

June 14, 2010

The Honorable Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1498-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2011 Rates

Dear Acting Administrator Tavenner:

The American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), the American Society for Gastrointestinal Endoscopy (ASGE) and the American Neurogastroenterology and Motility Society (ANMS), appreciate the opportunity to provide comments on CMS's proposed hospital inpatient rule, CMS-1498-P, published on May 4, 2010 in the *Federal Register*. Our four societies represent virtually all practicing gastroenterologists in the United States.

In this proposed rule, CMS proposes to implement an edit in which idiopathic gastroparesis is not considered a primary diagnosis, only a secondary diagnosis. We oppose adding gastroparesis code 536.3 to the "unacceptable principal diagnosis" edit in the Medicare Code Editor. We understand that a note in the ICD-9-CM manual directs users to sequence the code for the underlying disease first. However, this note and the proposed code edit based on it appear to have resulted from a misunderstanding about the clinical nature of gastroparesis. While gastroparesis is frequently due to diabetes or other underlying disorders, in about one-third to one-half of cases no underlying diagnosis is identified.^{1,4} Therefore, allowing code 536.3 to continue to be assigned and submitted as the principal diagnosis is necessary to report these cases of idiopathic gastroparesis.

There are several scientific publications to support this claim. Zárate, et al. (2003) state that delayed gastric emptying can be due to muscular, neural, or humoral abnormalities. In the absence of an identified cause, gastroparesis is labeled as idiopathic. It is noted that in almost 50% of cases, no apparent cause for gastroparesis is identified. ¹

Hasler (2007) affirms that idiopathic gastroparesis is at least as common as diabetic gastroparesis. Idiopathic gastroparesis shares presentation with some other functional GI disorders including functional dyspepsia, chronic nausea and functional vomiting (cyclic vomiting syndrome). When looking at symptoms, dominant nausea with minimal pain is more commonly diagnosed as idiopathic gastroparesis, while the opposite is more commonly diagnosed as functional dyspepsia. ²

Bielefeldt, et al. (2009) tested the hypothesis that pain and affect, rather than impaired emptying, determine symptom severity in patients with gastroparesis. Study results found that out of 55 patients, 29 (53%) were found to have idiopathic gastroparesis. In addition, patients with idiopathic gastroparesis were found to be significantly younger than those with diabetes or connective tissue disease-related gastroparesis. ³

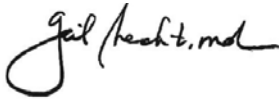
Khoo, et al. (2009) claims that no specific etiology can be found in more than a third of patients. Hospitalization rates for gastroparesis as a primary diagnosis have risen 158% in the United States over the last decade. A history of acute gastroenteritis and/or viral prodromal symptoms are present in about 25% of patients with idiopathic gastroparesis. ⁴

The ACG, AGA, ASGE and ANMS plan to submit an application for the September meeting of the CDC ICD-9-CM Coordination and Maintenance Committee to change the note to include gastroparesis as a primary diagnosis. We request that CMS delay this proposed edit until after the ICD-9-CM Coordination and Maintenance Committee can rule on this request, as we believe the note will be amended based on the body of evidence to support the claim.

Our societies appreciate the opportunity to provide comments on the 2010 hospital inpatient proposed rule. If we may provide any additional information, please contact Anne Marie Bicha, Director of Regulatory Affairs, AGA, at 240-482-3223, or abicha@gastro2.org; Brad Conway, Vice President of Public Affairs, ACG, at 301-263-9000, or bconway@acg.gi.org; Camille Bonta, consultant to ASGE at 202-320-3658, or cbonta@summithealthconsulting.com; or Lori Ennis, Executive Director, ANMS at 734-699-1130, or admin@motilitysociety.org.

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Sincerely:



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References

¹ Zárate N, et al. Severe idiopathic gastroparesis due to neuronal and interstitial cells of Cajal degeneration: pathological findings and management. *Gut* 2003;52:966-970.

² Hasler WL. Gastroparesis: Symptoms, Evaluation and Treatment. *Gastroenterol Clin N Am* 2007;36:619-647.

³ Bielefeldt K, Raza N, Zickmund SL. Different faces of gastroparesis. *World J Gastroenterol* 2009;15: 6052-6060.

⁴ Khoo J, et al. Pathophysiology and treatment of gastroparesis. *Expert Rev Gastroenterol* 2009;3:167-181.