Risks Associated with Long Term Proton Pump Inhibitor Use

Proton Pump Inhibitors (PPIs) are proven to be safe, effective, and well tolerated. Patients will benefit from their appropriate use; however, they are often used longer than indicated which can lead to safety concerns. The FDA recommends that when healthcare professionals prescribe PPIs, they should utilize the lowest dose and the shortest duration of therapy to adequately treat the patient's condition.

FDA approved dose and length of therapy for GERD		
PPI	FDA approved GERD dose	Length of Therapy
dexlansoprazole (Dexilant®)	30 mg daily	4 weeks
esomeprazole (Nexium®)	20 mg daily	4 weeks: may repeat an additional 4 weeks if not healed
lansoprazole (Prevacid®)	15 mg daily	8 weeks
omeprazole (Prilosec®)	20 mg daily	4-8 weeks
pantoprazole (Protonix®)	40 mg daily	8 weeks: may repeat an additional 8 weeks if not healed
rabeprazole (Aciphex®)	20 mg daily	4-8 weeks

*Zegerid® not payable by Idaho Medicaid

Safety information:

- Risk of Fracture: On May 25, 2010, the FDA revised the prescription label for the proton pump inhibitor (PPI) class of drugs to include new safety information about a possible increased risk of fractures of the hip, wrist, and spine with the use of these medications. There is an associated 25% increase in overall fractures and a 47% increase in spinal fractures in postmenopausal women.
- Hypomagnesemia: The FDA has also issued a statement warning that PPIs taken for prolonged periods of time (in most cases, longer than one year) may also cause low serum magnesium levels. Low serum magnesium levels can lead to muscle spasm, irregular heartbeat, and convulsions.
- Enteric infections: Reduction in acidity may promote bacterial colonization of the gastrointestinal tract which may result in *clostridium difficile* colitis or bacterial gastroenteritis.
- Community-acquired pneumonia**:** Reduction in acidity may allow ingested pathogens to colonize the stomach with subsequent translocation which increases the incidence of community-acquired pneumonias.

Other information:

- Rebound hypersecretion is observed in 60-90% of patients when PPIs are used for at least two to three months and may continue for three or more months.
- Asthmatics receiving a PPI had the same type and severity of symptoms as patients receiving placebo.
- Bedtime dosing is not useful for controlling most symptoms since the PPI level will not be high enough to decrease the morning gastric acid surge.
- Tapering PPIs by reducing the dose and then dosing every other day for a week or longer can help reduce breakthrough symptoms. Either antacids or histamine-2 (H2) blockers can also be used for breakthrough symptoms if needed.
- The FDA recommends that when healthcare professionals prescribe PPIs, they should utilize the lowest dose and shortest duration of therapy to adequately treat the patient's condition. If PPIs have been used for more than a few months, therapy should be discontinued if there is no clear indication for continuation.