True Decisions Inc.

An Independent Review Organization
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Notice of Independent Review Decision

DATE OF REVIEW: October 13, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Prescriptions for Tizanidine HCL and Indomethacin on 5/13/08

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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW
OD Guidelines
Peer Review 11/18/08
Records from 1/24/08 thru 8/25/08
Record from 6/2/08

PATIENT CLINICAL HISTORY [SUMMARY]:
This is a xx year old woman who reportedly developed neck pain and bilateral wrist pain 10 years ago. She failed to improve with CTS surgery. She has a history of disc bulges at C5-7. There is no emg provided. There is a note of normal emgs, but lists her as having a cervical radiculopathy. A reviewer advised an evaluation for the cause of her wrist pain. She also has a diagnosis of fibromyalgia. She is on several medications including different opioids, plus

indocmethacin and tinazadine. The latter two medications are what are being considered in the review. She had been in a chronic pain program without any improvement. She had a stomach bypass procedure. The drug screen is inconsistently positive for a benzodizepine, but she is not on one.

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

She complains of pain, but no spasticity was described. She is on tinazadine, a cetral muscle relaxer. The ODG notes its indication for spasticity. It has not been approved, but has been used, in myofascial pain and fibromyalgia. The Reviewer did not see any report from the treating doctor that it was helping. .

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.

The second issue is the use of Indocmethacin, an older NSAID. Some NSAIDs such as ibuprofen and naproxen are available over the counter. They are used for the treatment of arthritic pain. They are given to minimize the use of opiates. This lady is on multiple opioids. Indomethacin is associated with some more risks than ibuprofen. Why the latter would be preferable, some individuals respond better to indomethacin than other medications. This is an idiosyncrasy. All NSAIDs have similar risks. Her use for this medication would be justified if there was documentation in the material provided that it was helping her.

NSAIDs (non-steroidal anti-inflammatory drugs)
Specific recommendations:
Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008)
Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more

effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007)
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.
Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006)

Indomethacin (Indocin®, Indocin SR®, generic available): This medication is generally not recommended in the elderly due to increased risk of adverse effects. Dosing: Osteoarthritis, or ankylosing spondylitis: NOTE: If minor adverse effects develop as the dosage is increased, rapidly reduce the dose to a tolerated dose and closely observe the patient. If severe adverse reactions occur, discontinue. *Regular-release capsules, suspension (25 mg and 50 mg):* 25 mg PO 2—3 times a day with food or antacids; may increase dose by 25 mg/day PO every 7 days up to 150—200 mg/day. In patients who have persistent night pain and/or morning stiffness, administer a large portion of the total daily dose, up to 100 mg/dose, at bedtime. *Sustained-release capsules (75 mg):* Initially, 75 mg PO daily. Use the regular-release capsules to provide a higher dose, if needed. If 150 mg daily is tolerated and is needed, a 75 mg sustained-release capsule PO bid may be used. After the acute phase is under control, attempt to decrease the dosage to the lowest effective dosage or discontinue the drug. Moderate pain to severe pain including painful shoulder (bursitis and tendinitis) as well as off-label for bone pain: R*egular-release capsules, suspension (25 mg and 50 mg):* 75-150 mg/day PO in 3-4 divided doses. Discontinue the drug once the signs and symptoms of the inflammation have been controlled for several days. The usual length of therapy is 7-14 days. *Sustained-release capsules (75 mg):* 75 mg PO 1—2 times per day.

In essence, these medications may be appropriate, but no information was provided showing that these were helping her. They would be justified if Dr. wrote that she received some benefit from them. However, without the documentation from her treating doctor, the request is upheld and the medication is not medically necessary.

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)**