Service Specification No.	**0001**
Title	**Helicobacter Pylori (H.pylori)**
Nature of Service	**Provision of ^{13}C-urea breath tests for the detection of *Helicobacter pylori* provided by community providers within NHS Surrey Heartlands ICB**
Commissioning Lead	**NHS Surrey Heartlands ICB**
Contact details for commissioning lead	**Rachel Mackay** **Associate Director of Pharmacy & Medicines Optimisation**
Provider lead	**Named Pharmacy**
Start date – specification valid from	**1st April 2022**
End date – specification valid until	**31st March 2025**
Specification interim review date	**Annual**

1. Population Needs

1.1 National/local context and evidence base

1.1.1 Introduction

All community providers (herein referred to as 'providers') are expected to provide essential and those additional services they are contracted to provide to all their patients. This locally commissioned service (LCS) specification outlines the more specialised services to be provided. The specification of this service is designed to cover the aspects of clinical care of the patient, 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.

1.1.2 Background

Helicobacter pylori (*H.pylori*) is a bacteria strongly associated with peptic ulcer disease.[1-3] Nearly all duodenal ulcers and most gastric ulcers not associated with non-steroidal anti-inflammatory drugs (NSAIDs) are caused by *H.pylori*.[1-3] Eradicating *H.pylori* from these patients reduces recurrence rates and the risk of rebleeding.[1-3] Eradicating *H.pylori* from patients with non-ulcer dyspepsia reduces symptoms.[1-3]

NICE recommend testing patients with uncomplicated dyspepsia for *H.pylori* infection, giving eradication therapy to those found to be infected and re-testing those who remain symptomatic after such treatment.[1] The presence of *H.pylori* should be confirmed before starting eradication treatment.[1, 3] When testing for *H.pylori*, NICE recommends the following[1]:

- Test for *H.pylori*, using a ^{13}C-urea breath test or stool antigen test, or laboratory-based serology where its performance has been locally validated.
- ^{13}C-urea breath tests are the most accurate tests[4] (Public Health England, 2017)
- Do not use office-based serological test for *H.pylori* because of their inadequate performance.
- Re-testing should not routinely be offered after eradication but if needed, perform re-testing for *H.pylori* using ^{13}C-urea breath test. There is currently insufficient evidence to recommend the stool antigen test as a test of eradication.[1]

The ^{13}C-urea breath test is recognised as being the **non-invasive** test of choice for identifying *H.pylori*.[2] Non-invasive tests for *H.pylori* avoid the need for endoscopy and biopsy to confirm infection.[2] Urea breath tests are the only non-invasive tests that are specific for **active** infection.[5] In a systematic review of 30 published studies, ^{13}C-urea breath tests were more accurate than serological tests.[2] Serological tests remain positive for at least 6 months after bacteria have been eradicated so a positive test may indicate past rather than current infection (i.e. a false positive). Their use to confirm cure is not practical.[5] The stool antigen test requires stool collection, which many patients find unacceptable.[2]

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions** • Ensuring people feel supported to manage their condition • Improving functional ability in people with long-term conditions • Reducing time spent in hospital by people with long-term conditions • Enhancing quality of life for carers	✓
Domain 3	**Helping people to recover from episodes of ill-health or following injury** • Helping older people to recover their independence after illness or injury	✓
Domain 4	**Ensuring people have a positive experience of care** • Improving patients' access to primary care services • Improving people's experience of integrated care	✓
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm** • Patient safety incidents reported	✓

2.2 Local defined outcomes

- Improved, prompt access and choice for patients who require the test within a community setting.
- It enables appropriate and timely treatment for the management of dyspepsia which reduces the risk of developing peptic ulcer disease.
- Increasing the proportion of appropriate requests for endoscopy and reducing unnecessary and inappropriate outpatient attendances.
- Allowing the detection of active *H.pylori* infection.

3. Scope

3.1 Aims and objectives of service

3.1.1 Aim:

To reduce the risk of people with uncomplicated dyspepsia symptoms from developing peptic ulcer disease through the detection of *H.pylori* by accessing the high quality service from the provider who can provide a ^{13}C-urea breath test.

3.1.2 Objectives:

- To ensure that people with dyspepsia who require a *H.pylori* test (as advised by NICE[1]) have prompt access to the test within a community setting.
- To enable appropriate and timely treatment for the management of dyspepsia to reduce the risk of developing peptic ulcer disease.
- To improve access and choice for people.
- To increase the proportion of appropriate requests for endoscopy. This will reduce unnecessary and inappropriate outpatient attendances.

3.2 Choice of ^{13}C-urea breath test

- The Drug and Therapeutics Bulletin concluded that on the basis of convenience and cost, Diabact UBT® appeared to be the ^{13}C-urea breath testing kit of choice (2004).[2] However, currently there are a number of ^{13}C-urea breath testing kits available that are all similar in price.[3]
- For the purpose of this LCS, there is no preferred ^{13}C-urea breath testing kit of choice as all are similar in terms of cost and convenience.[3]

3.3 Population covered (inclusion and exclusion) criteria

3.3.1 Inclusion:

- ≥18 years [5 - 7]
- Registered with a Surrey Heartlands GP practice to be eligible for the service provided by the participating provider.
- Patients can only be accepted into the service on presentation with a FP10 prescription (or via EPS – Electronic Prescription service) for the ^{13}C-urea breath testing kit.

3.3.2 Exclusion:

- <18 years of age.[5 - 7]
- Not registered with a Surrey Heartlands GP practice.
- Presentation with 'alarm' symptoms e.g. progressive unintentional weight loss etc. Appropriate referral should be made when and where necessary.
- Hypersensitivity to the active substance or to any of the excipients of the ^{13}C-urea breath testing kit.
- The test must not be used in patients with documented or suspected gastric infection that might interfere with the urea breath test.[5, 6]
- The test must not be used in patients who are likely to be negatively affected by the any of the contraindications, cautions and/or warnings that are documented in the latest Summary of Product Characteristics of the ^{13}C-urea breath testing kits.
- **Any patient taking an antibiotic in the 4 weeks immediately preceding the test.[4, 5] This may suppress *H. pylori* giving a false negative result. The patient may be tested at least 4 weeks after completion of the course of antibiotics.[5, 6]**
- **Patients who have received proton pump inhibitors (PPIs) treatment within the 2 weeks immediately preceding the test. [5, 6] This may suppress *H. pylori* giving a false negative result. The patient may be tested at least 2 weeks after stopping PPIs. [5, 6]**

3.4 Service description/care pathway

3.4.1 Process at GP practice:

- The prescriber at the GP practice is responsible for the management of patients with dyspepsia and the appropriate referral for the ^{13}C-urea breath testing kit to the participating provider in line with NICE[1].
- The GP/prescriber will make a clinical judgment and assess need for the patient to be referred for a ^{13}C-urea breath testing kit.
- The GP/prescriber is required to issue a FP10 prescription (or via EPS) for such a test and provide the patient with full details of all providers commissioned to deliver this service to enable the patient to make an informed choice.

3.4.2 Service criteria for community pharmacy testing:

1. The provider will receive notification requesting to provide this service in one of the following ways:
   - Patient presents with a FP10 prescription from a Surrey Heartlands practice for a ^{13}C-urea breath testing kit OR
   - The provider receives the prescription via EPS from a Surrey Heartlands practice.

2. The provider will check the following before an appointment is offered:
   - Ensure that the patient meets the inclusion criteria.
   - Ensure that the exclusion criteria are not applicable to the patient.

3. If the patient meets the inclusion criteria and is not applicable to any of the exclusion criteria, on receipt of the prescription for the breath test, the provider will:
   - Make an appointment with the patient for a suitable time. The appointment should be within 5 working days of the patient requesting an appointment, unless he/she requests a later appointment**. If a patient has received an antibiotic in the previous 4 weeks or has taken a PPI in the previous 2 weeks, sufficient time should elapse before undertaking the test (see exclusion criteria).**
   - Ensure that the prescribed ^{13}C-urea breath testing kit will be obtained in time for the appointment.
   - **When an appointment is offered, the patient must be told to fast for at least 6 hours (e.g. overnight) before the test.** [5, 6]

4. On the day of the test, the provider will undertake the following:
   - Explain the *H. pylori* test process to the patient.
   - Have ready access to drinking water for the patient.
   - Ensure the dispensed ^{13}C-urea breath testing kit is still in date.
   - Perform the test in accordance with the manufacturer's instructions supplied with the test, in the private consultation room.
   - Inform the patient's GP if testing is postponed for any reason.
   - Once the test has been completed, the provider should:
     - Provide the patient with information on how and when the result will be communicated – it is the provider's responsibility to contact the patient to inform them of the result, give instructions on how to proceed and will liaise with the patient's GP for an appropriate course of treatment if the result is positive.
     - Provide advice to patients on the management of dyspepsia.
     - Ensure all specimens are labelled and dispatched in accordance with the manufacturer's instructions.
     - Complete the necessary forms and post the specimens to an approved and certified laboratory. [5, 6]
     - The bar codes from the tests used should be attached to the invoice claim form (appendix 2)

5. On receipt of the ^{13}C-urea breath test kit results the provider will undertake the following:
   - For a POSITIVE result:
     - Send a copy of the result to the patient's GP practice (within 5 working days), so it can be documented on the patient's medical record, within this highlight the need for the GP/prescriber to discuss appropriate H. pylori eradication treatment.
     - Inform the patient of their result and advise them the practice has been informed. Should the patient not be contacted within 7 days, the patient should contact the practice directly.

   - For a NEGATIVE result:
     - Phone the patient to inform them of their result and request that they see their GP/prescriber if they still have a requirement for symptomatic treatment.
     - Communicate the results of the test to the patient's GP/prescriber within 5 working days.
     - Send/take a copy of the result to the patient's GP practice so it can be documented on the patient's medical record.
   - Process the prescription as normal and dispose of any retained samples in line with the ^{13}C-urea breath test kit manufacturer's guidance.
   - Make a note of the date and result of the test on the patient's Patient Medication Record at the pharmacy.
   - Retain a copy of the ^{13}C-urea breath test kit results for three years in case of audit requirement.

6. Complete all necessary documentation for LCS claim, see sections 3.6 & 8 (appendix 2 & 3).

3.5 Interdependence with other services/providers

Partners will include

- GP practices and their associated staff
- Other local providers providing this LCS.

3.6 Monitoring and Audit

- The provider should audit the standards of the service on an annual basis to ensure compliance with the LCS requirements and identify areas for improvement, which the provider would need to address.
- The provider is required to submit an annual (1st April – 31st March) audit return form (appendix 3) to the ICB's Medicines Optimisation Team (MOT) on an annual basis (by the 30th April of each year).
- The level of service provided will be monitored by such means as required by Surrey Heartlands ICB.
- The provider should obtain feedback on the service from the patients who use it. This feedback should be reviewed by the provider and where appropriate, changes should be made in order to improve the quality of the service. If feedback obtained is related to changes in this LCS, this should be given to the ICB (section 9).

4. Training and Competence

- The provider has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge, are appropriately trained in the operation of the service and are aware of and operate within local protocols. This includes all locum pharmacists.
- The provider must be able to demonstrate that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service and regularly update their skills and knowledge e.g. through the Centre for Pharmacy Postgraduate Education (CPPE) or specific training on their role if CPPE resources are not appropriate or available.
- An appropriately trained member of the pharmacy team e.g. pharmacist, pharmacy technician can perform the test in accordance with the protocol and standard operation procedure.

5. Provider responsibilities

The provider must meet the following requirements in order to provide this service:

- Complete the one-off application form to provide the service (appendix 1). The ICB's Medicines Optimisation Team will then contact you to confirm acceptance of the request.
- Ensure a consultation room is available where the pharmacy staff and patient can sit whilst the test is undertaken. This consultation room should also provide a sufficient level of privacy and safety and should meet any national contractual requirements.
- Ensure there is ready supply of drinking water for the patient when needed.
- Must have a suitable Standard Operating Procedure for this service so that:
  - All requirements as set out in this LCS are met at all times AND
  - The service meets the required levels of safety, quality, clinical governance and effectiveness consistently in line with this service specification, contractual requirements, legislation, good practice requirements and national and local guidelines.
- Review its standard operating procedures for this service every two years.
- Ensure that the services are provided from the designated community provider premises only.
- Ensure that all pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained (section 4).
- If a test fails because there is insufficient expired breath in the sample tubes, the provider must report this to the patient's GP and the ICB's MOT (section 9). Providers should review their procedures if failed tests occur more than 3 times in a year.

- To complete a route cause analysis in line with the provider's policy in relation to any adverse or serious incidents. The investigation should identify key learnings and proposed actions with timescales for rectification and to prevent the adverse incident from occurring again.
- Notification of any clinical governance issues or untoward events in relation to the delivery of this service should be given to the ICB (section 9).
- Audit the service annually and obtain feedback from the patients who use the service in line with section 3.6.
- Must participate complete the annual audit return form and send to the ICB by 30th April of each year.
- Must have a current business continuity plan. If unable to offer the service in an appropriate timescale, the following should be undertaken by the provider:
  - Inform the patient that the service cannot be provided.
  - In agreement with the patient, find another participating provider who would be able to offer the service in an appropriate timescale.
  - If another participating provider is found and is suitable for the patient, arrange for the patient to be transferred.
  - If another participating provider cannot be found, inform the patient and their GP/prescriber.
  - If the service cannot be provided indefinitely, the provider must inform the ICB's Medicines Management Team (section 9).
- The provider should maintain appropriate records to ensure effective ongoing service delivery.
- All invoice claim forms (appendix 2) must be completed fully and sent on a monthly basis (section 8).
- Must maintain retain a copy of the ^{13}C-urea breath test kit results for three years in case of audit requirement. These forms, together with records of prescriptions, will enable the ICB to verify that the service provided reconciles with payment claims made should the need arise.
- The relevant GP/prescriber must receive notification on whether their patient has had a positive or negative result in line with section 3.4.2.

6. Commissioning Responsibilities

- The ICB's Medicines Optimisation Team (MOT) will contact the providers who have completed and sent the one-off request to provide the service form (appendix 1) to confirm acceptance of the request.
- The ICB's MOT will review all annual review forms to ensure compliance with the requirements set out within this LCS.
- Maintain a list of providers commissioned to provide this service.

7. Applicable Service Standards

7.1 Applicable standards

Applicable standards include but are not limited to:

- NICE guidance
- Applicable standards set out in guidance, legislation and / or issued by a competent body such as the General Pharmaceutical Council and the Royal Pharmaceutical Society.
- Surrey Heartlands Clinical Commissioning Group wide medicines management guidelines - See PAD for details: http://pad.res360.net/PAD/Search
- Community pharmacy contractual framework

7.2 Further information

- Surrey PAD https://surreyccg.res-systems.net/PAD/
- British National Formulary (BNF) http://www.bnf.org/products/bnf-online/
- Summaries of Product Characteristics (SPC) https://www.medicines.org.uk/emc/

8. Pricing and Costs

- Each community pharmacy contracted to provide this service will receive payment from the ICB following receipt of the invoice claim form (appendix 2) on a monthly basis via NHS Shared Business Services.
- A payment of £15 will be made for each test carried out.
- The invoice claim form (appendix 2):
  - Should be completed FULLY and submitted monthly by the 7th of each month to the following address: SOB, 92A Payables M665, Phoenix House, Topcliffe Lane, Wakefield, WF3 1WE
  - Should be legible as this will be scanned onto the NHS Share Business Services system so needs to be clear.
  - Is not printed on dark paper or in purple ink for scanning purposes.
  - All sections of the form should be **typed** and **NOT handwritten** (other than the signature).
  - Should **NOT** have staples as this may create problems when the form is scanned.
- Payment will not be made unless the invoice claim is fully completed including:
  - Attaching the bar codes from the tests used
  - The name, address and postcode of the pharmacy
  - Contact details and signature from the lead contact.
- Please **DO NOT** send any patient identifiable information to the ICB or NHS Shared Business Services.

9. Termination

The provider may terminate this agreement by giving NHS Surrey Heartlands ICB 3 months' notice in writing of its intention to do so. Such notice, once given, may only be withdrawn with the agreement of NHS Surrey Heartlands ICB who shall not be required to agree.

NHS Surrey Heartlands ICB may terminate this agreement:

- By giving 3 months' notice of termination in writing. Such notice, once given, may only be withdrawn with the agreement of the provider who shall not be required to agree.
- By giving any period of notice it considers appropriate, including none, if it considers this to be necessary in the interests of patient safety.
- If it is brought to the ICB's attention that a provider has breached the requirements as set out in this service specification then the provider may be asked to withdraw from providing the service.

10. Location of Provider Premises

The Surrey PAD (https://surreyccg.res-systems.net/PAD/) contains the list of providers who are commissioned to provide this service.

11. References

1. National Institute for Health and Care Excellence. Clinical guideline [CG184]: Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management. NICE September 2014. Available from: https://www.nice.org.uk/guidance/cg184/chapter/1-recommendations?unlid=624032523201579430 9#helicobacter-pylori-testing-and-eradication
2. Drug and therapeutics bulletin. Which test for Helicobacter pylori in primary care? DTB September 2004, Vol 42, No 9. Available from: http://dtb.bmj.com/content/42/9/71
3. Joint Formulary Committee. *British National Formulary.* London: BMJ Group and Pharmaceutical Press. Published date: March 2017. Available from: https://www.medicinescomplete.com/mc/bnf/current/.
4. Public Health England. Test and treat for Helicobacter pylori (HP) in dyspepsia. PHE July 2017, updated August 2019. Available from: HP_Quick_Reference_Guide_v18.0_August_2019_change_highlighted.pdf (publishing.service.gov.uk)

5. Medicines and Healthcare Products Regulatory Agency. Summary of Product Characteristics: Diabact UBT 50 mg tablets. Kibion AB. Published date: 2 December 2009. Available from: http://www.mhra.gov.uk/spc-pil/?prodName=DIABACT%20UBT%2050MG%20TABLETS&subsName=UREA%20C-13&pageID=SecondLevel.
6. European Medicines Agency. Summary of Product Characteristics: Pylobactell 100 mg Soluble Tablets. Torbet Laboratories Limited. Published date: 3 April 2017. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000151/human_med_001003.jsp&mid=WC0b01ac058001d124
7. Clinical Knowledge Summaries: Dyspepsia - unidentified cause. National Institute for Health and Care Excellence. Published date: September 2017. Available from: https://cks.nice.org.uk/dyspepsia-unidentified-cause#!scenarioclarification

Appendix 1:

Application to provide a ^{13}C-urea breath testing service for the detection of *Helicobacter pylori* from a community provider within NHS Surrey Heartlands

ALL SECTIONS ON THIS APPLICATION FORM MUST BE COMPLETED

Pharmacy stamp (including name and address):

Pharmacy premises questions	**Circle either Yes or No**
The pharmacy premises has a consultation room available?	Yes / No
Pharmacy staff and patient can sit in this consultation room whilst the test can be performed?	Yes / No
This consultation room can provide sufficient level of privacy and safety and meets any national contractual requirements?	Yes / No
There is ready supply of drinking water for the patient when needed?	Yes / No

I wish to provide this service and on appointment, I will ensure that the requirements as set out in the service specification are adhered to when providing this locally commissioned service.

Lead contact name (BLOCK CAPITALS):……..

Lead contact position:……

Lead contact signature:……

Lead contact email address:…….

Lead contact telephone number:…….

Date:……

Please return this completed form to:
The Medicines Optimisation Team Administrators via: syheartlandsicb.sdmmt@nhs.net

- On receipt of the completed application form, the Medicines Optimisation Team will contact you to confirm acceptance of the request.

Appendix 2:

INVOICE

^{13}C-urea breath test monthly invoice claim form

Requirements of this form

- **NO patient identifiable** data should be included. This includes any patient names, NHS numbers and addresses.
- All sections of the form should be **typed** and **NOT handwritten** (other than the signature).

Please note that payment will not be made unless this form has been completed FULLY in the line with the requirements above and bar code information below.

Pharmacy stamp (including pharmacy name, address and postcode):

Invoice Number*:

Billing address	Delivery address
NHS SURREY HEARTLANDS ICB **QXU PAYABLES M895 PHOENIX HOUSE,** **TOPCLIFFE LANE,** **WAKEFIELD, WEST YORKSHIRE** **WF3 1WE**	

Comments or special instructions:

ACCOUNT NUMBER	P.O. NUMBER	REQUISITIONER	DELIVERY NOTE	TERMS
	XXRMACKAY			

QUANTITY	DESCRIPTION	UNIT PRICE (£)	AMOUNT (£)
	Helicobacter pylori Breath Testing		
	Month covered: ……		
	Number of consultations	15.00	
	Spare kit		
Bank Details: Sort Code (XX-XX-XX)		SUBTOTAL	
Account Number (XXXXXXXX)		DISCOUNT AMOUNT	
Please Make Cheques Payable to (XXXXXXXXXXXXXX)		SHIPPING/HANDLING	
Remittance Address (XXXXXXXXXXXX)		VAT	
		TOTAL DUE	

*Invoices received without an invoice number will be returned. NHS Shared Business Services is able to process invoice numbers of up to 39 alphanumeric characters.

PTO (page 1 of 2 - Invoice)

Bar codes:

- Please stick the bar codes from tests used below. Please only **STICK** the bar codes and **DO NOT** use any staples as this will **NOT** be accepted by NHS Shared Business Services.
- If you need to attach more bar codes, please use a new sheet of paper.

Lead contact name (BLOCK CAPITALS):……..

Lead contact position:……

Lead contact signature:……..

Lead contact email address:……

Lead contact telephone number:……

Invoice date:……..

Appendix 3:

Annual audit return form 1st April – 31st March

Please return this FULLY completed form by the 30th April of each year to:
The Medicines Optimisation Team Administrators via: syheartlandsicb.sdmmt@nhs.net

Pharmacy stamp (including name and address):

- Please confirm that your standard operating procedures for this service have been updated within the last 24 months: ……

- Please confirm that that you have obtained feedback on the service from the patients who use in order to improve the quality of the service provided?
  ……

- If any of the patient feedback obtained was related to changes in this LCS, please include this below:
  ……

- Please confirm that pharmacists (including locum pharmacists) and staff involved in the provision of the service have undertaken CPD relevant to this service e.g. the CPPE training or specific training on their role if CPPE resources are not appropriate or available:
  ……

- Please confirm that pharmacists (including locum pharmacists) and staff involved in the provision of the service are aware of and operate within local protocols relevant to this service:
  ……

- Please answer the following in relation to the tests:
  - How many tests were undertaken in the last 12 months: ……
  - How many of the tests undertaken in the last 12 months had a positive result:……
  - How many of the tests undertaken in the last 12 months had a negative result:……
  - What was the number of failed tests (if any) in the last 12 months:……

Lead contact name (BLOCK CAPITALS):……

Lead contact position (BLOCK CAPITALS):……

Lead contact signature:……

Lead contact email address:……

Lead contact telephone number:……

Date:……..