



Notice of Independent Review Decision

DATE OF REVIEW: 5/9/08

Amended Date: 6/4/08

IRO CASE #:

NAME:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Determine the appropriateness of the previously denied request for retrospective prescriptions provided: Opana; Hydrocodone/Acetaminophen; Lunesta; Lryica; Provigil; and Methocarbamol. Which medications are not medically necessary and for what date?

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

Texas licensed Occupational Medicine Physician.

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)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

The previously denied request for retrospective prescriptions provided: Opana; Hydrocodone/Acetaminophen; Lunesta; Lryica; Provigil; and Methocarbamol.

See rationale.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Facsimile Cover Sheet dated 4/21/08.
- Confirmation of Receipt of a Request for a Review by an Independent Review Organization (IRO) dated 4/18/08.
- Company Request for IRO dated 4/18/08.
- Request Form Request for a Review by an Independent Review Organization dated 3/31/08.
- Notice to Utilization Review Agent of Assignment of Independent Review Organization dated 4/21/08.
- Letter of records submitted for review dated 4/23/08.
- Notice of Disputed Issue(s) and Refusal to pay Benefits dated 10/25/06.
- Explanation of Benefits dated 2/25/08, 2/26/08, 6/26/07, 7/24/07, 8/14/07, 9/7/07, 9/21/07, 10/22/07, 10/18/07, 11/28/07, 12/1/07, 12/14/07.
- Notice To CompPartners, Inc. of Case Assignment dated 4/21/08.
- Pre-Authorization Report dated 3/24/08, 3/11/08, 5/16/07, 2/2/07, 10/24/06, 10/3/06, 8/31/06.
- Comprehensive Pain Follow-Up dated 1/14/08, 11/5/07, 10/8/07, 9/10/07, 8/14/07, 7/30/07, 7/16/07, 6/18/07, 5/21/07, 4/23/07, 3/13/07.
- Emergency Department chart notes dated 12/14/07.
- Release from Responsibility for Patients Refusing Treatment/Ambulance Transport dated 12/14/07.
- Stat Care EMS form dated 12/14/07.
- ECG dated 12/14/08.
- Diagnostic Imaging Report dated 12/14/07.
- Independent medical examination report dated 11/13/07.
- Letter of Rebuttal dated 10/2/07.
- Report of Medical Evaluation dated 8/15/07.
- Designated Doctor Evaluation – Date of Exam 7/30/07.
- Procedure Notes dated 8/6/07.
- Anesthesia Record dated 8/6/07.
- Examination: CT of the Lumbar Spine – Post-Discogram dated 8/6/07.
- Request for Authorization of Reasonable and Necessary Services dated 7/26/07.
- Radiology Report – MRI Right Hip dated 7/26/07.
- Texas Department of Insurance Note to Treating Doctor and Carrier dated 6/27/07.
- Community Clinic Routine Visit dated 7/12/07, 5/11/07, 1/24/07, 1/15/07, 10/30/06, 8/7/06.
- Operative Report dated 6/4/07, 5/7/07, 4/9/07, 2/27/07.
- Encounter Notes dated 5/11/07, 3/6/07
- Pre-Op Assessment dated 5/21/07, 5/7/07.
- Intraoperative Record dated 5/7/07, 4/9/07.
- Post Anesthesia Care Unit Record dated 5/21/07, 4/9/07.
- Letter of medical necessity dated 4/22/07.
- Consultation dated 2/13/07.
- Chart note, transfer of care dated 1/31/07.
- Follow-Up Note dated 1/23/07, 1/2/07, 12/13/06, 12/7/06, 11/28/06, 11/21/06, 11/2/06, 11/15/06, 10/25/06, 10/4/06.

- Texas Workers' Compensation Work Status Report dated 1/23/07, 1/2/07, 12/13/06, 12/7/06, 11/28/06, 11/21/06, 6/25/06, 10/18/06.
- SOAP notes dated 1/23/07, 1/9/07.
- Outpatient Rehabilitation Physical Therapy Treatment Record dated 9/27/06, 9/29/06, 10/16/06, 10/3/06, 10/5/06, 10/9/06, 9/8/06, 9/18/06, 9/27/06, 9/29/06, 9/15/06, 9/19/06, 9/20/06, 9/25/06.
- EMG/NCV of the Lower Extremities dated 11/28/06, 9/26/06.
- Evoked Potential dated 10/18/06.
- Initial Report dated 9/26/06.
- Carotid Doppler Report dated 9/26/06.
- Clinical EEG dated 9/26/06.
- MRI of the Lumbar Spine dated 9/4/06.
- NON-ADL Doctor Request for Case-by-Case Exception dated 8/26/06.
- Emergency Care Record (Nurses) dated 7/31/06.
- Emergency Physician Record, Hip Injury dated xx/xx/xx.
- Radiology Report, Thoracic Spine dated 7/31/06.
- Radiology Report, Lumbar Spine dated 7/31/06.
- Radiology Report, Right Hip dated 7/31/06.
- Physical Exam dated 7/31/06.

PATIENT CLINICAL HISTORY (SUMMARY):

Age: xx years
 Gender: Female
 Date of Injury: xx/xx/xx
 Mechanism of Injury: Slip and fall injury.

Diagnosis: Low back pain with radiculopathy

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

The claimant is a xx-year-old female who sustained an injury on xx/xx/xx. According to reports, the claimant slipped and fell on the floor while at work. , on xx/xx/xx, she was taken to the local hospital emergency department for reevaluation of back and left buttock pain. Plain X-ray films of the spine revealed pre-existing degenerative disease. Steroid injections were provided to the right lumbar area and right greater trochanter. She was diagnosed with muscle strain injury to the right hip, and trochanteric bursitis. Several days later, the claimant sought out care with a primary care provider. She was treated with medications for presumed lumbar radiculopathy. She also was given a Medrol Dosepak and a TENS unit. MRI lumbar spine was done on 9/4/06 which did not show any acute changes, but rather confirmed the presence of degenerative changes. The claimant started care with neurologist Dr. on 9/26/06. She was complaining of ongoing low back pain with pain radiating into the right leg. Neurological exam was essentially normal. Electromyogram (EMG)/ nerve conduction velocity (NCV)

testing had shown “L3, L4 nerve root irritation, bilaterally.” The claimant was treated with Robaxin injections and PT, along with medications. Medication use in 1/07 included Lyrica, Robaxin, Vicodin and Duragesic patches. TENS was also to be employed. The claimant was seen by Dr. for a consultation on 2/13/07. Dr. concluded that the claimant was suffering from lumbar facet pain. He recommended changing the claimant’s medications, and providing facet joint blocks. The claimant received 2 sets of injections with fair results. Medications taken consisted of Lunesta, Lyrica and Opana. On 4/23/07, the claimant had residual tenderness along the right facet joint line. She had 60% improvement in symptoms. Pharmacological treatment was encouraged. Facet injections were again provided in 5/07. There is a note from 5/11/07, in which the claimant noted only modest response to her injections, although the claimant was working full time. She is using Opana, a powerful narcotic analgesics and Vicodin and Lunesta. The claimant was also using Relafen and Lyrica.

For Review (5/17/07): The Lunesta is a sleeping pill. ODG Treatment Guidelines indicates: *Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008).* Thus, this medication is acceptable for one month’s use. Treatment with this drug beyond that time is not supported by the available data.

ODG Treatment Guidelines regarding opioids indicates: *Recommendations for general conditions: - Neuropathic pain: Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See Opioids for neuropathic pain. - Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (≤70 days). This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-*

range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect. (Ballantyne, 2006) (Furlan, 2006) Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis). (Kalso, 2004) There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. (Martell-Annals, 2007.

The Opana usage is acceptable at this stage of the claimant's care. The Hydrocodone/Acetaminophen is not medically warranted. There is a request for the drug Lyrica, as well. ODG Guidelines note: Pregabalin (Lyrica®) has been documented to be effective in treatment of diabetic neuropathy and post herpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Therefore, this drug is not authorized as it is not indicated in this claimant's clinical situation. Lunesta, Lyrica and Opana 10 mg b.i.d., remain not medically appropriate, as per ODG Guidelines.

For review (6/11/07) Opana ER, 20 mg, #60. I believe the use of the Opana in this claimant is acceptable, as per ODG Guidelines regarding opioids, noting: *"Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction."* The claimant does not demonstrate addictive behaviors, and did return to work at her regular job.

For review on 6/22/07: Opana ER 40 mg, Opana 10 mg, Lyrica and Lunesta remain not medically appropriate, for the aforementioned reasons cited from ODG Guidelines, listed above. Opana ER 40 mg, BID, is acceptable, for the aforementioned reasons cited from ODG Guidelines above, in the treatment of chronic pain with Opioids. Regarding the additional use of Opana, 10 mg, q8h: This exceeds ODG recommended doses of opiates as per ODG Guidelines: In general, the total daily dose of opioid should not exceed 120 mg oral morphine equivalents. Opioid Dosing Calculator Morphine Equivalent Dose (MED) factor: Oxymorphone – 3 The use of all of the Opana medication (Oxymorphone) clearly exceeds the recommended dose of Morphine equivalent opiate drugs. Data at this juncture does not show any improved outcomes or functioning with this escalation of the medication dosing.

Medications were re-prescribed on 7/23/07. Opana 10 mg tablets: not medically indicated, as per ODG discussion above. Lunesta and Lyrica: not medically indicated, as per ODG discussion above. Opana ER, 40 mg, b.i.d. Acceptable, as per ODG discussion above. There is a note from a Designated Doctor evaluation from 8/8/07. The doctor notes that the claimant is NOT currently working at her job. The claimant was continuing to complain of pain in the low back with some radiation of pain into the legs. The claimant had been referred for a lumbar discogram, which was negative. Dr. suggested epidural steroid injections and continued pain management.

There are additional prescriptions from 8/22/07. Provigil was added to the claimant's medication list as well. From the Cephalon Provigil web site (<http://www.provigil.com/pat/default.aspx>): "Provigil is a prescription medicine used to improve wakefulness in adults who experience excessive sleepiness due to one of the following diagnosed sleep problems: obstructive sleep apnea/hypopnea syndrome, shift work sleep disorder, or narcolepsy." The use of this drug in this claimant is not medically appropriate or indicated.

There is a prescription for Methocarbamol beginning on 9/21/07. This medication is not acceptable. ODG Guidelines note: *Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. Drugs with the most limited published evidence in terms of clinical effectiveness include Chlorzoxazone, Methocarbamol, Dantrolene and Baclofen. (Chou, 2004)*

There is a progress note from Dr. from 10/8/07, at which time the claimant states she has 10/10 pain and is depressed. "She can barely walk for extended distances to walk her dogs." More drugs, as before, were prescribed. More prescriptions stem from 10/15/07. There is no change in the recommendations from before in regard to the use of Opana 10 mg, Lyrica, or Lunesta. The Opana ER use continues, as the claimant is clearly a chronic pain patient. However, we note ODG Guidelines, especially criteria a, b and c, for the future. "*When to Discontinue Opioids: See Opioid hyperalgesia. Also see Weaning of Medications. Prior to discontinuing, it should be determined that the claimant has not had treatment failure due to causes that can be corrected such as under-dosing or inappropriate dosing schedule. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. The claimant should not be abandoned. (a) If there is no overall improvement in function, unless there are extenuating circumstances (b) Continuing pain with the evidence of intolerable adverse effects (c) Decrease in functioning (d) Resolution of pain (e) If serious non-adherence is occurring"*

On 11/07, medications prescribed included Provigil, Opana 10 mg, Lyrica, Lunesta, and Opana ER. Provigil, noted above, is medically indicated for limited medical conditions; data does not support that the claimant is suffering from any of these. Lyrica, Lunesta and Opana 10 mg remains unacceptable. Opana 40 mg ER is acceptable to treat the claimant's chronic pain situation. However, as noted above, given that the claimant's functional performance remains poor, the reviewer would question the utility of continuing with this treatment plan (i.e. pharmacologic). There is an independent medical examination (IME) from Dr. from 11/13/07. The claimant was complaining of low back pain with radiation of

pain into the right buttocks and right leg. He noted “she probably is addicted to pain medication now. I think she should be treated by a pain management doctor and gotten off of narcotic pain relievers...”

The file ends with an evaluation by Dr. from 1/08, at which time he is noted to be changing the claimant’s medications to new opiate analgesics, anti-inflammatories and muscle relaxants.

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

- ACOEM – AMERICAN COLLEGE OF OCCUPATIONAL AND 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.
 - ODG Treatment Index, (web) 6th Edition, 2008, Integrated Treatment/Disability Duration Guidelines – Pain (Chronic).
 - Anti-epilepsy drugs (AEDs) for pain
 - Muscle relaxants (for pain)
 - Opioids
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR.
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE AND 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).

Physicians' Desk Reference, 2008.

Cephalon Provigil web site (<http://www.provigil.com/pat/default.aspx>)