

Case Number:	CM14-0066778		
Date Assigned:	07/11/2014	Date of Injury:	01/31/2013
Decision Date:	09/15/2014	UR Denial Date:	04/29/2014
Priority:	Standard	Application Received:	05/09/2014

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. The expert reviewer is Board Certified in Occupational Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 claimant injured her low back on 01/31/03. Dexilant DR (dexlansoprazole) is under review. She is status post L4-5 discectomy in January 2005 and a lumbar fusion in October 2008 with a spinal cord stimulator trial in August 2011. She has required pain medications. She has had psychological issues addressed. She has been on multiple medications. Dexilant DR is considered to be second line therapy as a proton pump inhibitor. She has been prescribed Dexilant for a number of months. It was noted on an office note by [REDACTED] on 10/22/13. She has a past medical history of gastric ulcer but no additional history is available. She complained of decreased appetite and irritable bowels but no other problems at that time. She has tried other medications but other PPIs are not mentioned. There was no abdominal examination. She was seen again and remained on her medications. There was no change in her history regarding her gastric ulcers. Aquatic therapy was ordered. The use of Dexilant DR is not mentioned under the treatment plan. She reported on 12/24/13 that her medications were helping. She was taking Ranitidine and Dexilant DR. A specific reason for use of Dexilant DR is not described. On 02/13/14, again her medications included ranitidine and Dexilant DR. Her failed medications did not mention any other proton pump inhibitors. On 03/04/14, there was no mention of any change in this type of medication. She was status quo regarding these medications on 04/15/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Dexilant Delayed Release (DR), 60mg, #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Inhibitors Page(s): 102.

Decision rationale: The history and documentation do not objectively support the request for Dexilant DR. The CA MTUS state on p. 102 re: NSAIDs/PPIs "patients at intermediate risk for gastrointestinal events and no cardiovascular NSAIDs, GI symptoms & cardiovascular risk: Recommend with precautions as indicated below: Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g. ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 gm four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxen plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)" The ODG formulary states "Recommended for patients at risk for gastrointestinal events. See NSAIDs, GI symptoms & cardiovascular risk. Prilosec (omeprazole), Prevacid (Lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Omeprazole provides a statistically significantly greater acid control than lansoprazole. (Miner, 2010) Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. For many people, Prilosec is more affordable than Nexium. Nexium is not available in a generic (as is Prilosec). Also, Prilosec is available as an over-the-counter product (Prilosec OTC), while Nexium is not. (Donnellan, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative

Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective."In this case, there is brief mention of a history of a gastric ulcer but the history is otherwise unclear and no current symptoms or physical findings involving the abdomen have been described. In addition, the ODG state that Dexilant DR is considered a second line medication and there is no evidence of trials of other first line PPIs such as omeprazole and lansoprazole. There is no documentation of any current GI conditions or increased risk to support the use of this medication. The medical necessity of this request has not been clearly demonstrated.