



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

Notice of Independent Review Decision-WC

DATE OF REVIEW: 1-17-12

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

99213 One Office/Outpatient Visit 10/24/11-4/30/12; J8499 Units: 3 Oral prescription; non-chemo, 10/24/11-4/30/12 Parafon Forte, Naprosyn, Tylenol XS

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

American Boards of Physical Medicine and Rehabilitation and 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)

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY [SUMMARY]:

xxxx Surgery performed by MD: Decompressive lumbar laminectomy, L5-S1, bilateral with discectomy and foraminotomy.

10-26-00 MRI of the lumbar spine without and with contrast showed post surgical changes at L5-S1 within minimal enhancing epidural fibrotic scarring at L5-S1. Moderate narrowing of the disc space at L5-S1 associated with disc dehydration, desiccation and degeneration and presence of minimal end plate degenerative changes. Disruption of the posterior annulus fibrosus at L1-L2 with rather focal central posterior subligamentous herniation of the disc at L1-L2. This shows minimal enhancement post intravenous injection of contrast.

10-29-07 MRI of the lumbar spine without contrast shows posterior bulging disc at L1-L2. Postsurgical changes due to previous laminectomy and discectomy at L5-S1. The rest of the study is unremarkable.

6-23-08 X-rays of the lumbar spine (flexion/extension) shows no fracture or dislocation.

3-21-11 MD., the claimant states has low back pain and irradiating down to the lower extremities associated with numbness and tingling sensation. States pain is constant. Patient has trouble sleeping. Pain level at present is at a 8/10. She indicates pain medications help. She still continues with same symptomatology. On exam, the findings on this patient of the lumbar spine showed straight leg raise on the left side at 70 degrees with low back pain and hip pain and straight leg raise on the right side at 90 degrees with low back pain. Motor was decreased on the left dorsiflexion, minimal. Sensory was decreased S1 ++ and L5 + distribution on the left side. Deep tendon reflexes were equal. Patient was able to walk on tiptoes and heels. Bends at 80 degrees with low back pain. Diagnosis: Post Op Lumbar Laminectomy of L4-L5 and L5-S1 done on 12/4/97. Treatment: The suggested treatment plans for this patient is medications. Patient was prescribed Naprosyn EC 375mgs one a day for inflammation, Parafon Forte DSC 1/2 tablet three times a day for muscle contracture, and Tylenol

Extra Strength for pain. Referrals are none. Medications are as previously mentioned. Prognosis is fair. Compliance is good. Patient is to return to the office in 4 months.

8-15-11 UR performed by MD., notes clinical data submitted indicates the worker sustained a work-related injury more than xxxxx ago for which spinal surgery was performed (single level decompression laminectomy) more than xxxxx ago. The clinical documentation submitted by the surgeon does not indicate the persistence of clinically significant physical impairment or functional limitations, or the presence of a chronic pain disorder for which regular follow-up office visits and the prescription of any medications might be considered reasonable end necessary. Of note, the recent-specialty-specific peer review also cited the lack of current objective clinical findings to support the medical necessity of ongoing care in the form of office visits or prescribed medications. The medical necessity for the Plan of Care as outline above cannot be established based upon the clinical data submitted at this time.

10-12-11 MD., letter of medical necessity: "This is a letter of medical necessity for medications: Naprosyn EC 375mgs, Parafon Forte DSC and Tylenol Extra Strength and follow up visits once a year. Patient has been under my care for her lower back problems as a result of on the job injury of xx/xx/xx when she xxxxx on her buttocks. She underwent surgical treatment for a Decompressive Lumbar Laminectomy of L5-S1 bilaterally with discectomy and foraminotomy on xxxx. Patient presents with chronic low back pain, and muscle stiffness. She has been on medication treatments such as Parafon Forte DSC, Naprosyn EC and Tylenol Extra Strength for management of her chronic low back pain and muscle stiffness and this has seem to have a effective result on patient's symptomatology. This medications treatment is relatively minimal for the control of her symptoms. Patient has only been allowed by the insurance company for follow up visits in my office once a year to monitor and have prescriptions filled. was last seen in my office on March 21, 2011. She still continues with low back pain and with pain irradiating down tot eh lower extremities associated with numbness and tingling sensation. She indicates of constant low back pain. Pain level has been at 8/10. Clinically she presents with positive straight leg raise at 70 degrees with low back pain, hip pain on the left side and on the right side is at 90 degrees with low back pain. Motor was decreased left dorsiflexion. Sensory is decreased on the S1 ++ and L5 + distribution on the left side. Patient had an evaluation done on August 15, 2011 by Dr.. I disagree with the physician's advisors determination of no further follow up visits or medications of Naprosyn EC, Parafon Forte DSC and Tylenol XS. Patient is in need of medications periodically to relief pain and muscle stiffness as a result of her work related injury. Patient is also in need of follow up visit annually to have prescriptions filled and monitor patient's evolution. On April 6, 2011, a certification of Parafon Forte DSC was given by Dr. pert. On April 11, 2011, a certification of Tylenol XS 1 tablet every 8 hours as needed was given by the Utilization review specialist, LVN. Patient has had an effective result from Naprosyn EC, Parafon Forte DSC and Tylenol Extra Strength which Is a minimal treatment to control her symptomatology and I feel patient should continue with these medications periodically and be allowed for follow up visits annually."

10-18-11 UR performed by, MD., notes the 60 year-old patient has been treated for post lumbar laminectomy pain syndrome subsequent to the work related incident of xx/xx/xx. Letter dated 10/12/11 indicated Parafon Forte DSC, Naprosyn EC and Tylenol Extra Strength have been taken for control of chronic low back pain and stiffness. The patient was most recently evaluated 3/21/11. Current clinical guidelines indicate the need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking. Two of the three medications can be obtained, with generic equivalents, without prescription. Muscle relaxants are typically not prescribed on a chronic basis; rather for management of acute exacerbation of low back related symptoms. Given the case history, the request for office visit and ongoing prescription of the requested medications is not supported.

10-24-11 MD., Letter of reconsideration: "This is a request for reconsideration for office visit and medications. On October 12, 2011 a request for medications and office visit was submitted but denied by insurance company. Patient has been prescribed Naprosyn EC 375mgs, Parafon forte DSC, and Tylenol Extra Strength and is in need of follow up visit once a year. Maria Martinez has been under my care for her lower back problems and she underwent surgical treatment for a Decompressive Lumbar Laminectomy of L5-S1 bilaterally with discectomy and foraminotomy on March 28, 2000. Due to her injury and surgical procedure she presents with chronic low back pain and muscle stiffness. She has been prescribed Naprosyn EC to decrease the inflammatory process, Parafon Forte DSC for muscle stiffness and Tylenol Extra strength as needed to decrease pain to the lower back. Patient Maria Martinez has had an effective result from Naprosyn EC, Parafon Forte DSC and Tylenol Extra Strength which is a relatively minimal treatment to control her symptomatology and I feel patient should continue with these medications periodically as needed for her discomfort and pain. is also in need of follow up visit to monitor patient and have prescriptions filled."

10-31-11 UR performed by MD., notes the date of Injury xx/xx/xx. This is a female claimant with low back pain. Mechanism of injury is not provided. An MRI of the lumbar spine with and without contrast on 10/26/2000 demonstrates postsurgical changes at L5-S1 with minimal enhancing epidural fibrotic scarring at L5-S1. There is moderate narrowing of the disc space at L5-S1 associated with disc dehydration, desiccation and degeneration and presence of minimal end plate degenerative changes. Disruption of the posterior annulus fibrosus at L1-L2 is noted with rather focal central posterior subligamentous herniation of the disc at L1-L2. This shows minimal enhancement post intravenous injection of contrast. An MRI of the lumbar spine without contrast on 10/29/2007 shows posterior bulging disc at L1-L2. There are postsurgical changes due to previous laminectomy and discectomy at L5-S1. The rest of the study is unremarkable. Flexion/extension views of the lumbar spine on 06123/2008 show no fracture or dislocation. The claimant is seen for a follow up visit with Dr. MD. The claimant complains of low back pain radiating down to the lower extremities associated with numbness and tingling sensation. She states the pain is constant and rates her pain as 8/10. She has trouble sleeping and she indicates pain medications help. She

still continues with the same symptomatology. Examination of the lumbar spine showed straight leg raise on the left side at 70 degrees with low back pain and hip pain, and straight leg raise on the right side at 90 degrees with low back pain. Motor was decreased on the left dorsiflexion, minimal. Sensory was decreased S1 ++ and L5 + distribution on the left side. The claimant bends at 80 degrees with low back pain. The suggested treatment plan for the claimant is medications. The claimant was prescribed Naprosyn EC 375 mgs one a day for inflammation, Parafon Forte DSC tablet three times a day for muscle contracture, and Tylenol Extra Strength for pain. Dr. MD, notes that a request for medications and an office visit was submitted on 10/12/2011 but was denied. The claimant has been under Dr. care for lower back problems, and she underwent surgical treatment for a decompressive lumbar laminectomy or L5-S1 bilaterally with discectomy and foraminotomy on 03/28/2000. Due to her injury and surgical Procedure, she presents with chronic low back pain and muscle stiffness. She has been prescribed Naprosyn EC to decrease the Inflammatory process, Parafon Forte DSC for muscle stiffness and Tylenol Extra Strength as needed to decrease pain to the lower back She has had an effective result from Naprosyn EP, Parafon Forte DSC and Tylenol Extra Strength, which is relatively minimal treatment to control her symptomatology, and the claimant should continue with these medications periodically as needed for her discomfort and pain. She is also in need of follow-up visits for monitoring and for having prescriptions filled. This is an appeal request for follow-up visit, Naprosyn, Parafon and Tylenol ES. The injured worker has low back pain following a xxxx date of injury. The patient has a history of surgery at L5-S1. The patient complains of low back pain radiating down to the lower extremities with numbness and tingling. The patient has chronic low back pain and muscle stiffness. This is an appeal request for follow-up visit Naprosyn, Parafon and Tylenol ES, Naprosyn and Tylenol ES are recommended for early use only. The patient has chronic low back pain. Parafon is recommended in combination with PT. The request for office visit, Parafon, Naprosyn, and Tylenol ES are not supported by ODG. Attempts at peer discussion were not successful. Recommend non-certification.

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

BASED ON THE RECORDS PROVIDED, PARTIAL APPROVAL FOR OFFICE VISIT X 1 SO THE PATIENT CAN DISCUSS THE MEDICATIONS MANAGEMENT IS REASONABLE. THE PARAFON FORTE IS A MUSCLE RELAXANT AND IS INDICATED FOR SHORT TERM USE ONLY. REGARDING THE USE OF TYLENOL XS AND NAPROXEN, THESE MEDICATIONS ARE ALSO INDICATED FOR SHORT TERM USE. THEREFORE, THE USE OF PARAFON FORTE, TYLENOL XS AND NAPROXEN IS NOT REASONABLE OR MEDICALLY NECESSARY.

ODG-TWC, last update 12-23-11 Occupational Disorders - Pain:

Office visits: Recommended as determined to be medically necessary. Evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical

role in the proper diagnosis and return to function of an injured worker, and they should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with eventual patient independence from the health care system through self care as soon as clinically feasible. The ODG Codes for Automated Approval (CAA), designed to automate claims management decision-making, indicates the number of E&M office visits (codes 99201-99285) reflecting the typical number of E&M encounters for a diagnosis, but this is not intended to limit or cap the number of E&M encounters that are medically necessary for a particular patient. Office visits that exceed the number of office visits listed in the CAA may serve as a “flag” to payors for possible evaluation, however, payors should not automatically deny payment for these if preauthorization has not been obtained. *Note:* The high quality medical studies required for treatment guidelines such as ODG provides guidance about specific treatments and diagnostic procedures, but not about the recommended number of E&M office visits. Studies have and are being conducted as to the value of “virtual visits” compared with inpatient visits, however the value of patient/doctor interventions has not been questioned.

Muscle relaxants: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) See the Low Back Chapter. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Schnitzer, 2004) (Van Tulder, 2004) (Airaksinen, 2006) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in *American Family Physician*, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)

Classifications: Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. (See, 2008) (van Tulder, 2006)

Chlorzoxazone (Parafon Forte®, Paraflex®, Relax™DS, Remular S™, generic available): this drug works primarily in the spinal cord and the subcortical areas of the brain. The mechanism of action is unknown but the effect is thought to be due to general depression of the central nervous system. Advantages over other muscle relaxants include reduced sedation and less evidence for abuse. (See, 2008)

Side Effects: Drowsiness and dizziness. Urine discoloration may occur. Avoid use in patients with hepatic impairment.

Dosing: 250-750 mg three times a day to four times a day.

Naprosyn: 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.

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)

Non-prescription medications: Recommended. Acetaminophen (safest); NSAIDs (aspirin, ibuprofen). (Bigos, 1999) A 2008 Cochrane review found that NSAIDs are not more effective than acetaminophen for acute low-back pain, but acetaminophen had fewer side effects, which support recommending NSAIDs as a treatment option after acetaminophen. (Roelofs-Cochrane, 2008) There should be caution about daily doses of acetaminophen and liver disease if over 4 g/day or in combination with other NSAIDs. (Watkins, 2006) See also NSAIDs (non-steroidal anti-inflammatory drugs).

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)**