

INDEPENDENT REVIEWERS OF TEXAS, INC.

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Notice of Independent Review Decision

DATE OF REVIEW: 11/02/11

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Item in dispute: Celebrex

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

Texas Board Certified Orthopedic Surgeon

REVIEW OUTCOME

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

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. 03/30/05 – MRI Left Knee
2. 05/13/05-09/24/10 – Clinical Note –MD
3. 06/02/05 – Operative Report
4. 06/29/05 – Physical Therapy Note
5. 12/08/07 – Pathology Results
6. 07/07/10 – Clinical Note –MD
7. 08/27/10 – Letter of Intent to Endorse RME Report Recommendations
8. 11/04/10 – Correspondence –MD
9. 11/19/10 – Letter of Clarification –MD
10. **Official Disability Guidelines**

PATIENT CLINICAL HISTORY (SUMMARY):

The employee is a female who sustained an injury on xx/xx/xx when she was hijacked and “worked over”.

An MRI of the left knee performed 03/30/05 revealed osteoarthritis. There were subcortical osteoarthritic changes at the lateral tibiofemoral joint. There was extensive fraying of the free edges of the menisci bilaterally and oblique horizontal tear of the

posterior horn of the medial meniscus and radial tear of the body of the lateral meniscus. There was a chronic tear of the anterior cruciate ligament. There was knee joint effusion and a small popliteal cyst.

The employee underwent arthroscopy with chondroplasty, patellofemoral medial, and lateral compartments with partial medial and lateral meniscectomies on 06/02/05.

The employee saw Dr. on 07/08/05. The employee reported 90% improvement following surgery. Physical examination revealed good range of motion of the left knee. There was no tenderness to palpation. The employee was advised to follow up in six weeks.

The employee received Hyalgan injections to the left knee on 08/30/05, 09/02/05, 09/13/05, and 09/20/05.

The employee saw Dr. on 11/15/05 with complaints of left knee pain with associated achiness and stiffness. The employee reported reduced pain with Celebrex. Physical examination revealed range of motion from 0 to 130 degrees with crepitus. There was minimal tenderness to palpation of the medial joint line. There was no effusion noted. The employee was continued on Celebrex.

The employee saw Dr. on 11/10/06 with complaints of left knee pain. Physical examination revealed mild tenderness to palpation of the medial joint line. There was patellofemoral crepitus noted. There was no evidence of effusion. The employee was prescribed Celebrex. The employee was recommended for Hyalgan injections.

The employee received Hyalgan injections to the left knee on 12/07/06, 12/12/06, 12/21/06, 12/28/06, and 01/04/07.

The employee saw Dr. on 02/01/07 with complaints of left knee pain. Physical examination revealed mild crepitus. There was no tenderness to palpation. The employee was prescribed Celebrex. The employee was recommended for repeat Hyalgan injections.

The employee received Hyalgan injections to the left knee on 12/18/07, 12/26/07, 01/03/08, 01/10/08, and 01/17/08.

The employee saw Dr. on 08/05/08 with complaints of left knee pain. Physical examination revealed full range of motion. There was no effusion noted. The employee was noted to be neurovascularly intact. The employee was assessed with left knee pain. The employee was prescribed Celebrex.

The employee saw Dr. on 04/28/09 with complaints of left knee pain. Physical examination revealed increased crepitus. There was mild tenderness to palpation. The employee was prescribed Celebrex.

The employee saw Dr. on 06/30/09 with complaints of increased left knee pain. Physical examination revealed tenderness to palpation of the left knee. The employee

was prescribed Celebrex. The employee was recommended for repeat Hyalgan injections.

The employee received Hyalgan injections to the left knee on 07/16/09, 07/23/09, 07/30/09, 08/06/09, and 08/13/09.

The employee saw Dr. on 09/10/09 with complaints of left knee pain. Physical examination revealed good range of motion of the left knee. The employee was noted to be neurovascularly intact. The employee was prescribed Celebrex.

The employee saw Dr. on 12/08/09 with complaints of left knee pain. Physical examination was not performed. The employee was prescribed Celebrex.

The employee was seen for a Required Medical Evaluation (RME) on 07/07/10. The employee's medications include Celebrex 200mg. Physical examination revealed full range of motion of the left knee. There was no evidence of effusion. There was slight laxity with Lachman's testing. The employee was noted to be neurovascularly intact. There was no tenderness to palpation of the joint lines. There were no masses to the back of the knee. Radiographs of the left knee revealed lateral spurring of the joint space. Alignment was in the 8-10 degrees of valgus bilaterally. The employee was assessed with fracture tibia and degenerative arthrosis status post arthroscopic surgery. The provider opines that the chronic use of Celebrex was not supported by **Official Disability Guidelines** seven years post injury.

The employee saw Dr. on 07/14/10 with complaints of left knee pain. Physical examination revealed mild effusion of the left knee. There was crepitus noted. The employee was assessed with left knee pain. The employee was prescribed Celebrex and recommended for Orthovisc injections.

The employee received Orthovisc injections to the left knee on 08/04/10, 08/11/10, and 08/18/10.

The employee saw Dr. on 09/24/10 with complaints of left knee pain. Physical examination was not performed. The employee was assessed with left knee pain and advised to follow up in six months.

A letter by Dr. dated 11/04/10 stated the employee required the continued use of Hyalgan and Celebrex to keep her comfortable and functional.

A Required Medical Evaluation (RME) report dated 06/07/10 indicated that the use of Celebrex would not be indicated as it was not support by the guidelines for her injury.

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

The employee sustained an injury to the left knee and was prescribed Celebrex in 2005. There are no updated records after November 2010 indicating that the employee has continued to use Celebrex. Current evidence based guidelines do recommend the use of COX-2 NSAIDs in the treatment of osteoarthritis; however, there are no updated

imaging studies of the left knee which identify progressive traumatic arthritis and there is little evidence to support the use of a COX-2 for long term use. This is indicated for chronic pain however for short term intervals.

Given the lack of any updated imaging evidence regarding the presence of progressive or traumatic arthritis or support in the literature regarding the long term continuous use of Celebrex and the ongoing and continued use of Celebrex after November 2010, medical necessity is not established.

I have received the documents you have sent me regarding the above captioned claimant. The report contained herein is based upon review of that documentation and my experience. The report assumes that documents you have presented to me are true, correct, and complete. Should additional information become available, that information may or may not alter the opinions contained in this report. These opinions do not constitute, per se, a recommendation for specific claims or administrative functions to be made or enforced.

You have the right to appeal this determination. Appeals of adverse decisions may also be placed with the DWC by filing a medical dispute resolution with form DWC-60 and following medical dispute resolution rules 133.305, 133.307, and 133.308. To file a complaint, The Texas Department of Insurance can be reached at (800) 252-7031 or in writing at: P.O. Box 149104, Austin, TX 78714.

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

Official Disability Guidelines, Online Version, Pain Chapter.

NSAIDS (Non-Steroidal Anti-Inflammatory Drugs): 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) Revised AGS practice guidelines on the management of persistent pain (including noncancer-related pain) in the elderly recommend that patients avoid NSAIDs and consider the use of low-dose opioid therapy instead, because the risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, usually outweigh the benefits. (AGS, 2009)