THE AGA INSTITUTE

4930 Del Ray Avenue
Bethesda, MD 20814-2513

PH 301-654-2055 MAIN
FX 301-654-5920

member@gastro.org
www.gastro.org

October 5, 2010

Alan Rosenberg, MD
VP Medical Policy, Technology Assessment and Credentialing
WellPoint, Inc.
233 S. Wacker Drive, Suite 3900
Chicago, IL 60606

Dear Dr. Rosenberg,

The American Gastroenterological Association is the trusted voice of the GI community. Founded in 1897, the AGA has grown to include 17,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology. The AGA Institute administers the practice, research and educational programs of the organization.

The AGA Institute is pleased to provide these comments on the WellPoint draft policy **Biofeedback for Muscle Re-education and Chronic Pain (MED.00062)**, specifically on the use of biofeedback for levator ani syndrome. The following outlines the opinion of the AGA on the current status of this procedure.

Levator ani syndrome (LAS) is defined by chronic or recurring episodes of rectal pain or aching in the absence of structural or systemic disease explanations for these symptoms. The Rome III criteria use the term "chronic proctalgia" to refer to the same symptoms. There is no consensus on its pathophysiology, although chronic tension or "spasm" of the striated pelvic floor muscles is the most common view. Current therapies for levator ani syndrome include digital massage of the levator muscles, electrogalvanic stimulation (EGS) and biofeedback. [1,2,3]

In the late nineties, several studies were conducted to assess the effectiveness of biofeedback for LAS. Heah and colleagues (1997) conducted a controlled study assessing the effects of biofeedback on pain relief and anorectal physiology in patients with LAS. Sixteen consecutive patients (9 men, 7 women; mean age, 50.1 (range, 39-66) years) with LAS were treated with biofeedback. Mean duration of pain was 32.5 (standard error of the mean, 6.7) months. All underwent a full course of biofeedback using a manometric balloon technique. Mean follow-up was 12.8 (standard error of the mean, 2.6) months. Pain score and anorectal physiology tests were administered prospectively by an independent observer before and after biofeedback. After biofeedback, the pain score was significantly improved (before biofeedback: median, 8 (range, 6-10); after biofeedback: median, 2 (range, 1-4); $P < 0.02$). Analgesic requirements were also significantly reduced (all 16 patients needed nonsteroidal anti-inflammatory drugs (NSAID) before biofeedback; only two patients needed NSAID after biofeedback; $P < 0.03$). There were no significant changes to the anorectal physiology parameters after BF. Although biofeedback had a negligible effect on anorectal physiologic measurements in LAS, it was effective in pain relief, with no side effects. [4]

Gilliland and colleagues (1997) conducted a review of patients receiving electromyography (EMG)-based biofeedback. Medical records of 86 patients who completed at least one session of biofeedback for rectal pain between February 1989 and August 1995 were retrospectively reviewed. All sessions were one-hour outpatient encounters with a trained biofeedback therapist. There were 31 male and 55 female patients with a median age of 68 (range, 12-96) years. Surgery (19.8 percent) or stress (15.1 percent) were frequently cited as precipitating factors for the development of rectal pain. Eleven patients completed only one session of biofeedback and were excluded from further analysis. Of the remaining patients, 28 complained of concomitant constipation. Assessment of the benefit of therapy was based on the patients' subjective reports of the level of symptoms, aided by a linear analog scale. Twenty six patients (34.7 percent) reported an improvement in symptoms. Outcome was not influenced by patients' ages ($P = 0.63$), duration of symptoms ($P = 1.0$), or a prior history of surgery ($P = 0.14$). Alleviation of symptoms was not significantly related to the presence of paradoxical puborectalis contraction demonstrated on either EMG ($P = 1$) or defecography ($P = 0.12$). Importantly, outcome was significantly improved in patients who completed the treatment schedule compared with those who self-discharged ($P < 0.001$). Although idiopathic rectal pain is difficult to treat, EMG-based biofeedback can produce alleviation of symptoms. However, success depends on patients' willingness to pursue a full course of therapy.[5]

In a prospective, randomized study, Rao and colleagues (2007) examined the effectiveness of biofeedback (manometric-assisted anal relaxation, muscle coordination, and simulated defecation training; biofeedback) with either sham feedback therapy (sham) or standard therapy (diet, exercise, laxatives; standard) in 77 subjects (69 women) with chronic constipation and dyssynergic defecation. At baseline and after treatment (3 months), physiological changes were assessed by anorectal manometry, balloon expulsion, and colonic transit study and symptomatic changes and stool characteristics by visual analog scale and prospective stool diary. Primary outcome measures (intention-to-treat analysis) included presence of dyssynergia, balloon expulsion time, number of complete spontaneous bowel movements, and global bowel satisfaction. Subjects in the biofeedback group were more likely to correct dyssynergia ($p < 0.0001$), improve defecation index ($p < 0.0001$), and decrease balloon expulsion time ($p = 0.02$) than other groups. Colonic transit improved after biofeedback or standard ($p = 0.01$) but not after sham. In the biofeedback group, the number of complete spontaneous bowel movements increased ($p < 0.02$) and was higher ($p < 0.05$) than in other groups, and use of digital maneuvers decreased ($p = 0.03$). Global bowel satisfaction was higher ($p = 0.04$) in the biofeedback than sham group. The authors concluded that biofeedback improves constipation and physiological characteristics of bowel function in patients with dyssynergia. This effect is mediated by modifying physiological behavior and colorectal function. Biofeedback is the preferred treatment for constipated patients with dyssynergia.[6]

In 2010, Rao and colleagues further examined the long-term effectiveness of biofeedback therapy in patients with dyssynergic defecation. 26 patients were randomly assigned to receive biofeedback therapy (manometric-assisted pelvic relaxation and simulated defecation training) or standard therapy (diet, exercise and laxatives) for 3 months followed by follow-up visits at 3-monthly intervals for 1 year. Patients who received biofeedback therapy demonstrated a significant increase in the number of complete spontaneous bowel movements at the 1 year follow-up compared with baseline and compared with patients who received standard therapy[7].

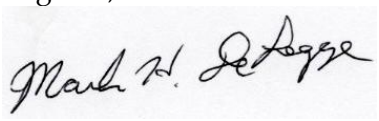
Chiarioni and colleagues (2010) conducted a randomized controlled trial to compare the effectiveness of massage, EGS and biofeedback along with psychologic counseling and assess physiologic mechanisms for treatment. Inclusion criteria were Rome II symptoms plus weekly pain. Patients were categorized as "highly likely" to have LAS if they reported tenderness with traction on the levator muscles or as "possible" LAS if they did not. All 157 patients received 9 sessions including psychologic counseling plus biofeedback, EGS, or massage. Outcomes were reassessed at 1, 3, 6, and 12 months. Among patients with "highly likely" LAS, adequate relief was reported by 87% for biofeedback, 45% for EGS, and 22% for massage. Pain days per month decreased from 14.7 at baseline to 3.3 after biofeedback, 8.9 after EGS, and 13.3 after massage. Pain intensity decreased from 6.8 (0–10 scale) at baseline to 1.8 after

biofeedback, 4.7 after EGS, and 6.0 after massage. Improvements were maintained for 12 months. Patients with only a "possible" diagnosis of LAS did not benefit from any treatment. Biofeedback and EGS improved LAS by increasing the ability to relax pelvic floor muscles and evacuate a water-filled balloon and by reducing the urge and pain thresholds. The authors concluded that biofeedback is the most effective of the three treatments and EGS is somewhat effective. Additionally, only patients with tenderness on rectal examination benefit.[3] As most patients who were highly likely to have levator ani syndrome also showed physiologic features of dyssynergic defecation, these two disorders could represent different manifestations of the same underlying disorder.

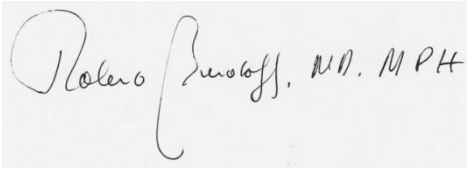
In view of these studies which show that biofeedback is beneficial in these patients, and that benefits are sustained for several years without additional training, the AGA concludes that biofeedback is a medically necessary therapy for patients with refractory or intractable levator ani syndrome and should be considered as such.

The AGA Institute is committed to providing payors with the most current and relevant clinical evidence on all technologies and procedures utilized in the practice of gastroenterology. If you have any questions, please contact Adam R. Borden, MHA, AGA Institute Manager of New Technologies and Reimbursement at 301-941-2629 or aborden@gastro.org.

Regards,



Mark H. DeLegge, MD, AGAF
Chair, AGA Institute Practice Management and Economics Committee



Robert Burakoff, MD, MPH, AGAF
Chair, AGA Public Affairs and Advocacy Committee

John M. Inadomi, MD, AGAF
Chair, AGA Institute Clinical Practice and Quality Management Committee

References

[1] Whitehead WE, Wald A, Diamant NE, et al. Functional disorders of the anus and rectum. In: Drossman DA, Corazziari E, Talley NJ, et al. editor. Rome II: The functional gastrointestinal disorders. 2nd ed. McLean, VA: Degnon Associates; 2000; p. 483–501.

[2] Wald A, Bharucha AE, Enck P, et al. Functional anorectal disorders. In: Drossman DA, Corazziari E, Delvaux M, et al. editor. Rome III: The Functional Gastrointestinal Disorders. 3rd ed. McLean, Virginia: Degnon Associates; 2006; p. 639–685.

[3] Chiarioni G, Nardo A, Vantini I, et al. Biofeedback Is Superior to Electrogalvanic Stimulation and Massage for Treatment of Levator Ani Syndrome. Gastroenterology 2010;138:1321-1329.

[4] Heah SM, Ho YH, Tan M, Leong AF. Biofeedback is effective treatment for levator ani syndrome. Dis Colon Rectum 1997;40:187-189.

[5] Gilliland R, Heymen JS, Altomare DF, et al. Biofeedback for intractable rectal pain: outcome and predictors of success. Dis Colon Rectum 1997;40:190-196.

[6] Rao SS, Seaton K, Miller M, et al. Randomized controlled trial of biofeedback, sham feedback, and standard therapy for dyssynergic defecation. Clin Gastroenterol Hepatol. 2007;5(3):331-338.

[7] Rao, S. S. C. *et al*. Long-term efficacy of biofeedback therapy for dyssynergic defecation: randomized controlled trial. Am. J. Gastroenterol. 105, 890–896 (2010)