

Non-invasive testing for Helicobacter Pylori Infection

Adjudication Guideline

Rule Category:
Medical

Ref: No:
2017-MN-028

Version Control:
Version No. 3.0

Effective Date:
27/08/2017

Revision Date:
31/01/2025

Approved by:
Daman

Responsible:
Medical Standards
& Research

**Related Adjudication
Guidelines:**
N/A

Table of Contents

1.	Abstract.....	3
1.1	For Members	3
1.2	For Medical Professionals	3
2.	Scope.....	4
3.	Adjudication Policy	4
3.1	Eligibility / Coverage Criteria	4
3.2	Requirements for Coverage.....	5
3.3	Non-Coverage.....	5
3.4	Payment and Coding Rules.....	5
4.	Denial Codes.....	6
5.	Appendices	6
5.1	References	6
5.2	Revision History	7

1. Abstract

1.1 For Members

Helicobacter pylori (H. pylori) is an organism that is present in about 50% of the global population. Chronic H pylori cause atrophic and metaplastic changes in the stomach, and it has a known association with peptic ulcer disease.

This guideline highlights the indications of testing and identification of the organism.

Sign and symptoms include nausea, vomiting, epigastric pain, heartburn, in patients who are infected with H pylori.

1.2 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 C labelled carbon dioxide formed in the stomach when the urease produced by H. Pylori breaks down a sample of C-labelled urea. Breath testing requires patient to fast before ingesting a standard sample of labelled C and produce a breath sample. One of the limitations of this method is the possibility of false negative results when antibiotics are used to eradicate H. Pylori. Precautions should be taken with diabetics and phenylketourics.

Some UBT products have age restrictions. 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.

2. Scope

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

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Test	Consideration
H. Pylori stool antigen test	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	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 eradication . Urea breath test can also be an inconvenient for some patients including children, handicapped individuals and elderly.

Overall, the Diagnostic accuracy of H. Pylori stool antigen testing (SAT) and Urea breath test (UBT) are comparable. It is recommended that either the breath or stool antigen tests are used as the preferred testing modalities for active H. pylori infection.

UBT may be difficult for certain patient populations due to the technique and inconvenience (fasting requirement and waiting period after eradication therapy).

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 test.

3.2 Requirements for Coverage

Daman has reconsidered its position towards H. Pylori testing via Serology and Urea Breath Testing based on the recent international recommendations, accordingly:

- Urea Breath Test will be covered if medically necessary for Enhanced and Thiqa plans.
- Coverage of Stool Antigen Testing will be in line with the SOB and as per medical necessity.
- 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.

3.3 Non-Coverage

- Daman will no longer be covering Serology for any plan.
- Urea Breath Test is not covered for basic plans
- H. Pylori antigen, serology or Urea breath testing are not covered under the Visitor Plan

3.4 Payment and Coding Rules

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

4. Denial Codes

Code	Code Description
MNEC-003	Service is not clinically indicated based on good clinical practice
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
MNEC-005	Service /supply may be appropriate, but too frequent
NCOV-003	Service(s) is (are) not covered

5. Appendices

5.1 References

- <http://bestpractice.bmj.com/best-practice/monograph/816/follow-up.html>
- <http://bestpractice.bmj.com/best-practice/monograph/816/diagnosis/tests.html>
- http://gut.bmj.com/content/45/suppl_1/I18
- https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100025c.pdf
- <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2036.2004.02203.x/pdf>
- <http://www.mayomedicallaboratories.com/articles/hottopics/2010-08a-h-pylori.html>
- <http://emedicine.staging.medscape.com/article/2117821-overview#showall>
- <https://www.geisingermedicallabs.com/catalog/details.cfm?tid=61>
- [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)
- https://www.oxhp.com/secure/policy/helicobacter_pylori_serology_testing.pdf
- 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
- <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>
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- https://www.uptodate.com/contents/indications-and-diagnostic-tests-for-helicobacter-pylori-infection-in-adults?search=helicobacter%20pylori%20diagnosis%20and%20treatment&source=search_result&selectedTitle=1%7E150&usage_type=default&display_rank=1#H18

5.2 Revision History

Date	Change(s)
27/08/2017	V 1.0 • Creation of Adjudication Guideline-External Instruction Template.
20/03/2019	V2.0 • Changes in Billing Urea Breath Test.
31/01/2025	V 3.0 • General Content Review • References Updated

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