensitive all the time in patient left foot. Patient continues to take Duragesic 100 mcg patch every 48 hours and hydrocodone 15/200 q.4 hours PRN for pain and Cymbalta for patient neuropathic pain. The claimant has tried gabapentin and Lyrica in the past, but these medications caused bad side effects, so patient continues to take Cymbalta for neuropathic pain. Patient is able to continue working and perform activities of daily living on patient current meds. In early XXXX, the claimant did have some increased lower back pain and left leg weakness. Patient completed a round of physical therapy which helped to improve patient symptoms. Patient saw good relief from the physical therapy. Patient has been doing a lot of traveling for XXXX. In regards to patient low back, there have been no changes. Patient is very happy with patient ability to function on patient current medications. PE: patient vapors, continues tender to palpation from L3 to S1, left greater than right. SLR positive at 60 degrees on the left. The claimant has

hyperpathia and allodynia in the left L5 distribution. Impression: 1. Residual lower back pain, bilateral leg pain and primary left foot pain status post L5-S1 PLIF at USMD on XXXX, 2. Left lower extremity symptoms of complex regional pain syndrome. Plan: hydrocodone and Duragesic patches are refilled, pain diaries exchanged, return in 30 days.

XXXXX: Follow up dictated by XXXX. CC: chronic lumbar pain, left leg and foot pain. Patient completed a round of physical therapy which helped to improve patient symptoms, patient saw good relief from the PT. PE: patient vapors, continues tender to palpation from L3 to S1, left greater than right. SLR positive at 70 degrees on the left. The claimant has hyperpathia and allodynia in the left L5 distribution. Impression: 1. Residual lower back pain, bilateral leg pain and primary left foot pain status post L5-S1 PLIF at USMD on XXXX, 2. Left lower extremity symptoms of complex regional pain syndrome. Plan: hydrocodone and Duragesic patches are refilled, pain diaries exchanged, return in 30 days.

XXXX: Follow up dictated by XXXX. Claimant has HEP including stretching. PE: patient vapors, continues tender to palpation from L3 to S1, left greater than right. SLR positive at 70 degrees on the left. The claimant has hyperpathia and allodynia in the left L5 distribution. Impression: 1. Residual lower back pain, bilateral leg pain and primary left foot pain status post L5-S1 PLIF at USMD on XXXX, 2. Left lower extremity symptoms of complex regional pain syndrome. Plan: hydrocodone and Duragesic patches are refilled, pain diaries exchanged, return in 30 days.

XXXX: MilleniumUDT Radar Report dictated by XXXX. Consistent results include fentanyl and hydrocodone.

XXXXX: Patient Comfort Assessment Guide dictated by XXXX. CC: back and left foot/leg pain described as aching, throbbing, shooting, stabbing, sharp, exhausting, nagging, numb and unbearable. Reported as continuous and worse in evening, worst at 8-9/10 and best 4-5/10 and average 7-8/10. Rest, elevation improves and too much activity makes it worse. Fentanyl relieves to 8/10, Cymbalta relieves to 6/10 and hydrocodone relieves to 7/10.

XXXX: Pre-Authorization Letter dictated by XXXX. The claimant is being followed for chronic low back, left foot and leg pain. Patient continues to have moderate to severe pain in the low back and lower extremities. Patient has developed regional pain syndrome in the left foot with edema, allodynia, hyperpathia, temperature changes, etc. Patient continues Duragesic 100 mcg patch every 48 hours with hydrocodone 15/200 Q4H PRN breakthrough pain and Cymbalta for neuropathic pain. Request preauthorization of 15 months' worth.

XXXX: UR performed by XXXX. Reason for denial: The ODG does not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there are an ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. This is a chronic pain patient and has been on opioids. However, there is no documentation that the medications provide pain relief and functional improvement. There is no documentation of VAS pain levels with or without the use of medications. In addition, there is no documentation of the absence of side effects and aberrant drug-seeking behaviors. There is no discussion of 4 A's assessment. There are no urine drug screen or controlled substance utilization review and evaluation system reports available for review to corroborate compliance. Medical necessity has not been established. Recommend non-certification for Hydro-Apap 15/200 mg Quantity: 180 Patient takes 1 cap every 4 hours when necessary (PRN) pain with 3 refills and Duragesic Patch 100 mcg Quantity: 15 Patient applies 1 patch every 48 hrs with 3 refills.

XXXXX: Letter of Appeal dictated by XXXX. The claimant continues Duragesic 100 mcg patch every 48 hours and hydrocodone 15/300 Q4H for breakthrough pain and Cymbalta for neuropathic pain. Gabapentin had been tried in the past, but the side effect profile was so severe it was intolerable. Patient can continue working and perform ADLs with patient current medications. The information requested has been included and therefore we are appealing this adverse determination.

XXXX: UR performed by XXXX. Reason for denial: The ODG does not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest dose possible dose; and unless there are an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Due to jurisdictional restrictions, the modification is not allowed. Recommend non-certification.

XXXX: Follow up dictated by XXXX. CC: chronic low back pain and primarily left leg pain. The claimant has tried gabapentin and Lyrica in the past, but these medications caused bad side effects, so patient continues to take Cymbalta for neuropathic pain. Patient can continue working and perform activities of daily living on patient current meds. In early XXXX, patient did have some increased lower back pain and left leg weakness. Patient saw good relief from PT and patient has a HEP including stretching. Patient is stable on conservative care for quite some time. PE: patient vapors, continues tender to palpation from L3 to S1, left greater than right. SLR positive at70 degrees on the right and 80 degrees on the left. The claimant has hyperpathia and allodynia in the left L5 distribution. Impression: 1. Residual lower back pain, bilateral leg pain and primary left foot pain status post L5-S1 PLIF at USMD on XXXX, 2. Left lower extremity symptoms of complex regional pain syndrome. Plan: hydrocodone and Duragesic patches are refilled, pain diaries exchanged, return in 30 days.

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

Based on the records submitted and peer-reviewed guidelines, this request is certified. The ODG does not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest dose possible dose; and unless there are an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. These criteria have been met and therefore this request should be certified. Furthermore, after reviewing the medical records and documentation provided, the request for 1. Hydro-Apap 15/200 mg Qty: 180 Patient takes 1 cap every 4 hrs prn pain With 3 refills, 2. Duragesic Patch 100 mcg Qty: 15 Patient applies 1 patch every 48 hrs with 3 refills is medically necessary and overturned/certified.

Per PDG:

Duragesic® (fentanyl transdermal system)	Not recommended as a first-line therapy. See Opioids, long-acting. Also, See Fentanyl Duragesic is a long-acting opioid. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by ALZA Corporation and marketed by Janssen Pharmaceutica (both subsidiaries of Johnson & Johnson). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. Due to the significant side effects, not for use in routine musculoskeletal pain. The FDA announced it will require color changes to the writing that appears on fentanyl pain patches (Duragesic and generics) so they can be seen more easily and to emphasize that unintended exposure can cause death. This is part of an effort to prevent accidental exposure to the patches, which can cause serious harm and death in children, pets, and others. (FDA, 2013) FDA is alerting the public about potential for deaths from accidental exposure to fentanyl transdermal patches. (FDA, 2015). [Duragesic ranked #9 in utilization (managed) for WC in 2014. (Coventry, 2014)]
Hydrocodone	Hydrocodone is a semi-synthetic opioid which had been considered the most potent oral opioid that does not require special documentation for prescribing in some states. See Opioids. See also Zohydro. The FDA has approved another ER single-entity opioid analgesic hydrocodone, this one with abuse-deterrent properties. See Hysingla. The FDA proposed that hydrocodone products be reclassified from Schedule III to Schedule II, further increasing controls on these drugs. The potency of hydrocodone, an active ingredient of the most commonly prescribed drug (of any type) in the U.S., is greater than morphine, an opioid that is a Schedule II substance. Schedule II drugs can be dispensed only by prescription, and no refills are allowed. Stringent record keeping, reporting, and physical security requirements are also in place for these substances. (FDA, 2013) On August 22, 2014 this was done by the DEA. (DEA, 2014) Hydrocodone was reclassified to Schedule II effective October 6, 2014. (FDA, 2014) At the same time as these additional proposed restrictions on hydrocodone, the FDA approved the first single-entity extended-release (ER) formulation of hydrocodone (Zohydro ER, Zogenix Inc). Zohydro does not have abuse-deterrent technology. According to the FDA, due to the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with ER/LA opioid formulations, Zohydro ER should be reserved for use in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. (FDA, 2013a) In December 2012, FDA's Anesthetic and Analgesic Drug Advisory Committee of independent experts voted 11 to 2 to recommended against approval of Zohydro

	for the treatment of moderate to severe chronic pain. The main concern of those voting against approval was that the potential for abuse of Zohydro; because the product does not include acetaminophen, they feared the potential for abuse might be even greater. Because of this and the greater risks with a new ER opioid, Zohydro is not recommended as a first-line drug in ODG.
Hydrocodone/ Acetaminophen (e.g., Vicodin®, Lortab®)	See Opioids for general guidelines, as well as specific Hydrocodone/Acetaminophen (Anexsia®, Co-Gesic®, Hycet™; Lorcet®, Lortab®; Margesic-H®, Maxidone™; Norco®, Stagesic®, Vicodin®, Xodol®, Zydone®) listing for more information and references. An FDA advisory committee recommended a transition from Schedule III to Schedule II for hydrocodone products (FDA, 2013). The Safe Prescribing Act proposed in U.S. Congress would legislatively reclassify hydrocodone combination products without going through the DEA. New York State made this transition to Schedule II in February 2013 as states have authority to upschedule. Now the DEA has officially rescheduled hydrocodone combination products from CIII to CII. (DEA, 2014) In this ED study, Vicodin failed to provide superior pain relief compared to Tylenol with codeine, and there was no significant difference in side effects. Clinicians should consider prescribing Tylenol with codeine instead of Vicodin when discharging nonelderly patients with acute extremity pain from the emergency department, except for patients in groups known to not metabolize codeine normally. Both medications decreased pain scores by approximately 50%, but hydrocodone/acetaminophen (Vicodin [5/500]) failed to provide clinically or statistically superior pain relief compared to codeine/acetaminophen (Tylenol#3 [30/300]). (Chang, 2014)

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**

☒ **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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**