



Medical Review Institute of America, Inc.  
America's External Review Network

DATE OF REVIEW: September 11, 2008

IRO Case #:

**Description of the services in dispute:**

Preauthorization – Zanaflex: 40 mg 1 tab po tis qhs #120 x 1 refill– lumbar and Naprelan: 375 mg 1 tab po qd #60 x 1 refill– lumbar.

**A description of the qualifications for each physician or other health care provider who reviewed the decision**

The physician providing this review is board certified in Anesthesiology and is a doctor of Osteopathy. The reviewer is currently an attending physician at a major medical center providing anesthesia and pain management services. The reviewer has participated in undergraduate and graduate research. The reviewer has been in active practice since 1988.

**Review Outcome**

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

Upheld

**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.**

Medical necessity does not exist for the requested Zanaflex: 40 mg 1 tab po tis qhs #120 x 1 refill– lumbar and Naprelan: 375 mg 1 tab po qd #60 x 1 refill– lumbar.

**Information provided to the IRO for review**

**Records Received From The State:**

Confirmation of receipt of a request for a review by an independent review organization, 8/22/08, 4 pages

Request for a review by an independent review organization, 8/22/08, 2 pages

Letter from , DO, 8/13/08, 3 pages

Notification of determination, 8/4/08, 3 pages

Precert form, 7/29/08, 1 pae

Prescription, 7/28/08, 1 page

Patient note, 7/30/08, 2 pages

Records Received From The Provider:

Carrier submission, 8/19/08, 6 pages  
Patient information, 4/7/08, 1 page  
Patient note, 4/14/08, 2 pages  
Procedure note, 4/9/08, 1 page  
Consent for minor surgery, 4/9/08, 1 page  
Receipt of notice of privacy practices written acknowledgement form, 4/7/08, 1 page  
Employee's request to change treating doctor - non network, 4/3/08, 1 page  
Patient signature form, 11/1/01, 1 page  
Patient note, 7/28/08, 1 page  
Patient note, 3/20/08, 1 page  
Patient note, 3/19/08, 1 page  
Employee's request to change treating doctor - non network, 4/2/08, 1 page  
Employee's request to change treating doctor - non network, 3/13/08, 1 page  
Letter from , 7/27/07, 2 pages  
Letter from , MD MPH, 7/12/07, 7 pages  
Patient note, 7/12/07, 1 page  
Operative report, 3/19/07, 1 page  
Radiology report, 3/19/07, 3 pages  
Patient note, 2/9/07, 1 page  
Letter from Dr. , DC, undated, 1 page  
MRI report, 2/6/06, 2 pages  
Patient note, 5/16/06, 2 pages  
Letter from , 1/18/06, 1 page  
Request for preauthorization, 1/9/06, 2 pages  
MRI report, 10/7/03, 1 page  
Imaging report, 8/24/04, 1 page  
Home medication list, 3/19/07, 1 page  
Discharge instructions, 3/19/07, 1 page  
Return visit patient questionnaire, 8/6/08, 2 page  
Patient note, undated, 1 page  
Return visit patient questionnaire, 8/5/08, 2 pages  
Return visit patient questionnaire, 7/30/08, 2 pages  
Return visit patient questionnaire, 7/28/08, 2 pages  
Return visit patient questionnaire, 7/6/08, 2 pages  
Prescription, 8/13/08, 1 page  
Return visit patient questionnaire, 5/12/08, 2 pages  
Return visit patient questionnaire, 4/17/08, 2 pages  
Return visit patient questionnaire, 4/16/08, 2 pages

Return visit patient questionnaire, 4/15/08, 2 pages  
Return visit patient questionnaire, 4/9/08, 2 pages  
Return visit patient questionnaire, 4/7/08, 2 pages  
Informed consent, 4/7/08, 2 pages  
Patient notes, 5/12/08, 3 pages  
Patient notes, 8/12/08, 1 page  
Letter from , DO, 8/6/08, 1 page  
Certificate to return to work, 8/6/08, 1 page  
Notification of determination, 8/1/08, 3 pages  
Patient notes, 8/6/08, 2 pages  
Patient note, 8/5/08, 2 pages  
Patient note, 8/28/08, 2 pages  
Prescription, 7/28/08, 1 page  
Patient note, 7/10/08, 1 page  
Patient note, 7/10/08, 2 pages  
Procedure note, 7/10/08, 1 page  
Consent for minor surgery, 7/10/08, 1 page  
Patient note, 7/7/08, 2 pages  
Procedure note, 7/7/08, 1 page  
Consent for minor surgery, 7/7/08, 1 page  
Patient note, 5/12/08, 2 pages  
Patient note, 4/17/08, 2 pages  
Patient note, 4/16/08, 2 pages  
Patient note, 4/15/08, 2 pages  
Prescription, 4/15/08, 1 page  
Patient note, 4/9/08, 2 pages  
Patient note, 4/7/08, 2 pages  
Prescriptions, 4/7/08, 1 page  
work status report, 10/24/07, 3 pages  
work status report, 1/8/08, 3 pages  
Patient note, 10/24/07, 2 pages  
work status report, 7/19/07, 3 pages  
Employee's request to change treating doctors - non network, 7/6/07, 1 pages  
work status report, 6/30/07, 3 pages  
Patient note, 5/5/07, 2 pages  
Patient note, 4/20/07, 2 pages  
work status report, 4/20/07, 1 page  
work status report, 5/31/07, 3 pages  
Patient note, 3/21/07, 1 page  
work status report, 3/1/07, 3 pages

work status report, 1/27/07, 3 pages  
Patient note, illegible date, 2 pages  
work status report, 10/4/06, 1 page  
Invoice, 12/5/06, 1 page  
Patient note, 10/9/06, 2 pages  
work status report, 9/14/06, 3 pages  
Patient note, undated, 1 page  
Report of medical evaluation, 10/20/06, 2 pages  
Patient note, 5/16/06, 2 pages  
work status report, 8/15/06, 3 pages  
work status report, 12/22/05, 1 page  
work status report, 5/20/06, 3 pages  
work status report, 4/3/06, 3 pages  
work status report, 3/3/06, 3 pages  
work status report, 2/6/06, 3 pages  
work status report, 1/12/06, 3 pages  
work status report, 12/30/05, 3 pages  
Patient notes, 12/22/08, 2 pages  
Progress notes, 12/20/05, 1 page  
work status report, 12/12/05, 1 page  
work status report, 12/5/05, 3 pages  
Patient note, 12/5/05, 2 pages  
work status report, 12/2/05, 1 page  
Consent for Botulinum Toxin neurolysis, 4/17/08, 1 page  
Required medical examination request, undated, 1 page  
Fax from , RN, to Dr. , MD, 6/5/06, 1 page  
Patient notes, undated, 2 pages  
Patient note, 12/2/05, 1 page  
Patient note, 4/7/05, 2 pages  
Institute information, 2007, 5 pages  
Job function evaluation, 1/18/06, 1 page  
Precert form, 8/8/08, 1 page  
Procedure notes, 4/14/08–5/16/08, 2 pages  
5 panel urine drug screen, 4/2/08, 5 pages

Records Received From The Insurance Company:

Carrier submission, 8/27/08, 7 pages  
Notification of determination, 18/4/08, 3 pages  
Review summary, 8/13/08, 3 pages  
Notice of disputed issue and refusal to pay benefits, 4/5/07, 1 page

Notice of disputed issue and refusal to pay benefits, 2/20/08, 1 page  
Peer review, 8/6/08, 3 pages  
Patient activity, 12/3/05–4/8/08, 1 page  
work status report, 12/2/05 1 page  
Exam note, 12/14/05, 2 pages  
work status report, 12/30/05, 2 pages  
Report of medical evaluation, 5/31/06 1 page  
Designated doctor examination, 5/24/06, 2 pages  
Patient note, 8/15/06, 1 page  
Designated doctor examination, 10/10/06, 3 pages  
Report of medical evaluation, 10/10/06, 1 page  
work status report, 2/9/07, 1 page  
Progress notes, 3/19/07, 1 page  
Treatment plan of care, 5/11/07, 1 page  
Discharge instructions, myelogram, 3/19/07, 1 page  
Home medication list, 3/19/07, 1 page  
Procedure order and precert form, 2/12/07, 1 page  
Physician orders, 3/19/07, 1 page  
Surgical procedure and site verification checklist, 3/29/07, 2 pages  
Patient note, 4/20/07, 2 pages  
Patient note, 5/3/07, 2 pages  
Patient note, 5/31/07, 2 pages  
work status report, 5/31/07, 1 page  
Patient note, 7/3/07, 3 pages  
Patient note, 7/6/07, 1 page  
Nursing admission assessment, 7/23/07, 1 page  
Patient note, 8/30/07, 3 pages  
5 panel urine drug screen, 4/7/08, 1 page  
Procedure note, 4/8/08, 1 page  
Consent for minor surgery. 4/8/08, 1 page  
Consent for Botulinum Toxin neurolysis, 4/17/08, 1 page  
Patient note, 5/19/08, 1 page  
Return visit patient questionnaire, 7/25/08, 2 pages  
Procedure note, 7/25/08, 1 page  
Consent for minor surgery, 7/10/08, 1 page  
Patient note, 7/10/08, 2 pages  
Patient note, 7/30/08, 1 page  
Medication record, 8/5/08, 1 page  
Letter from , DO, 8/14/08, 1 page  
Certificate to return to work, 8/14/08, 1 page

Visit notes, 12/20/05–4/12/06, 34 pages  
MRI report, 2/6/06, 1 page  
Letter from , 9/26/06, 2 pages  
Notice of disputed issue and refusal to pay benefits, 2/20/07, 1 page  
Notice of disputed issue and refusal to pay benefits, 4/5/07, 2 pages  
Notice of assignment of independent review organization, 8/25/08, 1 page  
Notice of assignment of independent review organization, 8/15/08, 1 page  
Fax from to , 8/15/08, 1 page  
Fax to , 8/19/08, 1 page  
Envelope copy, 8/27/08, 1 page  
CD, 9/2/08, 1 envelope

### **Patient clinical history [summary]**

The patient is a xx-year-old male with a date of injury in xx/xx. The patient had a L2 compression fracture and low back pain. He was initially on Tramadol, Flexeril, and Ambien. The Flexeril was changed to Zanaflex recently. In 2007 the Tramadol was changed to Hydrocodone, but this was discontinued due to marijuana in his urine. His current meds are Naprelan, Zanaflex, Lidoderm, and Nexium. Lumbar surgery was recommended, but was not done. He has had Botox with reportedly good relief and SI injections.

### **Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.**

Neither of these medications are recommended for long term usage by the ODG; Zanaflex is recommended for spasticity per the FDA, but is off label for treatment of low back pain. It can also increase liver enzymes. There are other muscle relaxants that are more appropriate. The use of NSAIDs like Naprelan chronically is also not recommended due to GI side effects. In this case the patient is already on Nexium (a PPI), which would indicate the presence of GI distress already whether inherent to him or due to the NSAID.

### **A description and the source of the screening criteria or other clinical basis used to make the decision:**

PDR 2008. Drug Compendia 2008.

ODG for Zanaflex: ANTISPASTICITY/ANTISPASMODIC DRUGS:

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.

ODG for Naprelan: 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)

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