ICD-10 Coding Guide

CPT coding information

NEW ICD-10 Codes

Two unique CPT codes are applicable to administration and analysis of BreathTek® UBT for *H. pylori*. The test is covered by Medicare and most insurance providers.

Procedural codes for *H. pylori* testing

83014	Drug administration and sample collection
83013	*Helicobacter pylori* breath test analysis for urease activity, non-radioactive isotope

Diagnosis codes*†

Several codes associated with *H. pylori* testing include:

Stomach

C16.9 Malignant neoplasm of stomach, unspecified; Gastric cancer NOS

C88.4 Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]

K25.0 Acute gastric ulcer with hemorrhage

K25.0 Acute gastric ulcer with hemorrhage ***AND***
K56.60 Unspecified intestinal obstruction

K25.4 Chronic or unspecified gastric ulcer with hemorrhage

K25.4 Chronic or unspecified gastric ulcer with hemorrhage ***AND***
K56.60 Unspecified intestinal obstruction

K25.7 Chronic gastric ulcer without hemorrhage or perforation

K25.7 Chronic gastric ulcer without hemorrhage or perforation ***AND***
K56.60 Unspecified intestinal obstruction

K25.9 Gastric ulcer, unspecified as acute or chronic, without hemorrhage or perforation

K25.9 Gastric ulcer, unspecified as acute or chronic, without hemorrhage or perforation ***AND***
K56.60 Unspecified intestinal obstruction

K30 Functional Dyspepsia

Gastritis

K29.00 Acute gastritis without bleeding

K29.01 Acute gastritis with bleeding

K29.30 Chronic superficial gastritis without bleeding

K29.31 Chronic superficial gastritis with bleeding

K29.40 Chronic atrophic gastritis without bleeding

K29.41 Chronic atrophic gastritis with bleeding

K29.50 Unspecified chronic gastritis without bleeding

K29.51 Unspecified chronic gastritis with bleeding

K29.70 Gastritis, unspecified, without bleeding

K29.71 Gastritis, unspecified, with bleeding

K29.80 Duodenitis without bleeding

K29.81 Duodenitis with bleeding

K29.90 Gastroduodenitis, unspecified, without bleeding

K29.91 Gastroduodenitis, unspecified, with bleeding

Duodenum

K26.0 Acute duodenal ulcer with hemorrhage

K26.0 Acute duodenal ulcer with hemorrhage ***AND***
K56.60 Unspecified intestinal obstruction

K26.3 Acute duodenal ulcer without hemorrhage or perforation

K26.3 Acute duodenal ulcer without hemorrhage or perforation ***AND***
K56.60 Unspecified intestinal obstruction

K26.4 Chronic or unspecified duodenal ulcer with hemorrhage

K26.4 Chronic or unspecified duodenal ulcer with hemorrhage ***AND***
K56.60 Unspecified intestinal obstruction

K26.9 Duodenal ulcer, unspecified as acute or chronic, without hemorrhage or perforation

K26.9 Duodenal ulcer, unspecified as acute or chronic, without hemorrhage or perforation ***AND***
K56.60 Unspecified intestinal obstruction

Other

B96.81 *Helicobacter pylori* as the cause of diseases classified elsewhere

This reimbursement information is being provided to help the health care professional understand and comply with billing and reimbursement requirements that may apply to products. Use of codes identified here does not guarantee coverage or payment at any specific level. Consult the patient's insurance carrier to verify coverage and reimbursement information.

**Partial list: Please contact individual plans for a list of codes that support medical necessity.*
†The listing of diagnosis codes does not imply that the use of a urea breath test is suitable for all of the conditions shown.

What is BreathTek UBT?

The BreathTek UBT Kit is intended for use in the qualitative detection of urease associated with *H. pylori* in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *H. pylori* infection in adult patients and pediatric patients 3 to 17 years old. The test may be used for monitoring treatment if used at least 4 weeks following completion of therapy. For these purposes, the system utilizes an Infrared Spectrophotometer for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples in clinical laboratories or point-of-care settings.

The BreathTek UBT Kit is for administration by a health care professional, as ordered by a licensed health care practitioner.

Test. Treat. Confirm.

- **Test:** Diagnose if *H. pylori* is the underlying issue[1]
- **Treat:** Consider an FDA-recommended therapy for patients who test positive[2,3]
- **Confirm:** Test again 4 weeks after the end of treatment to allow time for adequate recolonization if eradication is unsuccessful[4,5]

For more information, please visit www.BreathTek.com, or call 888-637-3835.

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.

Otsuka
Medical Device Division of
Otsuka America Pharmaceutical, Inc.

Urea Breath Test for *H. pylori*
BreathTek®

Brief Summary about BreathTek UBT

Intended Use

The BreathTek® UBT for *H. pylori Kit* (BreathTek UBT Kit) is intended for use in the qualitative detection of urease associated with *H. pylori* in the human stomach and is indicated as an aid in the initial diagnosis and post-treatment monitoring of *H. pylori* infection in adult patients and pediatric patients 3 to 17 years old. The test may be used for monitoring treatment if used at least 4 weeks following completion of therapy. For these purposes, the system utilizes an Infrared Spectrophotometer for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples, in clinical laboratories or point-of-care settings. The Pediatric Urea Hydrolysis Rate Calculation Application (*p*UHR-CA), provided as a web-based calculation program, is required to obtain pediatric test results.

The BreathTek UBT Kit is for administration by a health care professional, as ordered by a licensed health care practitioner.

Warnings and Precautions

- For *in vitro* diagnostic use only. The Pranactin®-Citric solution is taken orally as part of the diagnostic procedure and contains Phenylalanine (one of the protein components of Aspartame), 84 mg per dosage unit. (For reference, 12 ounces of typical diet cola soft drinks contain approximately 80 mg of Phenylalanine.)
- A negative result does not rule out the possibility of *H. pylori* infection. False negative results do occur with this procedure. If clinical signs are suggestive of *H. pylori* infection, retest with a new sample or an alternate method.
- False negative test results may be caused by:
  - — Ingestion of proton pump inhibitors (PPIs) within 2 weeks prior to performing the BreathTek UBT. If a negative result is obtained from a patient ingesting a PPI within 2 weeks prior to the BreathTek UBT, it may be a false-negative result and the test should be repeated 2 weeks after discontinuing the PPI treatment. A positive result for a patient on a PPI could be considered positive and be acted upon.
  - — Ingestion of antibiotics, or bismuth preparations within 2 weeks prior to performing the BreathTek UBT
  - — Premature POST-DOSE breath collection time for a patient with a marginally positive BreathTek UBT result
  - — Post-treatment assessment with the BreathTek UBT less than 4 weeks after completion of treatment for the eradication of *H. pylori*.
- False positive test results may be caused by:
  - — Urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmannii* or achlorhydria.
  - — Oral contamination associated with urease containing bacteria especially when not using the straw provided in the BreathTek UBT Kit.
- If particulate matter is visible in the reconstituted Pranactin-Citric solution after thorough mixing, the solution should not be used.
- Patients who are hypersensitive to mannitol, citric acid or Aspartame should avoid taking the drug solution as this drug solution contains these ingredients. Use with caution in patients with difficulty swallowing or who may be at high risk of aspiration due to medical or physical conditions.
- The safety of using the BreathTek UBT Kit during pregnancy and lactation is not established.
- For pediatric test results, the Urea Hydrolysis Rate (UHR) results must be calculated. Delta over Baseline (DOB) results in conjunction with the Pediatric Urea Hydrolysis Rate Calculation Application (*p*UHR-CA), provided as a web-based calculation program, is required to obtain pediatric test results. DOB results **cannot** be used to determine the infection status of pediatric patients. Use the web-based *p*UHR-CA (https://BreathTekKids.com) to calculate the UHR.
- Safety and effectiveness has not been established in children below the age of 3 years.

Adverse Events

During post-approval use of the BreathTek UBT in adults, the following adverse events have been identified: anaphylactic reaction, hypersensitivity, rash, burning sensation in the stomach, tingling in the skin, vomiting and diarrhea. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to establish a causal relationship to drug exposure.

In two clinical studies conducted in 176 (analyzed) pediatric patients ages 3 to 17 years to determine the initial diagnosis and post treatment monitoring of *H. pylori*, the following adverse events experienced by ≥1% of these patients were: vomiting (5.1%), oropharyngeal pain (4.5% to include throat irritation, sore throat, throat burning), nausea (2.3%), restlessness (2.3%), stomach ache/belly pain (1.1%), and diarrhea (1.1%). Most of the adverse events were experienced by patients within minutes to hours of ingestion of the Pranactin-Citric solution.

In another clinical study comparing the UBiT®-IR300 and POCone® in pediatric patients ages 3 to 17 years, the following adverse events were observed among the 99 subjects enrolled: 2 incidences of headache, and 1 incidence each of cough, dry mouth and acute upper respiratory infection.

January 2016 05US161BR0001

Please see accompanying Current Package Insert.

References: 1. Talley NJ, Vakil N; Practice Parameters Committee of the American College of Gastroenterology. Guidelines for the management of dyspepsia. *Am J Gastroenterol.* 2005;100(10):2324-2337. **2.** Chey WD, Wong BCY; Practice Parameters Committee of the American College of Gastroenterology. American College of Gastroenterology guideline on the management of Helicobacter pylori infection. *Am J Gastroenterol.* 2007;102(8):1808-1825. **3.** Vakil N, Megraud F. Eradication therapy for Helicobacter pylori. *Gastroenterology.* 2007;133(3):985-1001. **4.** Graham-Lomax K, Graham DY. *Contemporary Diagnosis and Management of H pylori-Associated Gastrointestinal Diseases.* 3rd ed. Newtown, PA: Handbooks in Health Care Co; 2005. **5.** Vakil N, Fendrick AM. How to test for Helicobacter pylori in 2005. *Cleve Clin J Med.* 2005;72(suppl 2):S8-S13.

Otsuka
Medical Device Division of
Otsuka America Pharmaceutical, Inc.

Urea Breath Test for *H. pylori*
BreathTek®

August 2016 05US16EBP0070