Gastroparesis evaluations

Clinical Policy ID: CCP.1357

Recent review date: 2/2025

Next review date: 6/2026

Policy contains: Gastric emptying breath test; gastric emptying scintigraphy; gastroparesis; wireless motility capsule.

Coverage policy

Gastroparesis evaluation is clinically proven and, therefore, may be medically necessary when all of the following criteria are met (Camilleri, 2022; Schol, 2021):

- Presence of symptoms of suspected gastroparesis, including, but not limited to, nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal pain.
- Absence of demonstrable mechanical obstruction of the gastric outlet.
- Non-diagnostic basic clinical investigations, including upper endoscopy.
- Documentation of delayed gastric emptying by either:
    - Gastric emptying scintigraphy of a radiolabeled solid meal.
        - If gastric emptying scintigraphy is contraindicated or not feasible, a wireless motility capsule (e.g., SmartPill™ Motility Testing System, Medtronic Inc., Minneapolis, Minnesota) or stable isotope breath test may be used.
- Evaluation by a gastroenterologist trained to use and interpret the results.

Limitations

All other modalities of verification of delayed gastric emptying in the absence of demonstrable mechanical obstruction of the gastric outlet are not medically necessary.

Contraindications to the wireless motility capsule include a history of gastric bezoar, swallowing disorders, dysphagia, suspected strictures/fistulae in the gastrointestinal tract, physiologic gastrointestinal obstruction, gastrointestinal surgery within the previous three months, Crohn's disease, diverticulitis, or those who have an implanted electromechanical medical device (such as pacemaker or infusion pump) (Rao, 2011).

The wireless motility capsule is investigational/not clinically proven and, therefore, not medically necessary in pediatric members, as it has not been approved for use in this population (U.S. Food and Drug Administration, 2017).

Alternative covered services

Routine patient evaluation and management by a network health care provider.

Background

Gastroparesis is a gastric motility disorder characterized by delayed gastric emptying of fluids and/or solids without evidence of a mechanical gastric outlet obstruction (Saliakellis, 2013). Approximately three of four cases of gastroparesis are idiopathic or related to diabetes mellitus (Ye, 2021). Among individuals with diabetes, the pathogenic changes in gastrointestinal function can damage the enteric nervous system leading to gastrointestinal motility disorders and increased disease morbidity (Rodrigues, 2012). Gastroparesis is associated with significant psychological distress and poor quality of life (Woodhouse, 2017).

Individuals typically present with nonspecific symptoms that may indicate several possible gastric disorders. These symptoms include nausea, vomiting, early satiety, postprandial fullness, bloating, weight loss, and upper abdominal pain. The differential diagnosis can be particularly challenging in children, in whom the most common symptoms are typically age-dependent. For example, nausea and abdominal pain are more frequent in older children and adolescents, while vomiting is more frequent in younger children (Usai-Satta, 2020).

Evaluation and management of suspected gastroparesis requires documentation of delayed gastric emptying and exclusion of other potential causes. Gastric emptying scintigraphy using Technecium-99, gastric emptying C13-spirulina (C13) breath testing, and wireless capsule endoscopy are available diagnostic alternatives. An upper gastrointestinal barium contrast study and esophagogastroduodenoscopy can rule out mechanical obstruction. Tests of gastric, small intestinal, and colonic motor function may provide adjunctive physiologic information for diagnosing and guiding the management of gastrointestinal dysmotilities (Usai-Satta, 2020).

Findings

Current available evidence, which consists of multiple clinical guidelines, systematic reviews, meta-analyses, and narrative reviews of generally moderate quality, collectively endorses scintigraphy as the standard diagnostic method.

Clinical Guidelines from Medical Societies

An updated guideline by the American College of Gastroenterology recommends gastric emptying scintigraphy of a solid phase meal as the standard test for its ability to provide a noninvasive, direct, and quantifiable measure of gastric emptying (Camilleri, 2022). This test is most reliable when measuring emptying of a solid meal over at least three hours (strong recommendation, moderate level of evidence). Additional guidance suggests that

radiopaque marker testing is not advised (conditional recommendation, very low level of evidence), and that wireless motility capsule testing or stable isotope carbon-13 breath testing may be considered alternatives to scintigraphy (conditional recommendation, low quality of evidence).

The American and European Neurogastroenterology and Motility Societies similarly note that wireless motility capsules and breath tests are safe, validated, and radiation-free options when scintigraphy is not feasible or is contraindicated, such as in pregnant women, breastfeeding women, and children (Rao, 2011). These societies also highlight scintigraphy and wireless motility capsules for assessing both regional and whole-gut transit, and recognize breath testing with lactulose for semiquantitative assessment of small bowel transit (Rao, 2011).

A subsequent European consensus group states that upper gastrointestinal endoscopy is mandatory for diagnosing gastroparesis, with scintigraphy, breath testing, wireless motility capsule assessment, and gastric ultrasound all valid diagnostic tools for this condition (Schol, 2021). The International Foundation for Gastrointestinal Disorders (2023) also notes that scintigraphy remains the standard for diagnosing gastroparesis, requiring an individual to ingest a meal with a radioactive tracer, then measuring the stomach's emptying rate over two to four hours.

Most recently, the American Neurogastroenterology and Motility Society, along with several other international organizations, reached consensus on diagnostic criteria that center on nausea or vomiting as cardinal symptoms, confirm delayed gastric emptying via four-hour solid-meal scintigraphy or carbon-13 breath testing, and exclude mechanical obstruction by endoscopy (Schol, 2025). The panel endorsed mixed-macronutrient meal testing and did not recommend wireless motility capsule assessment; however, no new coverage changes were indicated.

Systematic Reviews

In a systematic review, Stein (2013) identified the wireless motility capsule as an effective modality for diagnosing both gastric and colonic motility disorders when compared with other tests of motility. Although seven studies established comparable accuracy to scintigraphy for detecting delayed gastric emptying (sensitivity ranging from 59% to 86%, specificity from 64% to 81%), the review noted low quality of evidence overall. Variability in reporting and built-in bias (e.g., preselection of individuals likely to test positive) were the main limitations, but the wireless motility capsule remains a viable, useful test.

Another systematic review and meta-analysis examined gastric electrical activity monitoring in adults with delayed gastric emptying (Peralta-Palmezano, 2024). The authors included 31 studies (1,545 individuals with the condition and 340 controls) and found that delayed gastric emptying correlated with lower rates of normal gastric electrical patterns, higher rates of slow and fast electrical patterns, and reduced post-meal electrical response. Despite these findings, wide methodological variations limit the clinical use of this monitoring.

A further systematic review of 23 studies assessed persons with gastric emptying problems or upper gastrointestinal symptoms who were administered promotility agents (Vijayvargiya, 2019a). Outcomes were significantly better (P = .02) in those who received optimal testing (scintigraphy, breath test, or use of a solid meal longer than two hours) compared to those with suboptimal tests. This underscores the importance of standardized, validated diagnostic methods.

Lastly, a systematic review and meta-analysis screened 344 records from four databases and included nine studies (n = 1,700) of children who underwent gastric emptying scintigraphy at both two and four hours (Shargo, 2024). About 30% demonstrated delayed gastric emptying at two hours, increasing to 40% at four hours,

reflecting a 10% additional diagnostic yield. Twenty percent shifted from normal to delayed (or vice versa) between the two-hour and four-hour time points. Although heterogeneity ($I^2 > 90\%$) was high due to variation in protocols and meal composition, this review reinforces four-hour scintigraphy as beneficial, even in pediatric settings.

Meta-Analyses

In a meta-analysis of 25 studies (n = 4,287), delayed gastric emptying measured by either scintigraphy or breath tests showed a statistically significant correlation with early satiety and fullness in individuals with gastroparesis (Vijayvargiya, 2019b). These findings further support the use of validated tests that extend beyond two hours when assessing upper gastrointestinal symptoms.

Additional Studies and Narrative Reviews

Butler (2017), in a narrative review, observed that breath tests (for instance, the carbon-13 urea breath test for Helicobacter pylori diagnosis) are especially suitable for children, as the procedure is painless and noninvasive. Various stable isotope breath tests for gastric emptying have been validated against scintigraphy. These tests may rely on hydrogen measurements from nonabsorbable carbohydrates but can show variability once the tracer moves distally beyond the stomach.

Bruno (2013), also in a narrative review, found breath testing using carbon-13 octanoate or spirulina to be safe and valid for measuring the gastric emptying rate of solids in individuals with diabetes suspected of having gastroparesis, correlating well with scintigraphy. However, concurrent diseases, the choice of meal, breath-collection duration, and cutoff parameters can influence results.

A prospective comparison of 150 participants with gastroparesis symptoms demonstrated that wireless motility capsule testing produced more treatment changes, fewer ancillary tests, and increased prescription of prokinetics and laxatives compared to scintigraphy (Hasler, 2019). These results reinforce the potential utility of wireless motility capsule as either a supplementary or alternative diagnostic method.

In 2025, the findings section was condensed and revised thematically. We also added an international consensus statement on idiopathic gastroparesis (Schol, 2025), a systematic review and meta-analysis comparing two-hour versus four-hour gastric emptying scintigraphy protocols in pediatric participants (Shargo, 2024), and a systematic review and meta-analysis examining electrogastrography in adults with gastroparesis (Peralta-Palmezano, 2024).

References

On January 6, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Gastroparesis/diagnosis” (MeSH), “Gastric Emptying” (MeSH), “Breath Tests” (MeSH), “gastroparesis evaluation,” “impedance,” “intestinal motility,” and “wireless endoscopy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

1/2018: initial review date and clinical policy effective date: 3/2018

3/2019: Policy references updated. Wireless motility capsule added and policy ID changed.

2/2020: Policy references updated. Policy coverage modified.

2/2021: Policy references updated.

2/2022: Policy references updated.

2/2023: Policy references updated.

2/2024: Policy references updated.

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