Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: Aetna Better Health

Policy Number: 0616

Policy Name: Gastrointestinal Manometry

Type of Submission – Check all that apply:

☐ New Policy
☒ Revised Policy*
☐ Annual Review – No Revisions
☐ Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

CPB 0616 Gastrointestinal Manometry

Clinical content was last revised on 09/19/2014. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

Update History since the last PARP Submission:

03/04/2019-This CPB has been updated with additional references.

Name of Authorized Individual (Please type or print):

Dr. Bernard Lewin, M.D.

Signature of Authorized Individual:
Aetna considers antroduodenal manometry medically necessary for members with dyspepsia, gastroparesis, or chronic intestinal pseudo-obstruction with unexplained upper gastrointestinal symptoms (e.g., nausea, vomiting) if gastric emptying is normal or equivocal and severe symptoms persist despite empiric therapeutic trials of conservative management.

Aetna considers antroduodenal manometry experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established. Antroduodenal manometry has no proven additional value if tests of gastric function reveal delayed emptying or abnormal myoelectrical activity.

Aetna considers anorectal manometry as well as rectal sensation, tone, and compliance test medically necessary for evaluating anorectal function.

Aetna considers colonic manometry (colonic motility testing) experimental and investigational because its clinical utility has not been established.

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.
Background

This policy is consistent with the conclusions of a technical review by the American Gastroenterological Association (AGA) (Quigley et al, 2001).

Antroduodenal manometry is a relatively new technique for the evaluation of gastric and small intestinal motor function. Antroduodenal manometry is used to measure the contractile activity of the distal stomach and duodenum. Changes in intra-luminal pressure of the stomach and duodenum are measured through perfusion ports or solid-state transducers incorporated in a catheter that is positioned under fluoroscopic guidance. Results are recorded and may be analyzed either by direct visual inspection or using a computer. Recordings may last from 5 hours (stationary study) to 24 hours (ambulatory study).

Intra-luminal pressure changes are measured both in the fasting state and after meals. In the fasting state, the presence of the muscle contractions and their site of initiation, direction of propagation, frequency, and duration are assessed. After the meal, conversion to the fed state is identified, and the duration of the fed pattern is calculated. Post-prandial antral hypomotility is a common finding among those with unexplained nausea and vomiting and delayed gastric emptying, and manometry has also been reported as useful in identifying those with primary or diffuse motor disorders. However, the interpretation of antroduodenal manometric recordings requires substantial experience and recognition of the considerable range of normal variation. The specificity of many reportedly abnormal patterns has rarely been confirmed by correlation with histological studies.

A technical review from the AGA (Quigley et al, 2001) stated that, if tests of gastric function reveal delayed emptying or abnormal myoelectrical activity, antroduodenal manometry is of little added value. Antroduodenal manometry may be indicated when the gastric emptying or electrogastrography results are normal or equivocal and severe symptoms persist despite empiric therapeutic trials. Occasionally, findings consistent with chronic intestinal pseudo-obstruction may be revealed or features consistent with mechanical obstruction identified in patients in whom they
had not been detected radiographically. A normal antroduodenal manometry result may be of value in patients with unexplained nausea and vomiting: by demonstration of normal motor function in the antrum and the duodenum, any lingering questions regarding dysmotility can be resolved and the diagnostic evaluation redirected elsewhere.

Steinbrückner and associates (1996) reported that a motility pattern consisting of continuous simultaneous contractions at high frequency from the antrum down to the upper jejunum was associated with repeated vomiting.

Verhagen and colleagues (1999) evaluated the outcome of antroduodenal manometry studies and their effect on the clinical treatment of patients. Nausea and vomiting were the most predominant symptoms (37.4 %). In 49.5 % of the cases, the test was performed due to suspicion of a generalized motor disorder. A normal outcome was found in 37 studies. Non-specific motor abnormalities were reported in 72 % of the studies with an abnormal outcome. Pseudo-obstruction was diagnosed in 20 %. The manometric studies resulted in a new therapy in 12.6 %, a new diagnosis in 14.9 %, and referral to another specialist in 8 %. A positive clinical impact was found in 28.7 % of the patients. The authors concluded that antroduodenal manometry can be a helpful diagnostic technique in a specialized center.

These findings are in accord with those of Hyman et al (1990), who stated that antroduodenal manometry is a useful technique that elucidates the underlying gastrointestinal motility disorder present in the majority of children and adolescents with severe functional symptoms.

Glia and Lindberg (1998) studied the antroduodenal motor activity in 20 patients to ascertain whether patients with slow-transit constipation may have a generalized intestinal motor disorder. They found a significant proportion of patients with slow-transit constipation have manometric findings that indicate a generalized motor disorder of the gut. However, the clinical significance of these findings is unclear.

Byrne and Quigley (1997) concluded that in the evaluation of suspected foregut motor dysfunction, antroduodenal manometry may provide clinically useful information in selected patients; information which may not be available from standard diagnostic tests, including nuclear medicine gastric-emptying studies.
Stanghellini et al (2000) stated that only patients who remain undiagnosed after extensive traditional work-up and fail repeated courses with medical therapy should be referred for the manometric test.

Ghoshal et al (2008) stated that although antroduodenal manometry (ADM) is an important research tool, experience on its clinical utility is scanty. These researchers reported their experiences on this procedure. All ADM performed as a clinical service, using an 8-channel water perfusion system were retrospectively analyzed. Impact on clinical management was classified as: (i) new diagnosis made, (ii) change in management (e.g., new drug, decision regarding surgical treatment), (iii) further special investigation done, and (iv) referral to another specialty. Antroduodenal manometry was successful in 32/33 (97 %) patients (age of 30 years; range of 8 to 71); 6 patients were less than 12 years old. Clinical impression before ADM was: chronic intestinal pseudo-obstruction (CIPO) in 16 (50 %), suspected gastroparesis in 11 (34.3 %), dyspepsia in 5 (15.6 %). Consequent to ADM in patients with CIPO, a new diagnosis was made in 2 (intestinal neuronal dysplasia and celiac disease), new drugs were started in 5, surgery was performed in 3 and specific referral was sought in 3. Antroduodenal manometry confirmed gastroparesis in 9 of 11 patients. A new diagnosis was made in 3 patients, new drugs were started in 3, and 3 were referred. In 5 dyspeptic patients, ADM was normal and no therapy was suggested. Overall, 11 patients with CIPO and 4 with gastroparesis benefited after ADM. The authors concluded that ADM was found useful in CIPO and gastroparesis, helped in decision-making regarding surgery; however in non-specific indications its utility was limited.

Sha and colleagues (2009) evaluated gastric slow waves, antral and duodenal motility simultaneously, and ascertained the correlation among all these measures in patients with functional dyspepsia. A total of 31 patients with functional dyspepsia were assessed for severity of upper gastrointestinal symptoms with the electrogastrography (EGG) and ADM. The EGG and ADM were recorded for 3 to 4 hours in the fasting state and for 2 hours after a solid meal. Computerized spectral analysis methods were used to compute various EGG parameters. The EGG was abnormal in 71.0 % of patients. The abnormalities included normal slow waves lower than 70 % in the fasting state (51.6 % of patients) and in the fed state (48.4 % of patients), a decrease in dominant power in 28.9 % of patients. Antral motility was abnormal in 80.6 % of patients and duodenal motility was abnormal in 74.2 % of patients. For the EGG and antral motility, 19 of 31 patients had both abnormal EGG and abnormal antral motility; 2 of 31 patients had both normal EGG and
normal antral motility. For the EGG and duodenal motility, these values were 16/31 and 2/31, respectively. By both EGG and ADM, abnormal gastric motor function was found in 93.5 % of patients. However, quantitative one-to-one correlation between any of the EGG parameters and the antroduodenal dysmotility was not noted. The patients showed high symptom scores especially to upper abdominal pain, nausea, and belch. No one-to-one correlation was noted between the symptom scores and any of the EGG or motility parameters. The authors concluded that more than two-thirds of patients with functional dyspepsia have abnormalities in the EGG and antral/duodenal motility. The sensitivity of these 2 different methods is essentially the same. Electrogastrography and ADM can complement each other in demonstrating gastric motor dysfunction in patients with functional dyspepsia.

Anorectal manometry (AM) measures the pressures of the anal sphincter muscles, the sensation in the rectum, as well as the neural reflexes needed for normal bowel movements. Anorectal manometry uses a pressure sensitive tube to check the sensitivity and function of the rectum. It also measures the ability of the anal sphincter muscles to respond to signals. Anorectal manometry has been used to evaluate patients with chronic constipation or fecal incontinence. The rectal sensation, tone, and compliance test measures the sensory, motor and biomechanical function of the rectum.

Noviello et al (2009) evaluate the role of AM in children with severe constipation. From October 2003 to October 2006, a total of 85 children aged more than 1 year with severe constipation were seen. The mean age was 5 years (range of 1 to 13). At presentation, every child had abdominal and rectal examination in order to identify abdominal distension or fecal masses. Bowel preparation with enemas was performed before AM in patient with a rectal fecaloma. Myoelectric activity of the internal anal sphincter and resting anal tone was recorded; recto-anal inhibitory reflex (RAIR) was tested to exclude Hirschsprung’s disease. Anal tone was considered normal until 50 cm H(2)O. When the RAIR was absent, the patient underwent rectal suction biopsies (RSB) for histology and acetylcholinesterase histochemistry. In cases of normal or high anal tone with the RAIR present, the child had bowel cleaning, medical treatment, 2- and 6-month follow-up. Children with ineffective treatment at follow-up underwent RSB. In case of HD, a laparoscopic-assisted endorectal pull-through (ERPT) according to Georgeson’s technique was performed. A total of 70 % of the patients had bowel preparation before AM. In 4 patients the AM was impossible to assess because of crying. In
28 patients, the anal tone result was higher than 50 cm H(2)O and local treatment with anesthetic agents was used for 8 weeks. Seventeen patients underwent RSB: 11 patients with RAIR absent/unclear, 4 non-cooperative children and 2 patients with ineffective medical treatment at follow-up. Hirschsprung's disease was diagnosed in 2 patients and laparoscopic-assisted ERPT was performed. The remaining patients had good results at 6-month follow-up. The authors concluded that AM is a non-invasive diagnostic tool to study the mechanism of defecation in children with constipation in order to prescribe the appropriate treatment. This procedure can be used in every child aged more than 1 year with severe constipation and assessment of the RAIR can select the cases for RSB.

Pucciani and Ringressi (2012) evaluated the clinical usefulness of AM in patients affected by obstructed defecation (OD). Between January 2007 and December 2010, a total of 379 patients (287 women and 92 men) affected by OD were evaluated. After a preliminary clinical evaluation, defecography and AM were performed. The results were compared with those from 20 healthy control subjects. Overall anal resting pressure was not significantly different between patients and controls. Maximal voluntary contraction (MVC) data were significantly lower when compared with those of controls (p < 0.01). The straining test was considered positive in 143 patients. No significant difference was noted between patients and controls in maximal tolerated volume data. Patients had a significantly higher conscious rectal sensitivity threshold than controls (p < 0.02). The authors concluded that a positive straining test, low MVC and impaired rectal sensation are the main abnormalities detected by AM in patients with OD.

In a meta-analysis, Videlock et al (2013) estimated the prevalence of abnormal findings associated with dyssynergic defecation (DD) across testing modalities in patients referred for physiological testing for chronic constipation (CC). Systematic search of MEDLINE, EMBASE and PUBMED databases were conducted. These researchers included full manuscripts reporting DD prevalence in CC, and specific findings at pelvic floor diagnostic tests. Random effects models were used to calculate pooled DD prevalences (with 95 % confidence interval [CI]) according to individual tests and specific findings. A total of 79 studies on 7,581 CC patients were included. The median prevalence of any single abnormal finding associated with DD was 37.2 %, ranging from 14.9 % (95 % CI: 7.9 to 26.3) for absent opening of the ano-rectal angle (ARA) on defecography to 52.9 % (95 % CI: 44.3 to 61.3) for a dyssynergic pattern on ultrasound. The prevalence of a dyssynergic pattern on AM was 47.7 % (95 % CI: 39.5 to 56.1). The prevalence of DD was similar across
specialty and geographic area as well as when restricting to studies using Rome criteria to define constipation. The authors concluded that dyssynergic defecation is highly prevalent in CC and is commonly detected across testing modalities, type of patient referred, and geographical regions. They believed that the lower prevalence of findings associated with DD by defecography supports use of AM and balloon expulsion testing as an initial evaluation for CC.

The consensus statement of the Italian Association of Hospital Gastroenterologists and Italian Society of Colo-Rectal Surgery (AIGO/SICCR) on “Diagnosis and treatment of chronic constipation and obstructed defecation” (Bove et al, 2012) stated that “Colonic transit and anorectal manometry define the pathophysiologic subtypes. Balloon expulsion is a simple screening test for defecatory disorders, but it does not define the mechanisms. Defecography detects structural abnormalities and assesses functional parameters …. All these investigations are indicated to differentiate between slow transit constipation and obstructed defecation because the treatments differ between these conditions”.

The AGA’s medical position statement on “Constipation” (Bharucha et al, 2013) stated that “A careful digital rectal examination that includes assessment of pelvic floor motion during simulated evacuation is preferable to a cursory examination without these maneuvers and should be performed before referral for anorectal manometry. However, a normal digital rectal examination does not exclude defecatory disorders …. Anorectal manometry and a rectal balloon expulsion should be performed in patients who fail to respond to laxatives (Strong Recommendation, Moderate-Quality Evidence)".

Colon manometry or colonic motility testing records intra-luminal pressures within the colon using a manometric catheter, which is positioned endoscopically and clipped to the colonic mucosa. Pressure activity is recorded continuously for a minimum of 6 hours. This test has been proposed to evaluate defecation disorders (e.g., chronic constipation) and motility abnormalities.

**Colonic Manometry (Colonic Motility Testing)**

An American Gastroenterological Association guideline on nausea and vomiting (AGA, 2001) concluded that “the place of such tests of motor function as gastric emptying studies, electrogastrography, and manometry have not been defined, and the yield of such diagnostic studies has not been adequately compared with a
therapeutic trial of an antiemetic and/or prokinetic agents." An American Gastroenterological Association guideline on constipation (AGA, 2000) stated that colonic manometry “is not generally available and is not appropriate for most patients, except in research settings." The consensus opinion of the American Motility Society Clinical GI Motility Testing Task Force on the performance and clinical utility of EGG (Parkman et al, 2003) stated that no therapies have convincingly demonstrated in controlled studies that correcting abnormalities detected by EGG improves upper gastrointestinal symptoms. Proposed clinical indications for performance of EGG in patients with unexplained nausea, vomiting and dyspeptic symptoms must be validated by prospective controlled investigations.

Singh and colleagues (2013) examined if colonic manometric evaluation is useful for characterizing colonic sensorimotor dysfunction and for guiding therapy in slow transit constipation (STC). In 80 patients (70 females) with STC, 24-hr ambulatory colonic manometry was performed in by placing a 6-sensor solid-state probe, along with assessment of colonic sensation with Barostat. Anorectal manometry was also performed. Manometrically, patients were categorized as having colonic neuropathy or myopathy based on gastro-colonic response, waking response and high amplitude propagated contractions (HAPC); and based on colonic sensation, as colonic hyposensitivity or hypersensitivity. Clinical response to pharmacological, biofeedback, and surgical treatment was assessed at 1 year and correlated with manometric findings. A total of 47 (59 %) patients who had abnormal colonic manometry, with features suggestive of neuropathy (26 %), and myopathy (33 %); 41 % had normal colonic manometry. Patients who had abnormal colonic sensation were 74 % and 61 % had overlapping dyssynergic defecation. Patients with neuropathy were more likely to have colonic hyposensitivity; 64 % of patients with colonic myopathy or normal manometry improved with medical/biofeedback therapy when compared to 15 % with colonic neuropathy (p < 0.01). Selected patients with colonic neuropathy had excellent response to surgery, but many developed bacterial overgrowth. The authors concluded that colonic manometry demonstrated significant colonic sensorimotor dysfunction in STC patients and revealed considerable pathophysiological heterogeneity. They stated that it can be useful for characterizing the underlying pathophysiology and for guiding clinical management in STC, especially surgery. The major drawback of this study was the lack of a controlled comparator group.
Wiklendt et al (2013) developed an automated analysis technique that can reliably differentiate the motor patterns of patients with STC from those recorded in healthy controls. Pancolonic manometric data were recorded from 17 patients with STC and 14 healthy controls. The automated analysis involved calculation of an indicator value derived from cross-correlations calculated between adjacent recording sites in a manometric trace. The automated technique was conducted on blinded real data sets (observed) and then to determine the likelihood of positive indicator values occurring by chance, the channel number within each individual data set were randomized (expected) and reanalyzed. In controls, the observed indicator value (3.2 ± 1.4) was significantly greater than that predicted by chance (0.8 ± 1.5; p < 0.0001). In patients, the observed indicator value (-2.7 ± 1.8) did not differ from that predicted by chance (-3.5 ± 1.6; P = 0.1). The indicator value for controls differed significantly from that of patients (p < 0.0001), with all individual patients falling outside of the range of indicator values for controls. The authors concluded that automated analysis of colonic manometry data using cross-correlation separated all patients from controls. They stated that this automated technique indicated that the contractile motor patterns in STC patients differ from those recorded in healthy controls. The analytical technique may represent a means for defining subtypes of constipation. The major drawback of this study was its small sample size (n = 17).

An UpToDate review on “Motility testing: When does it help?” (Lembo, 2014) states that “Specialized motility tests such as antroduodenal manometry, electrogastrography, and colonic manometry are under development and will not be discussed”. Furthermore, an UpToDate review on “Constipation in children: Etiology and diagnosis” (Ferry, 2014) discusses the use of AM as well as colon transit studies; however, it does not mention colonic manometry/colonic motility testing.

Dinning et al (2015) stated that in the esophagus, high-resolution manometry (HRM) has become a standard diagnostic tool in the investigation of suspected motility disorders. However, at the opposite end of the digestive tract (i.e., the colon and anorectum), the use of HRM still remains in its infancy, with relatively few published studies in the scientific literature. Further, the clinical utility of those studies that have been performed is largely undetermined. These investigators reviewed all of the HRM studies published to date from both the colon and anorectum, explored the catheter types used, and attempts to determine the worth of HRM over traditional “low-resolution” recordings from the same regions.
Koppen and colleagues (2016) stated that children with intractable functional constipation (FC) may eventually require surgery, often guided by motility testing. However, there are no evidence-based guidelines for the surgical management of intractable FC in children. These investigators evaluated the diagnostic and surgical approach of pediatric surgeons and pediatric gastroenterologists towards children with intractable FC. A survey was administered to physicians attending an international conference held simultaneously in Columbus, OH and Nijmegen (the Netherlands). The survey included 4 questions based on cases with anorectal and colonic manometry results. A total of 74 physicians completed the questionnaire. Anorectal manometry was used by 70%; 52% of them would consider anal sphincter botulinum toxin injections for anal achalasia and 21% would use this to treat dyssynergia. Colonic manometry was used by 38%; 57% of them reported to use this to guide surgical decision-making. The surgical approach varied considerably among responders answering the case questions based on motility test results; the most commonly chosen treatments were antegrade continence enemas and anal botulinum injections. The authors concluded that surgical decision-making for children with intractable FC differs among physicians. They stated that there is a need for clinical guidelines regarding the role of anorectal and colonic manometry in surgical decision-making in children with intractable FC.

An UpToDate review on “Etiology and evaluation of chronic constipation in adults” (Wald, 2017) states that “Colonic manometry evaluates intraluminal pressure activity of the colon and rectum and provides detailed information about the qualitative aspects such as pattern of motor activity and quantitative aspects of colonic motility. It can be combined with a barostat apparatus to assess colonic tone, compliance, and sensation. Patients can be identified to have normal, myopathic, or neuropathic colon as well as sensory dysfunction. As yet, there is no evidence that such information has added value to the management of chronic constipation in clinical practice and this test is available for clinical use in only selected centers”.

In summary, there is currently insufficient evidence regarding the effectiveness of colon manometry or colonic motility testing. Patient selection criteria and the role of colonic manometry in the management of motility abnormalities (e.g., refractory constipation) must be better defined in well-designed studies.
Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+:"

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<th>Code</th>
<th>Code Description</th>
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<tr>
<td></td>
<td>CPT codes covered if selection criteria are met:</td>
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<tr>
<td>91120</td>
<td>Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)</td>
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<tr>
<td>91122</td>
<td>Anorectal manometry</td>
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<td>CPT codes not covered for indications listed in the CPB:</td>
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<td>91117</td>
<td>Colon motility (manometric) study, minimum 6 hours continuous recording (including provocations tests, eg, meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report</td>
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<td>Other CPT codes related to the CPB:</td>
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<td>43235</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)</td>
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<td>91010</td>
<td>Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report</td>
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<td>91020</td>
<td>Gastric motility (manometric studies)</td>
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<td>ICD-10 codes covered if selection criteria are met (not all-inclusive):</td>
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<td>K31.84</td>
<td>Gastroparesis</td>
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<tr>
<td>K56.0 - K56.7</td>
<td>Paralytic ileus and intestinal obstruction without hernia [includes chronic intestinal pseudo-obstruction]</td>
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<tr>
<td>K59.8</td>
<td>Other specified functional intestinal disorders</td>
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<tr>
<td>R11.0 - R11.2</td>
<td>Nausea and vomiting</td>
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</tbody>
</table>

The above policy is based on the following references:


23. Lembo AJ. Motility testing: When does it help? UpToDate [online serial]. Waltham, MA: UpToDate; reviewed April 2014.
29. Rosen R, Garza JM, Tipnis N, Nurko S. An ANMS-NASPGHAN consensus

30. Sanghavi RM, Medina-Centeno R, Barth B. Single balloon-assisted
colonoscopy for placement of colonic manometry catheters: Initial
ahead of print].
Amendment to
Aetna Clinical Policy Bulletin Number: 0616
Gastrointestinal Manometry

For the Pennsylvania Medical Assistance Plan, procedure 91117, colon motility study with manometry will be considered for medical necessity on a case by case basis.