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Non-invasive testing for Helicobacter Pylori Infection

Adjudication Guideline

Approved by:
Daman

Responsible:
Medical Standards & Research

Related Adjudication Guidelines:
None

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Abstract

For Members

Helicobacter pylori (H. pylori) is an organism that is present in about 50% of the global population. Chronic H pylori causes atrophic and even metaplastic changes in the stomach, and it has a known association with peptic ulcer disease ¹. Sign and symptoms include: nausea, vomiting, epigastric pain, heartburn, in patients who are infected with H pylori.

For Medical Professionals

In patients with suspected H pylori infection, the following laboratory studies are performed to confirm the diagnosis:

- **H pylori fecal antigen test:** Results of stool antigen test aid in the definitive diagnosis of active H. Pylori .The stool antigen test can be used with patients of all ages and does not have any restrictions. Patients do not need to be off proton pump inhibitors, H2 Blockers or bismuth before testing.
- **Urea breath test:** measures the ¹³C labelled carbon dioxide formed in the stomach when the urease produced by H. Pylori breaks down a sample of ¹³C- labelled urea. Breath testing requires patient to fast before ingesting a standard sample of labelled ¹³C and, at a predetermined time (approx. 1 hr.), and produce a breath sample. After collection, the breath sample is analysed by a mass spectrometer or scintillation counter. The performance characteristics of urea breath test for initial diagnosis and post-treatment monitoring for pediatric patients < 3 years of age have not been established ^{5, 12}.
- **H pylori serology:** assay for immunoglobulins (IgG), antibodies are present in serum for a very long time after eradication. Therefore, serology cannot be used to assess whether the H. Pylori infection is an active infection or a past exposure, or if eradication has taken place.

Scope

The scope of this adjudication rule highlights the coverage of Urea breath test (UBT), H-pylori stool analysis and serology for health insurance plans administered by Daman subject to policy terms and conditions.

Adjudication Policy

Eligibility / Coverage Criteria

Test	Sensitivity*	Specificity**	Advantages	Disadvantages
H. Pylori stool antigen test	94-95%	94-97%	<ul style="list-style-type: none"> Determine active infection. Can be used as a test of cure. 	The accuracy of the test may be reduced if the patient has upper gastrointestinal bleeding or if the stool is unformed or watery.
Urea Breath test	>90%	96%	<ul style="list-style-type: none"> Determine active infection. Can be used as a test of cure. 	<ul style="list-style-type: none"> Patient needs to be fasting. Patient should not have PPIs are withheld for 7 to 14 days and antibiotics and bismuth withheld for at least 28 days prior to urea breath testing to assess H pylori eradication³. Urea breath test can also be an inconvenient for some patients including children, handicapped individuals and elderly.
Serology	85-92%	79-83%	<ul style="list-style-type: none"> Convenient for patient. This test is not affected by medicines such as antibiotics, PPIs or H2 receptor antagonist. 	<ul style="list-style-type: none"> Cannot distinguish between past and present infection- a positive result mean the patient has been exposed bur may not mean the patient has current infection. Cannot be used as a test of cure.

*Sensitivity- reflects the ability of the test to correctly identify patients with conditions being tested for, therefore test with high sensitivity reduces the likelihood of a false negative results.

** Specificity - reflects the ability of the test to correctly identify patients without condition, therefore a test with high specificity reduces the likelihood of a false positive result.

The American Gastroenterological Association **no longer** recommends serology (antibody) testing for diagnosing infection or evaluating treatment effectiveness as it is unable to distinguish between active infection and previous exposure to H. Pylori. It does not confirm eradication^{14, 15}.

American College of Gastroenterology and the American Gastroenterology Association recommends **either** the breath **or** stool antigen tests as the preferred testing modalities for active H. pylori infection¹⁹. Diagnostic accuracy of the H. Pylori stool antigen is equivalent to urea breath test. Economic studies showed that the use of stool antigen testing was the most cost effective approach compared to urea breath testing as recommended in the European guideline with a Grade a, Level 1a evidence^{16, 17, 18, 22}. UBT may be difficult for certain patient populations due to the technique and inconvenience (fasting requirement and waiting period after eradication therapy). UBT should only be reserved for relevant medical conditions wherein the stool sample would be compromised for SAT.

Concurrent testing with both methods i.e. SAT and urea breath test is not necessary.

If documentation of H pylori infection eradication is required, this may be done at the end of 4 weeks with a urea breath test, or at the end of 12 weeks with a faecal antigen test².

Billing:

Daman has reconsidered its position towards H. Pylori testing via Serology and Urea Breath Testing based on the recent international recommendations ^{19, 16, 17, 18, 22}. Accordingly:

1. Daman will stop the coverage of H pylori serology for any plan.
2. Daman will no longer pay the UBT C14 for any plan.
3. Coverage of Urea Breath Test will be as follows:
 - a. Enhanced and Thiqa plans – Covered if medically necessary.
 - b. Basic plan – No longer covered.

Requirements for Coverage

- ICD and CPT codes must be coded to the highest level of specificity.
- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.

Non-Coverage

Plan	H. Pylori stool antigen	Urea breath test**	Serology
Visitor	Not covered	Not covered	Not covered
Basic	Covered	Not covered unless medically exempted condition*	Not covered
Enhanced	Covered	Covered	Not covered
Thiqa	Covered	Covered	Not covered

*Conditions exempted for Urea breath test for Basic plan such as: Gastrointestinal bleedings 11, 12, unformed stools¹³.

** Daman will no longer pay the UBT C14 for any plan.

Payment and Coding Rules

Please apply HAAD payment rules and regulations and relevant coding manuals for ICD, CPT.

Denial codes

Code description
Service is not clinically indicated based on good clinical practice
Service is not clinically indicated based on good clinical practice, without additional supporting diagnosis/activities
Service /supply may be appropriate , but too frequent
Service(s) is (are) not covered
Payment is included in allowance for another service

Adjudication Examples

Example 1

- **Question:** A claim of a 25 year old male, basic member is received, the following are the claimed diagnosis with the requested services. Is the claim payable?

Claimed diagnosis	Services requested by Clinician
Acute abdomen	Consultation Specialist
Acute gastritis without bleeding	Urea breath test, C-13
Vomiting, unspecified	
Helicobacter pylori as the cause of diseases classed elsewhere	

- **Answer:** Claim is payable for consultation and reject CPT for Urea breath test, C-13; with a denial code of NCOV-003.

Example 2

- **Question:** A claim of a 48 year old female enhanced member, is received, the following are the claimed diagnosis with the requested services. Is the claim payable?

Claimed diagnosis	Services requested by Clinician
Unspecified abdominal pain	CPT OFFICE OUTPT EST15 MIN
Gastritis	Urea breath test, C-13
Personal history of other infectious and parasitic diseases	

- **Answer:** Claim is payable for consultation and CPT Urea breath test, C-13.

Appendices

A. References

- 1) <http://emedicine.medscape.com/article/176938-overview>
- 2) <http://bestpractice.bmj.com/best-practice/monograph/816/follow-up.html>
- 3) <http://bestpractice.bmj.com/best-practice/monograph/816/diagnosis/tests.html>
- 4) http://gut.bmj.com/content/45/suppl_1/I18
- 5) https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100025c.pdf
- 6) <https://medlineplus.gov/ency/article/007501.htm>
- 7) <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2036.2004.02203.x/pdf>
- 8) <http://www.biohithealthcare.com/resource/files/other/limitations-of-helicobacter-pylori-diagnostics.pdf>
- 9) <http://s3.gi.org/physicians/guidelines/ManagementofHpylori.pdf>
- 10) http://www.mayomedicallaboratories.com/it-mmfiles/Helicobacter_pylori_Diagnostic_Algorithm.pdf
- 11) <http://www.mayomedicallaboratories.com/articles/hottopics/2010-08a-h-pylori.html>
- 12) <http://emedicine.staging.medscape.com/article/2117821-overview#showall>
- 13) <https://www.geisingermedicalabs.com/catalog/details.cfm?tid=61>
- 14) [http://www.gastrojournal.org/article/S0016-5085\(05\)01818-4/fulltext#H_pylori_Tests](http://www.gastrojournal.org/article/S0016-5085(05)01818-4/fulltext#H_pylori_Tests)
- 15) https://www.oxhp.com/secure/policy/helicobacter_pylori_serology_testing.pdf
- 16) https://www.researchgate.net/publication/49806505_Efficacy_and_cost-effectiveness_of_the_13C-urea_breath_test_as_the_primary_diagnostic_investigation_for_the_detection_of_Helicobacter_pylori_infection_compared_to_invasive_and_non-invasive_diagnostic
- 17) <http://web.a.ebscohost.com.proxy.library.rcsi.ie/ehost/detail/detail?vid=0&sid=a05519ff-1cf0-4444-9c69-d3cc8a68f844%40sessionmgr4007&bdata=JnNpdGU9ZWZWhvc3QtbGl2ZQ%3d%3d#AN=22973378&db=cmedm>
- 18) <http://web.a.ebscohost.com.proxy.library.rcsi.ie/ehost/detail/detail?vid=0&sid=c4b43d79-6e93-4490-8133-3ea4e21e2b1c%40sessionmgr4006&bdata=JnNpdGU9ZWZWhvc3QtbGl2ZQ%3d%3d#AN=16702847&db=cmedm>
- 19) <http://www.aafp.org/afp/recommendations/viewRecommendation.htm?recommendationId=318>
- 20) https://www.researchgate.net/publication/49806505_Efficacy_and_cost-effectiveness_of_the_13C-urea_breath_test_as_the_primary_diagnostic_investigation_for_the_detection_of_Helicobacter_pylori_infection_compared_to_invasive_and_non-invasive_diagnostic
- 21) <http://web.a.ebscohost.com.proxy.library.rcsi.ie/ehost/detail/detail?vid=0&sid=b7bee00d-4134-4e47-92bd-68a84e5b992f%40sessionmgr4008&bdata=JnNpdGU9ZWZWhvc3QtbGl2ZQ%3d%3d#AN=16270402&db=cmedm>
- 22) https://www.cadth.ca/media/pdf/htis/jan-2015/RC0620_Stool%20antigen%20test_Final.pdf

B. Revision History

Date	Change(s)
27/07/2017	Release of Version V1.0
20/03/2019	Release of Version V2.0 - Changes in Billing Urea Breath Tests