

GASTROENTEROLOGY WAIVERS

CONDITION: PEPTIC ULCER DISEASE (PUD) (ICD9 533.9)

Revised July 2002

AEROMEDICAL CONCERNS: Individuals presenting with acute hemorrhage and associated dizziness, perforation, pain, and/or vomiting are of primary concern in the aviation environment. Undetected chronic blood loss with no other symptoms can result in an iron deficiency anemia, which can lead to cardio-respiratory compromise in flight due to altitude or high G-maneuvers.

WAIVERS:

1. Initial Applicants:

a. Class 1A/1W - Exceptions to policy are rarely recommended.

b. Class 2, 3, and 4 - Waivers will be considered on a case-by-case basis and are normally granted for a single occurrence. Recurrent disease will be evaluated on a case-by-case basis.

2. Rated Aviation Personnel: All Classes - Waivers are normally recommended for a single occurrence, for *Helicobacter pylori* (*H. pylori*) induced ulcers after an appropriate treatment regimen, or for uncomplicated ulcers on approved maintenance drug therapy, currently asymptomatic, with ulcer healing demonstrated by endoscopy. Waivers for recurrent ulcer disease are considered on a case-by-case basis. Waivers are routinely recommended for conditions in response to a known precipitant, (e.g., NSAID ingestion). Complicated PUD consists of ulcers associated with hemorrhage, obstruction, perforation, or intractability of symptoms.

INFORMATION REQUIRED:

1. Aeromedical Summary including a history of caffeine, tobacco, and medication use, any hospital summaries or operative/endoscopy reports.
2. Labs: CBC, three stool hemocults and if a history of hemorrhage or heme positive stool, report PT/PTT and platelet count.
3. Internal medicine or gastroenterology consultations to exclude malignancy.
4. Endoscopy to demonstrate ulcer healing. If cancer is suspected, an endoscopy with biopsies is indicated.
5. Other required studies may include gastric analysis, basal and stimulated, serum gastrin by radioimmunoassay, stool examination for ova and parasites, biopsies, and/or CLO test for *H. pylori*. If ulcer is not present on endoscopy, further work-up is required to determine etiology of any bleeding. Other causes of chest pain and associated symptoms must be considered to include checking an EKG for evidence of myocardial damage.

FOLLOW-UP: Gastrointestinal/internal medicine evaluation if symptoms recur.

TREATMENT: Ninety percent of ulcers are caused by *H. pylori*, and successful eradication reduces the recurrence rate of PUD from 90 to 20 percent. PUD generally does not recur with current therapy unless NSAID use is present. *H. pylori* eradication consists of antibiotics and antisecretory drugs (H2 Blockers and PPIs). Long term acid inhibition is generally not needed after successful eradication. Various regimens of antibiotic therapy for *H. pylori* are acceptable as long as eradication is possible. Surgical intervention for peptic ulcer disease is now rare. Other approved medications include:

GI MEDICATIONS: All antacids (chronic use) and medications listed below are Class 3, except as noted. There are no additional requirements for a waiver other than the complete evaluation of the underlying condition and documentation of medication efficacy.

1. **Antacids (Tums, Roloids, Mylanta, Maalox, Gaviscon, etc.):** Chronic use is Class 3. Occasional or infrequent use is Class 1. Check electrolytes when used chronically.
2. **H2 Blockers (Cimetidine (Tagamet), Ranitidine (Zantac), Famotidine (Pepcid), Nizatidine (Axid)):** Occasional drowsiness is associated with these medications. When treatment is first initiated, a 72-hour observation while the aviator is Duties Not Including Flying (DNIF) is required to ensure the absence of any significant side effect.
3. **Proton Pump Inhibitor:** Omeprazole (Prilosec), Lansoprazole (Prevacid), Pantoprazole (Protonix), Rabeprazole (Aciphex), and Esomeprazole (Nexium).
4. **Sucralfate (Carafate):** Class 2A provided underlying condition does not require waiver.

DISCUSSION: Approximately 25 million Americans suffer from PUD at some point in their lifetime. Each year there are 500,000 to 850,000 new cases of PUD and more than 1 million ulcer-related hospitalizations. The most common ulcer symptom is gnawing or burning pain in the epigastrium. This pain typically occurs when the stomach is empty, between meals, and in the early morning hours, but it can also occur at other times. It may last from minutes to hours and may be relieved by eating food or by taking antacids. Less common ulcer symptoms include nausea, vomiting, and loss of appetite. Bleeding can also occur; prolonged bleeding may cause anemia leading to weakness and fatigue. If bleeding is heavy hematemesis, hematochezia, or melena may occur.

The causes of PUD can be divided into four major categories: *H. pylori* induced ulcers, NSAIDS, acid hypersecretory conditions (e.g. Zollinger-Ellison syndrome), and idiopathic. The use of H2 Blockers and PPIs has changed management of PUD from an inpatient to an outpatient setting. With continued use of chronic daily NSAIDS use, 1-10 percent of patients will suffer gastrointestinal bleeding or gastric/duodenal ulcers. The vast majority of PUD is caused by *H. pylori* and eradication is associated with a recurrence rate of less than 5 percent. The absence of

the organism 4 to 6 weeks after discontinuation of therapy is accepted as an indication of sustained eradication. Eradication is best measured by the non-invasive C14 breath test or a repeat invasive endoscopy with biopsy.

Gastric ulcers and ulcers of the small bowel are found in 21.7 and 8.4 percent, respectively, of users of nonsteroidal anti-inflammatory drugs. Between 3 and 5 percent of gastric ulcers are carcinomatous. The death rate from acute hemorrhage from duodenal ulcer is 6-10 percent and is up to 22 percent in cases of acute upper gastrointestinal hemorrhage. Bleeding stops spontaneously in 85 percent of those cases presenting with acute gastrointestinal hemorrhage. Of those who perforate, 10 percent will do so with no previous history of symptoms. The use of H2 blockers is associated with 80-90 percent of patients healing in 2-3 months, although healing can be delayed in smokers; subsequent relapse rates while on maintenance therapy are higher in smokers than nonsmokers. Without maintenance medication, the relapse rate has been reported to be 50-100 percent at 1 year with 30 percent of the relapses being asymptomatic. The risk of hemorrhage has been reported as 2.5-2.7 percent per year in patients not on maintenance medication. The rate increased to 5 percent per year if there was a history of previous ulcer complications. The annual risk of perforation in similar patients ranges from 0.8-2 percent in males. There is no evidence that painless ulcers are less likely to bleed or perforate, although one bleed is predictive of others. With surgery, 5-15 percent of duodenal ulcers will recur after highly selective vagotomy and 3 percent will relapse after partial gastrectomy. Recurrence rates are less if the patient abstains from tobacco and alcohol.

REFERENCE:

Smoot DT, Go MF, Cryer B. *Peptic Ulcer Disease*, Primary Care: Clinics in Office Practice; 2001;28(3):487-503.

Centers for Disease Control-information on H. pylori and current treatment regimens:
www.cdc.gov/ulcer/md.htm.