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**Date notice sent to all parties:** 02/04/16

**IRO CASE #:**

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

Prescription for 90 Duexis 800-26.6 mg. with one refill

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

Board Certified in Anesthesiology  
Fellowship Trained 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)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

Prescription for 90 Duexis 800-26.6 mg. with one refill – Upheld

**PATIENT CLINICAL HISTORY [SUMMARY]:**

This patient was allegedly injured on XX/XX/XX, fracturing her right lower leg and ankle. She underwent surgical repair in XX/XXXX with hardware. She apparently developed infection of the hardware and underwent removal of most of the hardware in XX/XXXX. In XX/XXXX, she was seen by her orthopedic surgeon, who noted “poorly localized” pain in the right ankle with swelling. Physical examination documented non-specific decreased range of motion. XX recommended referral for pain management consultation regarding possible

chronic pain syndrome. On XX/XX/XX, XX again followed-up with the patient. Physical examination documented improved range of motion of the right ankle with dysesthesia over the superficial peroneal nerve and along the sural nerve. There was mild swelling of the medial aspect of the ankle and a slightly ruddy discoloration of the right foot compared to the left with somewhat tight cool skin of the right foot relative to the left. He started the patient on Neurontin, Hydrocodone, and Ibuprofen. Initial evaluation for pain management consultation occurred on XX/XX/XX. At that time, the patient's pain level was rated 10/10.

Review of systems documented no history of gastrointestinal problems. Physical examination documented normal sensation in the lower extremities with good range of motion of the right foot and no swelling or redness. Minor trophic changes in the right foot were noted. Sensation and reflexes of the lower extremities were normal. The patient was started on Duexis 800 mg. three times daily, Gralise 1800 mg. daily, and Norco 7.5 mg. every three hours. She was also referred for aquatic therapy of the right foot. On XX/XX/XX, the patient followed-up with XX, who documented her ongoing pain level of 9/10. He apparently added Lidoderm and Ibuprofen to the medications and documented the same physical examination. On XX/XX/XX, XX wrote a letter of medical necessity regarding Lidoderm and Duexis, stating that these medications were medically necessary because the patient had a history of low back pain and chronic pain syndrome and was "doing reasonably well" on the medications, despite documenting an ongoing pain level of 9/10.

XX examined the patient on XX/XX/XX and diagnosed her with CRPS of the right ankle, posttraumatic arthritis of the right ankle, and painful hardware of the right ankle. Hardware removal was recommended. XX followed-up with the patient on XX/XX/XX, documenting her ongoing pain level of 8/10 with medication. He now added Celebrex 200 mg. twice daily to the Duexis tid, Gabapentin 600 mg bid, Gralise 1800 mg q.d., Ibuprofen 800 mg tid, and Lidoderm. XX prescribed Neurontin 600 mg., Voltaren 1%, and Lidoderm 5% on 12/04/14. XX followed-up with the patient on XX/XX/XX, documenting the same pain complaints as before with a pain level of 9/10, despite continued use of Celebrex, Duexis, Gabapentin, Gralise, Ibuprofen, Lidoderm, Neurontin, and Norco, as well as Voltaren Gel. Physical examination remained essentially unchanged. XX requested surgery to remove the residual hardware of the right foot, which was approved on XX/XX/XX. On XX/XX/XX, the patient returned to XX who noted her ongoing pain level of 8/10 "with medication," noting that she was continuing to take all the same medications, but now also using Pennsaid applied to the affected area. She also continued to use Voltaren transdermally, Lidoderm Patch, Duexis, Neurontin, and Lyrica. On XX/XX/XX, XX, provided a non-authorization for the requested prescription for Duexis. On XX/XX/XX, XX, provided another non-authorization for the request for continuation of Duexis. Both physicians recommending non-authorization based on Official Disability Guidelines (ODG).

On xxxxx, XX followed-up with the patient, now stating her pain level was 5/10 and that Duexis was “significantly” helping pain without causing stomach issues”. Physical examination continued to demonstrate no edema and no focal neurological findings. XX recommended continuation of Lyrica 75 mg. three times daily, Duexis 800 mg. three times daily, Norco, Voltaren Gel, and Lidoderm Patch.

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

Despite having a diagnosis of complex regional pain syndrome (CRPS), the physical examinations documented are neither significantly consistent with nor demonstrate sufficient evidence of CRPS per the ODG criteria. In addition, this patient has no history of gastrointestinal disease or prior ulcers that would necessitate the use of a combination medication such as Duexis, which, in reality, is merely a combination of an anti-inflammatory and an H2 blocker. There is no support in the ODG for the use of Duexis as a first-line agent, especially in the absence of gastrointestinal disease. The combination of medications supplied in Duexis can easily be reproduced with over-the-counter anti-inflammatories and H2 blockers. Therefore, the use of Duexis is neither supported by the ODG nor proven to be medically necessary in the medical records that I have been provided, as this patient has no history of gastrointestinal disease nor any history of gastrointestinal intolerance of other anti-inflammatories. Finally, and perhaps most importantly, except for the most recent progress note on XX/XX/XX, every other progress note from XX documented no significant change in pain complaints or pain level while the patient was taking Duexis. Based upon the documentation provided, ODG guidelines, and the lack of any significant history of gastrointestinal disease, the continued use of Duexis is not medically reasonable or necessary and can easily be substituted with the use of over-the-counter anti-inflammatories and H2 blockers. Therefore, the prescription for 90 Duexis 800-26.6 mg. is not appropriate or medically necessary and the prior recommendations for non-authorization are upheld at this time.

**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)**