



## **Indiana Medicaid Therapeutics Committee** **Therapeutic Class Review Summary**

### **Therapeutic Class:**

Anti-Ulcer Preparations

### **Overview:**

The medications in this class of drugs are effective in ulcer prevention and treatment, although their specific indications differ. Misoprostol's indication is for reducing the risk of NSAID-induced gastric ulcers, and it has not been shown to reduce the risk of duodenal ulcers in patients taking NSAIDs. Sucralfate is indicated for short-term treatment of active duodenal ulcers and the tablets may be used for maintenance therapy. While both medications are generally well tolerated, misoprostol's adverse event profile commonly includes gastrointestinal related events such as abdominal pain and diarrhea. In clinical trials, these adverse events with misoprostol led to discontinuation of therapy more frequently compared to placebo. However, the efficacy of misoprostol in preventing NSAID-induced ulcers potentially outweighs the risk of gastrointestinal related adverse events. A lower dose can be used when intolerance occurs.

Use of misoprostol in women of child-bearing age should be limited and include only those with a negative pregnancy test and who understand the abortifacient properties of the medication. This information is contained in a black box warning in misoprostol's labeling and is indicative of the drug's pregnancy category X rating. Sucralfate has no significant warnings and is considered a pregnancy category B drug.

In clinical studies, misoprostol prevented gastric ulceration greater than placebo, greater than ranitidine, and similarly to lansoprazole. However, lansoprazole was better tolerated compared with misoprostol. One study comparing misoprostol to sucralfate in gastric ulcer prevention (Agrawal et al.<sup>13</sup>) in patients chronically using NSAIDs showed a significant benefit towards misoprostol. Sucralfate efficacy in treating duodenal and gastric ulcers, as compared with cimetidine, is comparable.



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<b>GENERIC NAME</b>	<b>TRADE NAME</b>	<b>MANUFACTURER</b>	<b>GENERIC</b>
Misoprostol	Cytotec <sup>®</sup>	Pfizer Pharmaceuticals, Inc.	Y
Sucralfate	Carafate <sup>®</sup>	Axcan Scandipharm, Inc.	Y

### **Summary:**

Both medications in this class are available generically. Each offers benefits in ulcer prevention/treatment, although the agents offer different benefits based on indication. The criteria for selection of an agent for the preferred drug list should include consideration of indications, safety, efficacy, and cost.