

# The DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205

Phone: 888-950-4333 Fax: 888-9504-4443

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## Notice of Independent Review Decision

**January 31, 2013**

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Appeal for Rx: Celebrex 200mg 1 tablet Daily with Food, count # 30 with 3 refills

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. The physician is certified in pain management. The physician is a member of the Texas Medical Board. The physician has a private practice of Physical Medicine & Rehabilitation, Electro Diagnostic Medicine & Pain Management in Texas. The physician has published in medical journals. The physician is a member of his state and national medical societies.

**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 medical necessity exists for each of the health care services in dispute.

*Upon Independent Review, the reviewer finds that the previous adverse determinations should be Overturned*

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

Records Received: 1 document received totaling 16 pages via fax 1/17/13 Texas Department of Insurance IRO request and Letter of authorization, 1 documents totaling 16 pages received via fax 1/17/13 URA response to disputed services including administrative and medical records. Dates of documents range from xx/xx/xx (DOI) to 01/17/13.

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## PATIENT CLINICAL HISTORY [SUMMARY]:

man with reported lumbar injury xx/xx/xx. Patient referred who recommended CT/myelogram which was not preauthorized. Patient reportedly paid for the testing himself and ESIs were recommended but not preauthorized. Celebrex and nordo have been used to modify the patient's pain symptoms. After having problems with other NSAIDs the change to Celebrex has not produced problems. Denial of the Celebrex is due in part to the length of time patient has been on NSAIDs and that other NSAID choices are better.

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

Celebrex is a "YES" drug in the ODG Formulary. There is indication the provider has attempted use of other NSAID medication, but Celebrex has been tolerated and effective. The ODG formulary does indicate that these medications are accepted but to be used under close monitoring by the prescribing physician.

As the treating doctor has the responsibility for choice of medication within the ODG formulary and if there is evidence of supervision and change if complications arise, it appears medically reasonable per ODG Formulary to authorize the Celebrex at this time.

## DESCRIPTION AND SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE YOUR DECISION: ODG Formulary

Celebrex® (celecoxib) ODG Formulary "YES" drug	Celebrex® is the brandname for celecoxib, and it is produced by Pfizer. Celecoxib is a non-steroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. See <a href="#">Anti-inflammatory medications</a> . See <a href="#">NSAIDs</a> (non-steroidal anti-inflammatory drugs) for specific patient decision-making criteria. Unlike other NSAIDs, celecoxib does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures.
Celecoxib (Celebrex®) ODG Formulary "YES" drug	See <a href="#">Celebrex®</a> above. See also <a href="#">NSAIDs</a> (non-steroidal anti-inflammatory drugs); <a href="#">NSAIDs, GI symptoms &amp; cardiovascular risk</a> ; <a href="#">NSAIDs, hypertension and renal function</a> ; & <a href="#">NSAIDs, specific drug list &amp; adverse effects</a> for general guidelines, as well as specific <a href="#">Celecoxib</a> (Celebrex®) listing for more information and references. A large systematic review of available evidence on NSAIDs confirms that naproxen and low-dose ibuprofen are least likely to increase cardiovascular risk. Celecoxib (Celebrex), on the whole, had a slightly increased risk of cardiovascular events at low and high doses, although there were few studies testing doses >200 mg/day. Celecoxib, especially at doses >400 mg/day, should be avoided in patients at high risk of cardiovascular disease. ( <a href="#">McGettigan, 2011</a> ) [Celebrex ranked #6 in amount billed for WC in 2011. ( <a href="#">Coventry, 2012</a> )]
NSAIDs, specific drug list & adverse	Recommended with cautions below. Disease-State Warnings for all NSAIDs: All NSAIDs have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs should never be used right before or

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effects	<p>after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). <a href="#">See NSAIDs, GI Symptoms and Cardiovascular Risks</a>. Other disease-related concerns (non-boxed warnings): Hepatic: Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDs. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended. Overall Dosing Recommendation: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. Specific NSAID Classes are outlined below:</p> <p>Selective COX-2 NSAIDs: Celecoxib (Celebrex®) is the only available COX-2 in the United States. No generic is available. Mechanism of Action: Inhibits prostaglandin synthesis by decreasing cyclooxygenase-2 (COX-2). At therapeutic concentrations, cyclooxygenase-1 (COX-1) is not inhibited. In animal models it works as an anti-inflammatory, analgesic, and antipyretic. It does not have an anti-platelet effect and is not a substitute for aspirin for cardiac prophylaxis. Use: Relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and treatment of acute moderate pain. Side Effects: See <a href="#">NSAIDs, hypertension and renal function</a>; &amp; <a href="#">NSAIDs, GI Symptoms and Cardiovascular Risks</a>. Cardiovascular: Hypertension (≤13%) CNS: headache (15.8%), dizziness (1% - 2%), insomnia (2.3%); GI: diarrhea (4% to 11%), dyspepsia (8.8% vs. 12.8% for ibuprofen and 6.2% for placebo), diarrhea (5.6%), abdominal pain (4.1% vs. 9% for ibuprofen and 2.8% for placebo), N/V (3.5%), gastroesophageal reflux (≤ 5%), flatulence (2.2%); Neuromuscular/ skeletal: arthralgia (7%), back pain (3%); Respiratory: upper respiratory tract infection (8%), cough (7%), sinusitis (5%), rhinitis (2%), pharyngitis (2%); Skin Rash (2%) – discontinue if rash develops; Peripheral Edema (2.1%). Recommended Dose: 200 mg a day (single dose or 100 mg twice a day). (Celebrex® package insert)</p> <p>Combination (NSAID/GI protectant): Arthrotec® (diclofenac/ misoprostol) 50mg/200mcg, 75mg/20mcg. [Black Box Warning]: Do not administer Arthrotec®/misoprostol to pregnant women because it can cause abortion. Mechanism of action: Combines a diclofenac (an NSAID) with misoprostol, an agent that inhibits basal and nocturnal gastric acid secretion and has some mucosal protective properties. Misoprostol is available as Cytotec®. Uses: Indicated for the treatment of the signs and symptoms of osteoarthritis in patients at high risk for developing NSAID-induced gastric or duodenal ulcers and their complications. These two products are available as separate medications if you need to individualize therapy. Side Effects: See diclofenac. Misoprostol side effects: (vs. diclofenac alone). The following symptoms were increased over and above that found for diclofenac alone with the addition of misoprostol: Abdominal pain (21% with Arthrotec and 15% with diclofenac); Diarrhea (19% with Arthrotec vs. 11% with diclofenac); Dyspepsia (14% for Arthrotec vs. 11% for diclofenac); Nausea/vomiting (11% for Arthrotec vs. 6% for diclofenac); Flatulence (9% for Arthrotec vs. 4% for diclofenac). Diarrhea and abdominal pain usually resolve in 2 to 7</p>
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days. Dosing: The recommended dose for OA is diclofenac 50mg/misoprostol 200mcg t.i.d. In patients that may not tolerate this dose, 50mg/200mcg b.i.d and 75mg/200mcg b.i.d. may be prescribed, but are somewhat less effective in ulcer prevention. (Arthrotec® Package Insert) ([Bocanegra, 1998](#))

**NONSELECTIVE NSAIDS:** (Inhibits COX-1 and COX-2) Mechanism of action: Inhibits prostaglandin synthesis by decreasing the activity of the enzymes COX-1 and COX-2, which results in decreased formation of prostaglandins involved in the physiologic response of pain and inflammation. Side Effects: See Disease-state warnings above. Other common side effects include the following. CNS: headache, dizziness, insomnia; Skin: rash including life-threatening skin reactions (Stevens-Johnson syndrome) **\*\*Discontinue if rash develops\*\***; GI: abdominal cramps, nausea/vomiting, diarrhea, constipation, flatulence; Otic: Tinnitus; Hematologic: Anemia. Specific NSAIDS are listed below:

Diclofenac Sodium (Voltaren®, Voltaren-XR®) generic available: (Voltaren®, diclofenac sodium enteric-coated tablet Package Insert), (Voltaren®-XR, diclofenac sodium extended-release tablets Package Insert)

Diclofenac Potassium (Cataflam®, generic available): (Cataflam®, diclofenac potassium immediate-release tablets Package Insert) Different formulations of diclofenac are not necessarily bioequivalent. Dosing:

Cataflam®: Osteoarthritis: Adults: 50 mg PO 2—3 times daily. Dosages > 150 mg/day PO are not recommended. Pain: 50mg PO 3 times per day (max dose is 150mg/day). An initial dose of 100 mg PO followed by 50-mg doses may provide better relief. Voltaren®: Osteoarthritis: 50 mg PO 2—3 times daily or 75 mg PO twice daily. Dosages > 150 mg/day PO are not recommended. Ankylosing spondylitis: 25 mg PO 4 times a day with an extra 25-mg dose at bedtime if necessary. Voltaren®-XR: 100 mg PO once daily for chronic therapy. Voltaren®-XR is not indicated for the management of acute pain and should only be used as chronic maintenance therapy.

Diflunisal (Dolobid®, generic available): Dosing: Mild to moderate pain (arthralgia, bone pain, myalgia); 1 gm initially, followed by 500mg every 12 hours; some patients may require 500mg PO every 8 hours (Max 1500mg/day). Osteoarthritis: 250-500mg PO twice daily (Max 1500mg/day). (Dolubid® Package Insert)

Etodolac (Lodine®, Lodine XL®, generic available): Dosing: Lodine®: Mild to moderate pain (acute); 200-400mg PO every 6 to 8 hours (max 1000mg daily). Osteoarthritis: 300mg PO 2-3 times daily or 400 – 500mg twice daily (doses > 1000mg/day have not been evaluated). Lodine®-XL: Osteoarthritis: 400 to 1000 mg once daily. A therapeutic response may not be seen for 1-2 weeks.

Fenoprofen (Nalfon®, generic available): 200, 600 mg. Dosing: osteoarthritis; (off-label use for ankylosing spondylitis); 300 – 600mg PO 3 to 4 times per day (Max daily dose is 3200mg). Improvement may take as long as 2 to 3 weeks. Mild to moderate pain (off-label use for bone pain): 200mg PO every 4 to 6 hours as needed.

Flurbiprofen (Ansaid®, generic available): 50, 100 mg. Dosing: Osteoarthritis and mild to moderate pain: 200-300mg per day at intervals of 2 to 4 divided doses. The maximum daily dose is 300 mg/day and the maximum divided dose is 100 mg (for instance, 100 mg twice a day).

Ibuprofen (Motrin®, Advil® [otc], generic available): 300, 400, 600, 800 mg. Dosing: Osteoarthritis and off-label for ankylosing spondylitis: 1200 mg to 3200 mg daily. Individual patients may show no better response to 3200 mg as 2400 mg, and sufficient clinical improvement should be observed to offset potential risk of treatment with the increased dose. Higher doses are

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generally recommended for rheumatoid arthritis: 400-800 mg PO 3-4 times a day, use the lowest effective dose. Higher doses are usually necessary for osteoarthritis. Doses should not exceed 3200 mg/day. Mild pain to moderate pain: 400 mg PO every 4-6 hours as needed. Doses greater than 400 mg have not provided greater relief of pain.

Indomethacin (Indocin®, Indocin SR®, generic available): This medication is generally not recommended in the elderly due to increased risk of adverse effects. Indocin is not commonly used any more, now that its risks are known, so it is not recommended as a first-line NSAID. 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: Regular-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.

Ketoprofen 50, 75 mg, Ketoprofen ER 200 mg: Dosing: Osteoarthritis: Regular release capsule 50mg four times per day or 75mg three times per day (max 300mg/day). XR capsule 200mg once daily. Mild to moderate pain: Regular release capsule 50mg every 6 to 8 hours (Max 300mg/day); Extended-release capsules are not recommended for acute pain.

Ketorolac (Toradol®, generic available): 10 mg. [Boxed Warning]: The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not be given as an initial dose. (Toradol® Package Insert) The FDA has approved a nasal formulation of ketorolac (Sprix) for short-term pain management. ([FDA, 2010](#))

Mefenamic Acid (Ponstel®, generic available): 250 mg. Mild and moderate pain: Initially, 500 mg PO followed by 250 mg every 6 hours as needed for no longer than 7 days. (Ponstel® Package Insert)

Meloxicam (Mobic®, generic available): 7.5, 15 mg. Dosing: Osteoarthritis: The usual initial dose is 7.5 mg/day, although some patients may receive additional benefit with an increase to 15 mg a day. The maximum dose is 15 mg/day. Use for mild to moderate pain is off-label. (Mobic® Package Insert)

Nabumetone (Relafen®, generic available): 500, 750 mg. Dosing: Osteoarthritis: The recommended starting dose is 1000 mg PO. The dose

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can be divided into 500 mg PO twice a day. Additional relief may be obtained with a dose of 1500 mg to 2000 mg per day. The maximum dose is 2000 mg/day. Patients weighing less than 50 kg may be less likely to require doses greater than 1000 mg/day. The lowest effective dose of nabumetone should be sought for each patient. Use for moderate pain is off-label.

(Relafen® Package Insert)

Naproxen (Naprosyn®): delayed release (EC-Naprosyn®), as Sodium salt (Anaprox®, Anaprox DS®, Aleve® [otc]) Generic available; extended-release (Naprelan®): 375 mg. Different dose strengths and formulations of the drug are not necessarily bioequivalent. Dosing Information:

Osteoarthritis or ankylosing spondylitis: Dividing the daily dose into 3 doses versus 2 doses for immediate-release and delayed-release formulations generally does not affect response. Morning and evening doses do not have to be equal in size. The dose may be increased to 1500 mg/day of naproxyn for limited periods when a higher level of analgesic/anti-inflammatory activity is required (for up to 6 months). Naprosyn® or naproxyn: 250-500 mg PO twice daily. Anaprox: 275-550 mg PO twice daily. (total dose may be increased to 1650 mg a day for limited periods). EC-Naprosyn: 375 mg or 500 mg twice daily. The tablet should not be broken, crushed or chewed to maintain integrity of the enteric coating. Naprelan®: Two 375 mg tablets (750 mg) PO once daily or two 500 mg tablets (1000 mg) once daily. If required (and a lower dose was tolerated) Naprelan® can be increased to 1500 mg once daily for limited periods (when higher analgesia is required). Pain: Naprosyn® or naproxyn: 250-500 mg PO twice daily. The maximum dose on day one should not exceed 1250 mg and 1000 mg on subsequent days. Anaprox: 275-550 mg PO twice daily. The maximum dose on day one should not exceed 1375 mg and 1100 mg on subsequent days. Anaprox is recommended for the management of acute painful conditions because the sodium salt is more rapidly absorbed. EC-Naprosyn: 375 mg or 500 mg twice daily. Extended-release Naprelan®: Not recommended due to delay in absorption (Naprelan® Package Insert) and risk of upper GI bleeding/perforation. ([Massó, 2010](#))

Oxaprozin (Daypro®, generic available): 600 mg. Dosing: Osteoarthritis: Two 600 mg caplets (1200 mg total) given PO once daily. The maximum dose is 1800 mg/day (26 mg/kg, whichever is lower). For patients with low body weight (i.e., < 50 kg or 110 pounds), an initial dosage of 600 mg PO once daily is recommended. Patients with severe renal impairment should initiate therapy at 600 mg/day. An increase to 1200 mg can be cautiously increased, but only with close monitoring. For quick onset of action, a one-time loading dose of 1200 to 1800 mg can be given (do not exceed 26 mg/kg). Mild to moderate pain: Used off-label. (Daypro® Package Insert)

Piroxicam (Feldene®, generic available): 10, 20 mg. Dosing: Osteoarthritis: 20 mg PO once daily. Adjust dose, as needed. The daily dose may be divided in two doses, if desired. This drug has a long half-life and steady state is not reached for 7-12 days. There is a progressive response over several weeks and therapy effect should not be assessed for two weeks after initiating therapy. Elderly: Initially, 10 mg PO once daily. Adjust dose, as needed, up to 20 mg/day. Pain: Not recommended. (Feldene Package Insert)

Sulindac (Clinoril®, generic available): 150, 200 mg. Dosing Information: Osteoarthritis, ankylosing spondylitis: Initially, 150 mg PO twice daily. Adjust dosage as needed. May increase up to 200 mg PO twice daily depending on patient response. The maximum dose is 400 mg a day. Acute Painful Shoulder (bursitis/tendinitis): 200 mg PO twice a day. Therapy for 7-14 days is usually adequate. Mild to moderate pain: Off label. (Clinoril® Package

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	<p>Insert)</p> <p>Tolmetin (Tolectin®, Tolectin DS, Tolectin 600mg, generic available): Dosing Information: Osteoarthritis (acute and chronic): Initially, 400 mg PO three times a day. If needed, adjust dose upward or downward after 1-2 weeks. Maintenance dosage is usually 600-1800 mg/day PO in 3-4 divided doses. (Max dose is 1800mg/day). Symptomatic improvement may occur within 7 days, with progressive improvement during successive weeks of therapy. (<a href="#">Clinical Pharmacology, 2008</a>) (<a href="#">Lexi-Comp, 2008</a>)</p>
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**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)**