CPT coding information
Two unique CPT codes are available to administrators and analysts of BreathTek® UBT for H. pylori.
These codes are based on Medicare and most insurance provider 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.

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.

Brief Summary about BreathTek UBT

The BreathTek UBT Kit is standardized 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. The BreathTek UBT can be used as an alternative diagnostic test to determine the infection status, unspecified as acute or chronic, without hemorrhage or perforation.

Copyright Statement

©2015 Otsuka America Pharmaceutical, Inc. All rights reserved.

ICD-10 Coding Guide

NEW ICD-10 Codes

Procedural codes for fit testing

E0014 Drug administration and sample collection
E0303 Helicobacter pylori breath test analysis for activity, noninvasive test

Diagnosis codes*†

Several codes associated with H. pylori testing include:

K06.0 Unspecified type of gastritis without hemorrhage or perforation
K06.1 Acute gastritis with hemorrhage or perforation
K06.2 Chronic gastritis with hemorrhage or perforation
K06.3 Acute gastritis without hemorrhage or perforation
K06.4 Chronic gastritis without hemorrhage or perforation
K06.5 Unspecified gastritis
K06.9 Acute or unspecified gastritis
K29.00 Acute gastritis without bleeding
K29.30 Chronic superficial gastritis without bleeding
K29.41 Chronic atrophic gastritis with bleeding
K29.91 Gastroduodenitis, unspecified, with bleeding
K25.30 Acute duodenal ulcer without hemorrhage or perforation
K25.40 Chronic or unspecified duodenal ulcer with hemorrhage
K25.70 Chronic gastric ulcer without hemorrhage or perforation
K25.80 Acute gastric ulcer without hemorrhage or perforation
K26.3 Acute duodenal ulcer without hemorrhage or perforation
K26.4 Chronic or unspecified duodenal ulcer with hemorrhage
K26.7 Acute duodenal ulcer with hemorrhage or perforation
K27.3 Acute or unspecified duodenal ulcer with hemorrhage
K27.4 Chronic or unspecified duodenal ulcer with hemorrhage
K27.7 Acute duodenal ulcer with hemorrhage or perforation
K29.01 Acute gastritis with bleeding
K29.31 Chronic superficial gastritis with bleeding
K29.40 Chronic atrophic gastritis without bleeding
K29.50 Unspecified chronic gastritis without bleeding
K29.71 Gastritis, unspecified, with bleeding
K56.51 Unspecified jejunal obstruction
K56.52 Unspecified ileal obstruction
K56.60 Unspecified intestinal obstruction
K56.90 Unspecified small intestine obstruction

Other

B81.61 Helicobacter pylori on the cause of disease classified elsewhere

What is BreathTek UBT?

The BreathTek UBT Kit is standardized 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. The BreathTek UBT can be used as an alternative diagnostic test to determine the infection status, unspecified as acute or chronic, without hemorrhage or perforation.

CPT coding information

Two unique CPT codes are available to administrators and analysts of BreathTek® UBT for H. pylori. These codes are based on Medicare and most insurance provider 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.

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.

Test. Treat. Confirm.

• Test: Diagnostic if H. pylori is the underlying issue
• Treat: As per FDA-recommended therapy for patients who test positive2,3
• Confirm: Test again 4 weeks after the end of treatment to allow time for adequate resolution if indications is unchanged4

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

Please see accompanying BRIEF SUMMARY and enclosed Current Package Insert.

The BreathTek UBT Kit (BreathTek UBT Kit) is intended for use in the qualitative detection of urease associated with H. pylori in the 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 kit consists of BreathTek®, a breath collection device, a BreathTek® UBT Kit, a BreathTek® POST-DOSE breath collection kit, and a BreathTek® Breathable® UHR-CA, a web-based calculation program, is required to obtain pediatric test results.

Warnings and Precautions

• False negative test results may be caused by:
  - Ingestion of protein 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 result and the result is negative 2 weeks after discontinuing the PPI treatment.
  - Ingestion of antibiotics, or bismuth preparations within 2 weeks prior to performing the BreathTek UBT.
  - Positive test results for a patient on a PPI could be considered positive and be acted upon.

• False positive test results may be caused by urease associated with other gastric spiral organisms observed in humans such as Helicobacter, Campylobacter, and quitinia.

• If a patient matter is unstable in the reconstituted PracinCitr solution after thawing, the solution should not be used.

• Patients who are hypersensitive to mannitol, citric acid or Aspartame should avoid taking the drug solution or this drug solution contains these ingredients. Use with caution in patients with allergy sensitivity or allergy to 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.

• No information is available on the use of the PracinCitr solution during pregnancy.

• For pediatric test results, the Urea Hydrolysis Rate (UHR) results must be calculated. The Delta over Baseline (DOB) results are only used to calculate the UHR metrics to determine H. pylori infection in pediatric patients. DOB results cannot be used to determine the infection status of pediatric patients. Use the web-based pHit-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 Kit in adults, the following adverse events have been identified: anaphylactic reaction, respiratory infection, and mature POST-DOSE breath collection time for a patient with a marginally positive BreathTek UBT result

• False negative test results may be caused by urease associated with other gastric spiral organisms observed in humans such as Helicobacter, Campylobacter, and quitinia.

• If a patient matter is unstable in the reconstituted PracinCitr solution after thawing, the solution should not be used.

• Patients who are hypersensitive to mannitol, citric acid or Aspartame should avoid taking the drug solution or this drug solution contains these ingredients. Use with caution in patients with allergy sensitivity or allergy to 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.

• No information is available on the use of the PracinCitr solution during pregnancy.

• For pediatric test results, the Urea Hydrolysis Rate (UHR) results must be calculated. The Delta over Baseline (DOB) results are only used to calculate the UHR metrics to determine H. pylori infection in pediatric patients. DOB results cannot be used to determine the infection status of pediatric patients. Use the web-based pHit-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 Kit in adults, the following adverse events have been identified: anaphylactic reaction, respiratory infection, and mature POST-DOSE breath collection time for a patient with a marginally positive BreathTek UBT result

• False negative test results may be caused by urease associated with other gastric spiral organisms observed in humans such as Helicobacter, Campylobacter, and quitinia.

• If a patient matter is unstable in the reconstituted PracinCitr solution after thawing, the solution should not be used.

• Patients who are hypersensitive to mannitol, citric acid or Aspartame should avoid taking the drug solution or this drug solution contains these ingredients. Use with caution in patients with allergy sensitivity or allergy to 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.

• No information is available on the use of the PracinCitr solution during pregnancy.

• For pediatric test results, the Urea Hydrolysis Rate (UHR) results must be calculated. The Delta over Baseline (DOB) results are only used to calculate the UHR metrics to determine H. pylori infection in pediatric patients. DOB results cannot be used to determine the infection status of pediatric patients. Use the web-based pHit-CA (https://BreathTekKids.com) to calculate the UHR.

• Safety and effectiveness has not been established in children below the age of 3 years.

References:

Brief Summary about BreathTek UBT

The BreathTek UBT Kit (BreathTek UBT Kit) is intended for use in the qualitative detection of urease associated with H. pylori in the 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. This 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 13CO2 to 12CO2 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.

The listing of diagnosis codes does not imply that the use of a urea breath test is suitable for all of the conditions shown.

• Confirm:
  - Diagnose if
    - H. pylori

Testing include:

• Codes associated with urease associated with other gastric spiral organisms observed in humans such as Helicobacter, Campylobacter, and quitinia.

Two unique CPT codes are applicable to administration and analysis of BreathTek® UBT for

K25.9
K29.30  Chronic superficial gastritis without bleeding
K56.60  Unspecified intestinal obstruction
K25.4    Chronic or unspecified gastric ulcer with hemorrhage
K56.60  Unspecified intestinal obstruction
K25.0    Acute gastric ulcer with hemorrhage
K25.0    Acute gastric ulcer with hemorrhage
C88.4
H. pylori
hemorrhage or perforation
Gastric ulcer
hemorrhage or perforation
Gastric ulcer
mucosa-associated lymphoid tissue [MALT-lymphoma]

ICD-10 Coding Guide