

Gastrointestinal Motility and Manometry Testing	
Type: Medical Necessity and Investigational / Experimental	Policy Specific Section: Medicine
Original Policy Date: February 24, 1993	Effective Date: January 21, 2011

Description

Manometry is a measurement of pressure within various portions of the gastrointestinal (GI) tract. Manometry is performed by passing a catheter containing solid-state or liquid-filled pressure transducers through the mouth or anus into the lumen of the organ to be studied. Manometry typically evaluates motility disorders in patients with negative studies for structural lesions and may be used in the esophagus, stomach, duodenum, sphincter of Oddi, and rectum.

Policy

Esophageal manometry is considered **medically necessary** for **any** of the following indications:

- To establish the diagnosis of dysphagia when obstruction (e.g., a stricture) cannot be found
- For placement of intraluminal devices (e.g., pH probes) when positioning depends on the relationship to functional landmarks, such as the lower esophageal sphincter
- For the preoperative assessment of patients being considered for anti-reflux surgery if there is any question of an alternative diagnosis, especially achalasia
- For the preoperative assessment of peristaltic function in patients being considered for anti-reflux surgery
- For the evaluation of dysphagia in patients who have undergone either anti-reflux surgery or treatment for achalasia

Esophageal manometry is considered **not medically necessary** for **any** of the following indications:

- Making or confirming a suspected diagnosis of gastroesophageal reflux disease
- As the initial test for chest pain or other esophageal symptoms

Antroduodenal manometry is considered **medically necessary** for **either** of the following indications:

- Diagnosis of dyspepsia, gastroparesis or chronic intestinal pseudo-obstruction with unexplained upper gastrointestinal symptoms (e.g., nausea, vomiting) when **both** of the following criteria are met:
 - Gastric emptying or electrogastrography is normal or equivocal
 - Severe symptoms persist despite empiric therapeutic trials of conservative management
- Preoperative evaluation for gastric electrical stimulator (Please refer to the BSC Medical Policy: Gastric Electrical Stimulation)

Antroduodenal manometry is considered **investigational** for **all other** indications.

Colonic manometry is considered **investigational** for **all** indications.

Anorectal manometry is considered **medically necessary** for **either** of the following indications:

- Failure of conservative treatment, an otherwise negative diagnostic evaluation and **any** of the following:
 - Fecal incontinence due to functional weakness of one or both sphincter muscles
 - Pelvic floor dyssynergia
 - Hirschsprungs disease
 - Anatomic defects of the anal sphincters
- Preoperative evaluation for defecation disorders

Rectal sensory testing is considered **medically necessary** for fecal incontinence.

Anal canal sensory testing is considered **not medically necessary** for constipation or fecal incontinence.

Policy Guideline

There is no specific code for colonic manometry with and without provocation, or anal canal sensory testing.

Conservative care may consist of education and counseling regarding bowel function, diet (high fiber and increased fluids), laxatives (bulk agents as first line and osmotic agents as second line therapy), modification of current therapy (e.g. where the patient is on opioids), physical activity and behavioral therapies.

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:

http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Rationale

Esophageal Manometry

Esophageal manometry measures the pressure in the upper and lower esophageal sphincters, determines the effectiveness and coordination of propulsive movements, and detects abnormal contractions. Esophageal manometry has evolved from a research tool to a diagnostic modality with wide availability. However, it is not indicated as a screening tool and should be performed only when a diagnosis has not been achieved by careful history, barium radiology, or endoscopy.

Numerous studies have demonstrated manometric abnormalities associated with gastroesophageal reflux disease (GERD) but, from a diagnostic viewpoint, the utility of each is limited by issues of sensitivity or specificity (Castell et al., 2005).

In 2005, the American Gastroenterological Association (AGA) published both a Medical Position Statement and a Technical Review on the Clinical Use of Esophageal Manometry (Pandolfino & Kahrilas, 2005; Castell et al., 2005). The summary of the AGA Medical Position Statement (2005) recommendations for the clinical use of esophageal manometry state:

Indications for esophageal manometry:

- To establish the diagnosis of dysphasia when obstruction (e.g., a stricture) cannot be found. This is particularly important if achalasia is suspected
- For placement of intraluminal devices (e.g., pH probes) when positioning depends on the relationship to functional landmarks, such as the lower esophageal sphincter
- For the preoperative assessment of patients being considered for anti-reflux surgery if there is any question of an alternative diagnosis, especially achalasia

Possible indications for esophageal manometry:

- For the preoperative assessment of peristaltic function in patients being considered for anti-reflux surgery
- For evaluation of dysphagia in patients who have undergone either anti-reflux surgery or treatment for achalasia

Esophageal Manometry is not indicated:

- For making or confirming a suspected diagnosis of GERD
- As the initial test for chest pain or other esophageal symptoms because of the low specificity of the findings and the low likelihood of detecting a clinically significant motility disorder

This policy is consistent with the conclusions of the 2005 AGA Medical Position Statement for the Clinical Use of Esophageal Manometry.

Antroduodenal Manometry

Antroduodenal manometry (ADM) is used to measure the contractile activity of the distal stomach and duodenum. Changes in intraluminal pressure of the stomach and duodenum are measured through perfusion ports or solid-state transducers incorporated into a catheter that is positioned under fluoroscopic guidance. Results are recorded and may be analyzed either by direct visual inspection or by using a computer. Recordings may last from five hours (stationary study) to 24 hours (ambulatory study).

Intraluminal 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. 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.

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.

A technical review on nausea and vomiting from the AGA states that if tests of gastric function reveal delayed emptying or abnormal myoelectrical activity, ADM is of little added value (Hammer et al., 2001). The review continues:

- Antroduodenal manometry may be indicated when gastric emptying or electrogastrography (EGG) results are normal or equivocal and severe symptoms persist despite empiric therapeutic trials
- Occasionally, findings consistent with chronic intestinal pseudo-obstruction with mechanical obstruction may be identified in patients with negative radiographic studies
- A normal ADM result may be of value in patients with unexplained nausea and vomiting to rule out a diagnosis of dysmotility, or a demonstration of normal motor function in the antrum and duodenum

A technical review on gastroparesis from the AGA (Barnett et al., 2004) lists the proposed indications for ADM:

- Characterization of motor dysfunction in patients with unexplained nausea and vomiting
- Delineation of the cause of gastric or small bowel stasis (e.g., visceral neuropathy or myopathy)
- Support of a suspected diagnosis of chronic intestinal pseudo-obstruction

There is no consensus regarding the management of patients with gastroparesis who do not respond to antiemetic or prokinetic therapy, or who develop severe medication-induced side effects. Non-pharmacologic treatment for patients who are truly refractory to all attempts at pharmacotherapy and with severe gastroparesis, may include gastrostomy-tube decompression and percutaneous endoscopic jejunostomy (PEJ) feeding, parenteral nutrition, or compassionate use of gastric electrical stimulation (Barnett et al., 2004; Abell et al., 2006; Camilleri, 2007). The use of gastric stimulation is based largely on small case series, its mechanism of action is unclear and no long-term randomized trials have been conducted. Further investigation is needed to confirm the effectiveness of gastric stimulation for refractory gastroparesis.

Ghoshal et al., (2008) stated that although ADM is an important research tool, data on its clinical utility is scanty. All ADM performed as a clinical service during a six year period (2001 to 2006) using an 8-channel water perfusion system were retrospectively analyzed. Impact on clinical management was classified as: new diagnosis made, change in management (e.g., new drug, decision regarding surgical treatment), further special investigation done, or referral to another specialty. Antroduodenal manometry was successful in 32 of 33 (97%) patients. The authors concluded that ADM was found useful in chronic intestinal pseudo-obstruction and gastroparesis and 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, to ascertain the correlation among all these measures in patients with functional dyspepsia. A total of 31 patients were assessed for severity of upper gastrointestinal (GI) symptoms with EGG and ADM. The EGG and ADM were recorded for three to four hours in the fasting state and for two hours after a solid meal. The authors concluded more than two-thirds of patients with functional dyspepsia had abnormalities in EGG and antral/duodenal motility. The sensitivity of these two different methods was essentially the same. Electrogastrography and ADM can complement each other in demonstrating gastric motor dysfunction in patients with functional dyspepsia.

Colonic manometry

Colonic motility studies are used to assess the flow of intraluminal contents, the motions of the colonic wall that induce flow, and the control systems that integrate and regulate these processes. The approaches employed have consisted of manometric techniques to record colonic contractions, barostatic methods to measure colonic tone, and recordings of myoelectric signals from the colon that initiate and control muscular contractions. However, the study of colonic motility in a clinical setting proves to be difficult. Accurate positioning of the probes via colonoscopy requires pre-procedure cleansing of the colon, which raises the possibility of altered physiology. In contrast to other segments of the GI tract, contents move through the colon in hours or days, instead of seconds to minutes; thus, prolonged observations are needed. Moreover, in contrast to the upper GI tract, in which reliable manometric recordings can be obtained, the larger diameter of the colon hinders the accurate detection of manometric events. Furthermore, interpretation of intraluminal pressure measurements is complicated, as many contractions of the colonic wall do not occlude the lumen and therefore are detectable by manometry only if they cause significant pressure changes. Finally, all of these techniques,

which continue to be used extensively in a research context, have not yet been standardized for routine clinical use.

An AGA guideline on constipation (Locke et al., 2000) stated that colonic manometry "is not generally available and is not appropriate for most patients, except in research settings."

Van den Berg et al., (2009) evaluated the relationship between colonic manometry and biopsy specimens of children prior to surgery. Study participants included children with Hirschsprung disease (n = 4), chronic intestinal pseudo-obstruction (n = 1), and idiopathic intractable constipation (n = 8). Thirty-seven ganglionic segments were studied. In this cohort, the researchers were unable to classify specific manometric findings as reflective of myopathic or neuropathic abnormalities in patients with motility disorders. The researchers advised caution when predicting the type of neuromuscular disorder based on colonic manometry.

No additional studies were identified to evaluate if the use of colonic manometry would result in improved health outcomes of patients with defecation disorders. The data is inadequate to permit scientific conclusions.

Anorectal manometry/Sensory Testing

Anorectal manometry evaluates the anorectal sphincter mechanism and rectal sensation in patients by means of a pressure transducer in the anus. Established standards resulting in satisfactory measurements of anal canal pressures and anal sphincter responses include open-tipped or side-opening water-perfused catheters, direct online solid-state microtransducers or air- or water-filled balloons of various sizes and configurations.

In patients with chronic constipation, anal manometry and a rectal balloon expulsion test, occasionally supplemented by defecography, are useful to identify a functional defecatory disorder. In fecal incontinence, diagnostic testing complements the clinical assessment for evaluating the pathophysiology and guiding management. Manometry measures anal resting and squeeze pressures, which predominantly reflect internal and external anal sphincter function, respectively. Defecation may be indirectly assessed by measuring the recto-anal pressure gradient during straining and by the rectal balloon expulsion test.

In 1999, the AGA published a Technical Review and a Medical Position Statement on Anorectal Testing Techniques (Barnett et al., 1999). The tests included in this review assessed characteristics of defecation and continence, and the sensory mechanisms involved in symptom production. The Medical Position Statement stated:

- Clinical practice and uncontrolled studies suggest the following indications for anorectal manometry: (1) fecal incontinence - to define functional weakness of one or both sphincter muscles, in which anal endosonography is complimentary in demonstrating whether this weakness is caused by anatomic derangement, and to perform and predict response to biofeedback training; (2) pelvic floor dyssynergia - to support findings of other tests and to perform, monitor outcome, and possibly predict response to biofeedback training; (3) Hirschsprung's disease; (4) anatomic defects of the anal sphincters - vectormanometry, if no other method (e.g., ultrasonography) is available, in which six to eight radially oriented recording sites are necessary for adequate resolution.
- Sensory Testing

- o Rectal sensation: (1) significant loss of the ability to sense rectal distention (rectal sensory threshold) is a sufficient but not a necessary condition for fecal incontinence; (2) the first detectable sensation (rectal sensory threshold) to rectal balloon distention is of value in the biofeedback training of patients with fecal incontinence (normalization or reduction of the threshold correlates with success), and poor or absent sensation makes a good response unlikely; (3) the maximum tolerable volume, if less than 100 mL, may have value in indicating the presence of visceral hypersensitivity, poor rectal compliance, or rectal irritability, and thereby influence the direction of therapy; and (4) in patients with constipation, there is insufficient information to support use of sensory thresholds for diagnosis and biofeedback training.
- o Anal canal sensation: at present, assessment of anal canal sensation is not of established value for the diagnosis and management of constipation or fecal incontinence.

The results of 372 anorectal manometries (ARM) performed consecutively in children with chronic constipation were evaluated (Morais et al., 2005). Absence of the inhibitory recto-anal reflex was considered suggestive of Hirschsprung's disease and diagnosis was confirmed by traditional diagnostic methods. Absence of the inhibitory recto-anal reflex was found in 14 (3.8%) of the 372 anorectal manometry examinations. Diagnosis of Hirschsprung disease was confirmed in nine out of 14 patients by characterization of aganglionosis upon rectal biopsy. In the other five patients, rectal biopsy was not performed in view of a satisfactory evolution with the clinical treatment for constipation. In four out of the five patients the inhibitory recto-anal reflex was demonstrated with a second anorectal manometry examination. The authors concluded ARM accurately identified a small group of patients in which more than half had Hirschsprung's disease.

A review states ARM is an important tool in testing anorectal disorders (Karoui et al., 2005). The step-by-step ARM using a small balloon tube is easy to perform, well standardized and reproducible. The parameters studied by ARM are the rectoanal inhibitory reflex, anal resting pressure, sustained voluntary contraction of anal canal and rectal sensation. The most important indications include anal incontinence, distal constipation and preoperative evaluation before sphincteroplasty or surgical rectocele repair.

A systematic review was conducted to determine and compare the diagnostic accuracy of contrast enema (CE), ARM and rectal suction biopsy (RSB) in infants suspected of Hirschsprung disease (de Lorijn F et al., 2006). Searches were limited to articles published after 1966 in PubMed and after 1980 in EMBASE.com. The most accurate test was RSB (14 studies for a total of 993 patients). Sensitivity and specificity of ARM (nine studies for a total of 400 patients) were similar to those of RSB, while CE (12 studies for a total of 425 patients) were significantly lower than those of RSB and ARM. The authors concluded RSB and ARM are the most accurate tests in the diagnostic workup of Hirschsprung disease.

Constipation of obstructed defecation may be due to mechanical causes or functional disorders of the anorectal region. Mechanical causes may be related to morphological abnormalities of the anorectum (e.g., megarectum, rectal prolapse, rectocele, enterocele, neoplasms, and stenosis). Functional disorders are associated with neurological disorders and dysfunction of the pelvic

floor muscles or anorectal muscles (e.g., anismus, descending perineum syndrome, Hirschsprung's disease). A review by Andromanakos et al., (2006) states, "evaluation of patients with severe constipation includes a good history, physical examination and specialized investigations (colonic transit time, anorectal manometry, rectal balloon expulsion test, defecography, EGG), which contribute to the diagnosis and the differential diagnosis of the cause of the obstructed defecation."

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy

Type	Number	Description
CPT	0240T	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with 3-dimensional high resolution esophageal pressure topography
	0241T	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with stimulation or perfusion during 3-dimensional high resolution esophageal pressure topography study (eg, stimulant, acid or alkali perfusion) (List separately in addition to code for primary procedure)
	91010	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study;

Type	Number	Description
	91013	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with stimulation or perfusion during 2-dimensional data study (eg, stimulant, acid or alkali perfusion) (List separately in addition to code for primary procedure)
	91020	Gastric motility (manometric) studies
	91022	Duodenal motility (manometric) study
	91117	Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, eg, meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report
	91120	Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)
	91122	Anorectal manometry
HCPC	None	
ICD9 Procedure		
	89.32	Esophageal manometry
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider **MUST** confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Documentation Required for Clinical Review

Pre Service

- Diagnostic test results, including endoscopy, gastric emptying, colonic transit time, electrogastrography
- History and physical including: previous treatment plan and response

Post Service

- History and physical including: previous treatment plan and response
- Manometry results
- Diagnostic test results including:
 - Colonic transit time
 - Electrogastrography
 - Endoscopy
 - Gastric emptying

Tables

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Gastric Electric Stimulation

Definitions

Chronic intestinal pseudo-obstruction (CIPO) - A rare motility disorder where coordinated contractions (peristalsis) in the intestinal tract become altered and inefficient, negatively

impacting nutrient absorption. The most common symptoms in children are nausea, vomiting, abdominal distention and pain, and constipation. Diarrhea, early satiety (fullness), food aversion, and weight loss may also be present. Over time, CIPO can cause bacterial infections, malnutrition, and muscle problems in other parts of the body.

Achalasia - A rare swallowing disorder in which the lower esophageal sphincter fails to relax, creating a barrier that prevents food and liquids from passing into the stomach, and the lower two-thirds of the esophagus does not propel food toward the stomach properly.

Barostatic - A pressure-sensing device to measure gastric accommodation and/or peristaltic motility in the gastrointestinal (GI) tract, including the esophagus, stomach, and the small and/or large intestines. The device consists of catheters with balloons and an electronic controller that varies the amount of air in the balloon to maintain constant pressure. This device is used mainly in research studies assessing sensory threshold and altered visceral perception, particularly in functional GI disorders.

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Key / Related Searchable Words

N/A

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
2/24/1993	New Policy Adoption	Medical Policy Committee
8/1/2000	Administrative Review	Administrative Review
3/1/2001	Removed from Archives	Medical Policy Committee

Effective Date	Action	Reason
4/2/2010	Policy title change from Gastroduodenal and Colonic Motility Studies Policy revision with position change	Medical Policy Committee
1/21/2011	Coding Update	Administrative Review

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.