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| <b>Case Number:</b>   | CM15-0046846 |                              |            |
| <b>Date Assigned:</b> | 03/19/2015   | <b>Date of Injury:</b>       | 12/02/2006 |
| <b>Decision Date:</b> | 05/01/2015   | <b>UR Denial Date:</b>       | 02/12/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 03/12/2015 |

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: California  
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 51 year old female, who sustained an industrial injury on 12/02/2006. Diagnoses include low back pain, myalgia and fibromyalgia. Treatment to date has included stimulator implantation, home care, specialist care, injections and medications. Per the Primary Treating Physician's Progress Report dated 7/22/2014, the injured worker reported very severe low back pain and spasms. The pain was aggravated a week ago. She is having a flare up. The stimulator is working for leg pain but not the back. When she uses that for the back she reports abdominal spasms. Physical examination revealed the lumbar spine is sensitive to the touch and tender to palpation. There is twitch sign present. The battery site is clean and dry with no redness. She underwent a trigger point injection to the bilateral lumbar spinous, paraspinal and gluteus musculature. The plan of care included home care seven days a week, orthopedic surgeon care, reprogramming of stimulator for the low back, rheumatology care, orthopedic upper extremity specialist care, home assistance care weekly for 35 hours and refill of medications and authorization was requested for Dexilant 60mg #30.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Dexilant 60 mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 69. Decision based on Non-MTUS Citation [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/022287s019lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022287s019lbl.pdf).

**Decision rationale:** The patient presents with pain and weakness in her lower back and lower extremity. The request is for DEXILANT 60MG #30. Per 01/17/15 progress report, the patient is currently taking Lyrica, Ambien, Tramadol, MiraLax, Proctofoam cream, Zofran, Lidoderm patch, Xeljanz, Methotrexatem, Folic acid, Alendronate and Dexilant. One of the diagnoses is severe gastritis. Work statue is unknown. MTUS guidelines page 69 recommends prophylactic use of PPIs when appropriate GI assessments have been provided. The patient must be determined to be at risk for GI events, such as age > 65 years, history of peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID (e.g., NSAID + low-dose ASA). According to [http:// www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/022287s019lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022287s019lbl.pdf) labeled indications for Dexilant: "for Healing of Erosive Esophagitis. Dexilant is indicated for healing of all grades of erosive esophagitis, EE, for up to eight weeks. Dexilant is also indicated to maintain healing of EE and relief of heartburn for up to six months. Dexilant is indicated for the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease, GERD, for four weeks." In this case, one of the treater's diagnoses is "severe gastritis" indicating some kind of GI issue in the past or currently but the treater does not discuss any on-going issues with GI system. There is no documentation of any current reflux problems, stomach irritation or other symptoms and no discussion as to how this medication has been effective. There is no description of GI risk assessment as required by MTUS for a prophylactic use of PPI. The patient is not on any NSAID either. Given the lack adequate discussion regarding the need for PPI, the request IS NOT medically necessary.