

SENT VIA EMAIL OR FAX ON
Aug/10/2010

True Decisions Inc.

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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Aug/09/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Medication from 11/1/09 thru 7/6/10
Tizanidine 12/4/09, 11/2/09, 11/24/09, 5/5/10, 4/1/10, 3/2/10,
1/31/10, 1/2/10
Phenytoin Sod Ext 7/1/10
Prednisone 2/11/10
Proair HFA 2/11/10
Promethazine VC-Dodeine 11/25/09
Propoxyphen-Apap 2/18/10
Lamotrigine 7/1/10
Lebaquin 2/11/10
Nexium 7/1/10
Ondansetron 7/5/10
Hydrocodne 3/2/10, 1/31/10, 1/2/10, 12/3/09, 6/4/10, 7/5/10, 5/5/10,
4/1/10, 5/26/10, 3/28/10, 11/14/09,
Lebehalol 12/3/09
Clonidine HCL 6/4/10, 5/5/10, 4/1/10, 3/2/10, 2/18/10, 1/15/10, 7/1/10
Clonazepam 3/2/10, 5/5/10, 4/1/10
Ciprofloxacin HCL 12/23/09, 11/14/09,
Alprazolam 11/2/09, 3/28/10, 11/25/09, 1/31/10, 1/2/10, 12/4/09
Azithromycin 11/25/09
Ciprofloxacin HCL 7/5/10, 4/5/10, 3/28/10

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

Board Certified in Physical Medicine and Rehabilitation
Subspecialty Board Certified in Pain Management
Subspecialty Board Certified in Electrodiagnostic Medicine
Residency Training PMR and ORTHOPAEDIC SURGERY

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)

Tizanidine 12/4/09, 11/2/09, 11/24/09, 5/5/10, 4/1/10, 3/2/10,
1/31/10, 1/2/10 Medically necessary
Phenytoin Sod Ext 7/1/10 Medically necessary
Prednisone 2/11/10 Medically necessary

Proair HFA 2/11/10 Medically necessary
Promethazine VC-Dodeine 11/25/09 Medically necessary
Propoxyphen-Apap 2/18/10 Medically necessary
Lamotrigine 7/1/10 Medically necessary
Lebaquin 2/11/10 Medically necessary
Nexium 7/1/10 Medically necessary
Ondansetron 7/5/10 Not medically necessary
Hydrocodne 3/2/10, 1/31/10, 1/2/10, 12/3/09, 6/4/10, 7/5/10, 5/5/10,
4/1/10, 5/26/10, 3/28/10, 11/14/09 Medically necessary
Lebehalol 12/3/09 Not medically necessary
Clonidine HCL 6/4/10, 5/5/10, 4/1/10, 3/2/10, 2/18/10, 1/15/10, 7/1/10 Medically necessary
Clonazepam 3/2/10, 5/5/10, 4/1/10 Medically necessary
Ciprofloxacin HCL 12/23/09, 11/14/09 Medically necessary
Alprazolam 11/2/09, 3/28/10, 11/25/09, 1/31/10, 1/2/10, 12/4/09 Medically necessary
Azithromycin 11/25/09 Medically necessary
Ciprofloxacin HCL 7/5/10, 4/5/10, 3/28/10 Medically necessary

INFORMATION PROVIDED TO THE IRO FOR REVIEW

OD Guidelines
Letter from Dr. No Date
Dr. 9/11/09
Peer Review 5/5/09

PATIENT CLINICAL HISTORY SUMMARY

Apparently this man sustained a head injury in xxxx. He had a T8 compression fracture at the same time with neck and low back pain. Dr. wrote that this man had developed epilepsy after the injury. The remaining records did not provide this. He had degenerative changes in the neck and low back, although there are comments about a cervical fracture. Dr. felt he had a somatiform personality in his assessment. Dr. disagreed.

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

The IRO reviewer finds it easier to discuss the medications in categories.

The ODG requests information that was not provided, especially for the AED and pain medications. Dr. provided his letter, but that did not generate the detailed information requested. The letter implied that this information and procedures are being followed.

The first drugs to be discussed are the antiepilepsy medications. These are phenytoin and lamotrigine. Their justification would be validated by the presence of a seizure disorder. In the absence of the neurologist records, the IRO reviewer must rely on the report from Dr.. Of interest, Clonazepam and other benzodiazepams can be used for seizures. These are medically justified.

Anticonvulsants

Recommended. For adult patients with severe TBI, prophylaxis with phenytoin is effective in decreasing the risk of early post-traumatic seizures and can be administered for 1 or 2 weeks without a significant increase in drug-related side effects. AED prophylaxis is not shown to be effective in decreasing the risk of late post-traumatic seizures, nor is it associated with a reduction in mortality rate or neurological disability. ([Chang, 2003](#)) ([Colorado, 2005](#)) ([Haltiner, 1999](#)) ([Haltiner, 1996](#)) ([Schierhout, 1998](#)) ([Smith, 1996](#)) ([Temkin, 2001](#)) ([Temkin, 1999](#)) ([Young, 1983](#))

Clonidine is for blood pressure issues. Dr. said that was not for the work related injury. It is medically justified for treatment of hypertension.

The IRO reviewer did not see where he had any pulmonary issues from the injury. Proair is used for asthma management. The IRO reviewer presumes prednisone was used for the same purpose. The Nexium would be used for gastric prophylaxis from the prednisone. There is medical justification for its use for pulmonary problems.

The antibiotics, Lebaquin, Azithromycin and Ciprofloxacin would be related to the treatment of infections and medically necessary.

The IRO reviewer could not find Lebehalol. I wonder if this was another drug, such as labetalol, a BP medication. However, without knowing more about the medication and not finding the drug in the ODG, the request is not medically necessary.

Ondansetron is used for nausea. The IRO reviewer could not see its use in this case unless it was related to the pulmonary issue. Its use would not be medically justified for this condition.

Promethazine with codeine is a cough suppressant and would again fall into the pulmonary medications. This would not be related to the injury however, the drug is medically necessary for this treatment.

Alprazolam and Clonazepam are anti-anxiety drugs. The latter was substituted. There may be anxiety issues following the TBI. This would be justified, but not both at the same time, as Dr. noted. The IRO reviewer could not find a discussion in the ODG. They would be justified.

Tizanidine is used for muscle spasm. The ODG frowns on the long-term use of muscle relaxers, but some patients respond well to this. Its use would be medically justified.

Tizanidine (Zanaflex®, generic available) is a centrally acting alpha₂-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. ([Malanga, 2008](#)) Eight studies have demonstrated efficacy for low back pain. ([Chou, 2007](#)) One study (conducted only in females) demonstrated a significant decrease in pain associated with subacute and chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. ([Malanga, 2002](#)) May also provide benefit as an adjunct treatment for fibromyalgia. ([ICSI, 2007](#))

Side effects: somnolence, dizziness, dry mouth, hypotension, weakness, hepatotoxicity (LFTs should be monitored baseline, 1, 3, and 6 months). ([See, 2008](#))

Dosing: 4 mg initial dose; titrate gradually by 2 – 4 mg every 6 – 8 hours until therapeutic effect with tolerable side-effects; maximum 36 mg per day. ([See, 2008](#))

Use with caution in renal impairment; should be avoided in hepatic impairment.

Tizanidine use has been associated with hepatic aminotransaminase elevations that are usually asymptomatic and reversible with discontinuation. This medication is related to clonidine and should not be discontinued abruptly. Weaning should occur gradually, particularly in patients that have had prolonged use. ([Zanaflex-FDA, 2008](#))

Benzodiazepines

The Hydrocodone and propoxyphene are pain medications. The role of controlled substance use in chronic pain has been debated. The ODG has sections for and against its use. The APS has warnings about propoxyphene and cardiac issues. The ODG will accept the use for the pain from the injury.

Opioids for chronic pain

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. Long-term efficacy is unclear (>16 weeks), and there is also limited evidence for the use of opioids for chronic low back pain. ([Martell-Annals, 2007](#)) 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](#)) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. ([Deshpande, 2007](#))

Opioids, criteria for use....

If partial analgesia is not obtained, opioids should be discontinued.

4) On-Going Management. Actions Should Include:

- (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.
- (b) The lowest possible dose should be prescribed to improve pain and function.
- (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of [function](#), or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. *The 4 A's for Ongoing Monitoring:* Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. ([Passik, 2000](#))
- (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.
- (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. ([Webster, 2008](#))
- (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).
- (g) Continuing review of overall situation with regard to nonopioid means of pain control.
- (h) Consideration of a consultation with a [multidisciplinary pain clinic](#) if doses of opioids are required beyond what is usually required for the condition or pain does

not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. ([Sullivan, 2006](#)) ([Sullivan, 2005](#)) ([Wilsey, 2008](#)) ([Savage, 2008](#)) ([Ballyantyne, 2007](#))

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

ACOEM-AMERICA 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)