

True Resolutions Inc.

An Independent Review Organization
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Notice of Independent Review Decision

DATE OF REVIEW: May 13, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

1. Ultracet (dose not given), one tablet BID #60 tablets
2. Zoloft (50mg), one tablet BID, #60 tablets
3. Prevacid (30mg), one tablet QD, #30 tablets
4. Levsin (.125mg), one tablet Q6hours, prn, #60 tablets
5. Ketoprofen (200mg), one tablet QD, #30 tablets
6. Flexeril (10mg), one tablet BID, #60 tablets
7. Tranadol (37.5mg) one tablet BID, #60 tablets
8. N-6 pain cream (40g) apply BID

A 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

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)

Zoloft is the only medication that is medically necessary.

All the other medications are not medically necessary.

PATIENT CLINICAL HISTORY (SUMMARY):

This is a man who reportedly injured his back on xx/xx/xx. He had ongoing neck, right upper extremity/elbow pain, low back pain and reportedly either a lumbar strain or radiculopathy. He had been in a pain program. His current treating physician, Dr., describes disc herniations and bulges. He gained weight. He had several IMEs and designated doctor examinations. His cervical MRI is normal. His lumbar x-ray showed degenerative changes. He reportedly has some foraminal narrowing in the lumbar spine at

L4/5 and L5/S1. He had normal cervical emgs. His pain is more on the right side, but there was a note that one lumbar MRI showed effacement of the right L5 nerve root. Other physicians felt he had a lumbar sprain.

He is depressed. He has symptom magnification reported. Dr. states that the man reportedly improved with DRS treatment (a motorized traction device) and worsened with PT and FCE. ESIs did not help and facet blocks made it worse. He gets relief staying in a recliner. He does not exercise or walk much from the descriptions of inactivity, lack of use of the pedometer, therabands, etc. He is depressed. Dr. evaluated him for a PhD program. He described him as depressed. He also noted that this man had “Persistent psychological problems that have been compromising all aspects of his functioning.” These were pre-existing.

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

Ultracet and tramadol are the same medication, except for acetaminophen. This is a pain medication used for chronic pain. It is not classified as a narcotic in this country, but cases of addiction have occurred. It should be considered under the same considerations of any narcotic for pain management.

The Federal and state regulations, and the guides from the Pain Societies are such that the goal of a pain medication is to improve function in a measurable way. Nothing in the chart would suggest that this is happening. The inactivity described by Dr. and Dr. are of concern.

Chronic pain can be a manifestation of depression. At the same time, chronic pain can cause depression. One goal of pain medications is to reduce the pain and reduce depression. The Reviewer did not see that documented here. Zoloft is an antidepressant. It can be continued for the depression.

Ketoprofen is an NSAID. It can be used for pain. Long term use has multiple medical problems. It can be used for the degenerative changes in his back.

Prevacid is for any ulcers that could develop while taking NSAIDs. Proton pump inhibitors are accepted prophylaxis against COX-1 GI effects. This would be appropriate for use if the Ketoprofen is approved.

Levsin is an antispasmodic. It can be used for hyperactive bladder, spasmodic colon, etc. It is not related to his injury directly or to the effects of any of the medications.

Flexeril is a muscle relaxer for spasms. The Reviewer did not see any description of spasms. Therefore the Reviewer does not see a reason to continue it. Even the manufacturer of the brand name suggests its main use is for an acute and not chronic condition.

N-6 pain cream. The Reviewer could not find this on the internet. The Reviewer saw some reviewer's comments on it. Topical analgesics are used to give relief and improve activity. That does not appear to be happening here.

In summary, the Reviewer does not overrule the decision regarding the Ultram, Ketoprofen or N6 as they are not improving function. In turn, Prevacid would not be needed. Flexeril is not necessary as there are no spasms described. Again, it is not improving function. Levsin has no relationship to his injury or to the effects of any of the medications.

Zoloft is medically necessary to treat.

From the ODG

Medications for subacute & chronic pain

Recommended as indicated below. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to [improvements in function](#) and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. ([Mens, 2005](#)) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. ([Chou, 2006](#)) There are multiple medication choices in the Procedure Summary.

Opioids for chronic pain

Recommendations for general conditions:

... - 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](#)) **There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function.** ([Deshpande, 2007](#)) ...

Outcomes measures: **It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: 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.** ([Nicholas, 2006](#)) ([Ballantyne, 2006](#)) A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. ([Eriksen, 2006](#))...

NSAIDs (non-steroidal anti-inflammatory drugs)

Specific recommendations:...

Back Pain - Chronic low back pain: **Recommended as an option for short-term symptomatic relief.** A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. **The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another.** ([Roelofs-Cochrane, 2008](#)) See also [Anti-inflammatory medications](#)....

Cyclobenzaprine (Flexeril®)

Recommended as an option, using a short course of therapy. See [Medications for subacute & chronic pain](#) for other preferred options. Cyclobenzaprine (Flexeril®) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. **The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better.** ([Browning, 2001](#)) Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. ([Tofferi, 2004](#)) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See [Antidepressants](#). Cyclobenzaprine is associated with a [number needed to treat](#) of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. ([Kinkade, 2007](#)) Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by Ortho McNeil Pharmaceutical.

SRIs (selective serotonin reuptake inhibitors)

Not recommended as a primary treatment for chronic pain. Selective serotonin reuptake inhibitors (SSRIs), a class of antidepressants that inhibit serotonin reuptake without action on noradrenaline, are controversial based on controlled trials. It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain. More information is needed regarding the role of SSRIs and pain. SSRIs have not been shown to be effective for low back pain. See [Antidepressants for chronic pain](#) for general guidelines, as well as specific [SSRI](#) listing for more information and references.

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)**