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**Service Specification for Helicobacter pylori infection (H pylori)**

**Period: 1st April 2017 to 31st March 2018**

**Date of Review: Annual**

**Introduction**

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients.

This specification outlines the more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services.

No part of the specification by commission, omission or implication defines or redefines essential or additional services.

# Background

NICE Clinical Guideline 184 (2014) “Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management” reiterates the previous 2004 guidance that the first 2 steps for the management of un-investigated dyspepsia or “reflux-like” symptoms, after reviewing and managing any potential contributing medication, are empirical full dose proton pump inhibitor (PPI) therapy for 1 month or H pylori “test and treat” in no specified order.

For the purposes of “test and treat” there are 3 tests available – stool antigen testing, breath testing (carbon-13 urea breath test) and serological testing. Serological testing is rarely used now due to having a lower specificity when compared with the stool antigen and the C13 breath test. None of these tests, however, should be done within 2 weeks of receiving a PPI or less than 1 month since receiving antibiotics.

Over the last couple of years there has been marked variation in the number of carbon-13 urea breath tests being done by different practices across Doncaster, ranging from none/minimal to several per month per 1000 patients. The breath test itself is time consuming for both the patient and the provider, requiring an additional appointment and specific kit that needs to be obtained. **Having reviewed the evidence and taken input from Primary Care and Gastroenterology, the CCG supports the use of stool antigen testing as the default Primary Care investigation for “test and treat.”** There may be individual situations, such as severe constipation, chronic diarrhoea or practical difficulties in getting a stool sample, where a breath test or referral for endoscopy and CLO testing remains the most appropriate option, but these will be in the minority.

When re-testing for H pylori is required post-eradication treatment, there is insufficient evidence for NICE to recommend the stool antigen test for this purpose and this decision is supported by Gastroenterology. **Therefore, the breath test remains the Primary Care investigation for persistence or recurrence of symptoms post-eradication treatment.** This is to be done at least one month, but preferably two months, after treatment with the patient being off proton pump inhibitors for at least two weeks in addition before the test can be carried out.

# Service Outline

Attached is a flow chart, which clearly defines process already covered under essential services and the process to be covered under this specification.

# Accreditation

The testing can be performed by a GP or Nurse or a Health Care Assistant with training and working to a protocol.

**Performance and Payment**

Activity data should be submitted on a monthly basis to the CCG

The practice will be required to submit audit information on request.

Activity should be submitted within 14 days of month end for activity undertaken in month.

Activity for March 2018 should be submitted within 7 days of month end. DCCG reserve the right to withhold payment on activity not received within these time scales

**Carbon-13 urea breath test Flowchart**

Specification from this point onwards

**Clinical decision taken that 13C-urea breath test is the most appropriate investigation (see background)**

Offer H Pylori test patient information leaflet

Make sure that patient will not have taken PPI within 2 weeks or antibiotics within 4 weeks of the test

Offer an alginate if necessary for symptom relief

Patient should not take antibacterial drugs 4 weeks before test

Obtain Diabact UBT or Issue FP10

Book appointment for test

The patient should fast for at least six hours preceding the test.

**Carbon-13 Urea Breath Test**

1. Fill in the Breath Test Report Form. Keep one of the extra bar code labels as reference label for the patient journal.
2. **Baseline sample**.
	1. Two baseline samples are collected in the test tubes marked with 00 MINUTE (blue screw caps).
	2. Remove the stopper from the tube, unwrap the straw and place the straw into the container.
	3. Gently exhale through the straw, until condensation appears in the tip of the container.
	4. Remove the straw promptly and reseal the container immediately.
3. **Tablet intake**
	1. Swallow the urea tablet together with a glass of water and rest for 10 minutes in an upright position (standing or sitting).
4. **10-MINUTE sample**
	1. Two post-urea breath samples are collected in the sample tubes marked ”10-MINUTE” (red screw caps).
5. On completion of the test, return the containers and the completed Breath Test Report Form to the box. Fill in the laboratory address in the space provided on the back of the lid. Seal the box with the enclosed SECURITY label , ensuring that the address side is up, and send the box to a qualified laboratory for analysis.

Too small an amount of CO2 (less than 2%) in the sample could give false results. To avoid leakage, make sure that the caps of the test tubes are properly closed. Observe that if the cap is closed too tightly, leakage may occur as the rubber membrane may be deformed.

# Explanation of analysis results

Δδ-value: the difference in parts per thousand (‰ ) between the 00-MINUTE value and the 10 MINUTE value.

Helicobacter pylori status:

<1.5 ‰ Δδ--value = Negative Helicobacter pylori status.

>1.5 ‰ Δδ--value = Positive Helicobacter pylori status.

The tablets must be swallowed whole. If the patient chews the tablets, the test must be performed again as the risk of false positive results increase. A new test may be performed the following day.

For patients who test positive, provide a 7-day course of treatment consisting of lansoprazole 30mg/omeprazole 20mg/pantoprazole 40mg twice daily plus one of:

1/ amoxicillin 1 g and clarithromycin 500 mg, both twice daily

2/ clarithromycin 250mg and metronidazole 400mg, both twice daily

3/ an alternative as per section 1.9

<https://www.nice.org.uk/guidance/CG184/chapter/1-Recommendations#helicobacter-pylori-testing-and-eradication>