Supporting Early Diagnosis of Cancer (Community Pharmacy Pilot)

Service Level Agreement & Service Specification

Peninsula Cancer Alliance Area
Pharmacy Local Enhanced Service
July 2023

NHS England

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PART 2
Service Specification (Schedule 1)
1. **Agreement and Registration**

This Agreement is between:

**NHS England** *(the Commissioner)*

Wellington House, 133-155 Waterloo Road, Lambeth, London SE1 8UG

**And the Provider:** *(“the pharmacy”)*

Trading name and address of pharmacy

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Contractor ODS code: F……………………………………………………………………

For the provision of Supporting Early Diagnosis of Cancer (Community Pharmacy Pilot). The service is an Enhanced Service as defined by Part 4 paragraph 14(1)(q) - of the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 (as amended) and as further detailed in Schedule 1.

By signing up to this Service Level Agreement, you are agreeing that you fully comply with the Terms of Service as outlined in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and agree to comply with the full terms and conditions as outlined in this Service Level Agreement and service specification.

Failure to comply with the Terms of Service as outlined in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and the full terms and conditions as outlined in this Service Level Agreement may result in suspension of the scheme. Before any suspension the pharmacy and Commissioner will discuss the reason for the suspension to identify a possible resolution.

Sign up for this service is via the NHS BSA website [here](#)

By registering to sign up to the service you are agreeing to the terms and conditions outlined in this Service Level Agreement.

2. **Purpose**
The purpose of the Supporting Early Diagnosis of Cancer (Community Pharmacy Pilot) is to improve clinical outcomes for patients through early diagnosis of cancer and reducing health inequalities.

3. **Period**
   
   This agreement is for the scheme to be available
   
   - **during all pharmacy opening hours**
   
   The agreement and service delivery (proof of concept) will cover the period from 1st July 2023 to 31st March 2025.

4. **Termination**
   
   One month’s notice of termination must be given if the pharmacy or NHSE wishes to terminate the agreement before the given end date.
   
   The Commissioner may suspend or terminate this agreement forthwith if there are reasonable grounds for concern including, but not limited to, malpractice, negligence, or fraud on the part of the pharmacy.

5. **Obligations**
   
   The pharmacy will provide the service in accordance with the specification (**Schedule 1**) and ensure that all substantive and locum pharmacists are aware of it and will have completed the training to be able to deliver the service (listed in **Annex A** – ‘Training prior to commencing the Service’ of the Schedule 1 Service Specification).
   
   The Commissioner will manage the service in accordance with the specification (**Schedule 1**).

6. **Standards**
   
   The service will be provided in accordance with the standards detailed in the specification (**Schedule 1**).

7. **Eligibility criteria**
   
   Service providers will need to satisfy the following criteria to demonstrate the ability to take part in the pilot:
   
   - Located within the geography of Peninsula Cancer Alliance
   - Be in good standing with NHS England
   - Have a consultation room which meets the General Pharmaceutical Council (GPhC) Standards for Registered Premises and has IT capabilities (a computer or tablet)

8. **Confidentiality**
   
   Both parties shall adhere to applicable data protection legislation including the General Data Protection Regulation 2018 and to the Freedom of Information Act 2000.
   
   Any approaches by the media for comments or interviews must be referred to the Commissioner.
9. **Indemnity**

The pharmacy shall maintain adequate insurance for public liability and professional indemnity against any claims which may arise out of the terms and conditions of this agreement.

Any litigation resulting from an accident or negligence on the part of the pharmacy is the responsibility of the pharmacy who will meet the costs and any claims for compensation, at no cost to the Commissioner.
Supporting Early Diagnosis of Cancer (Community Pharmacy Pilot)

Service Specification

Pharmacy Local Enhanced Service
NHS England

Supporting Early Diagnosis of Cancer (Community Pharmacy Pilot) Scheme

SERVICE SPECIFICATION (Schedule 1)

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Any questions or queries should be directed to:

england.pharmacyintegration@nhs.net
NHS England

Supporting Early Diagnosis of Cancer (Community Pharmacy Pilot) Scheme
SERVICE SPECIFICATION (Schedule 1)

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1. Service description and background

1.1. This pilot will specifically evaluate the implementation by community pharmacy of direct referrals to secondary care diagnostics/Rapid Diagnostic Service (RDS) triage teams for people with suspected cancer signs and symptoms. The pilot will initially focus on testing safety and technical feasibility with a small number of Community Pharmacies before expanding to full pilot roll out and data collection to evaluate the benefits of direct referrals from Community Pharmacy for people presenting with suspected cancer symptoms.

1.2. Developing a direct referral service from community pharmacy to secondary care diagnostics/RDS triage teams for people with suspected cancer symptoms has the potential to improve patient outcomes and reduce health inequalities. It is hoped it will support the NHS Long Term Plan’s aims of 75% of cancer patients being diagnosed at Stage 1 or 2.

1.3. NHS England (NHSE) is commissioning this pilot as a Local Pharmacy Enhanced Service.

1.4. The key objectives of this pilot are:

- To test the feasibility and acceptability of referral routes into secondary care and diagnostic centres
- To undertake quantitative and qualitative evaluation including patient experience and the experience of community pharmacy, primary and secondary care/RDS teams.
- To test a new funding model, which aims to fairly remunerate provision of a quality service.

1.5. The decision to refer will be made during the consultation with the patient in the pharmacy consultation room, so that the appropriate next steps can be organised within a single episode of care.

1.6. Upon the patient’s presentation at the pharmacy, the pharmacist will conduct an appropriate clinical assessment (using the referral criteria outlined in the clinical protocol) in the pharmacy consultation room and record the consultation notes and make the referral (if needed). An online MS Form will be used to capture the consultation.

1.7. The clinical assessment would result in one of three outcomes based on the referral criteria, namely:

a) **The individual does not meet the referral criteria**

- No referral should be made.
- Self-care advice and assurance should be provided to support the individual
- A safety netting plan should be put in place in case symptoms persist/worsen.

b) **The individual meets the criteria for onward investigation in Primary Care**

- Pharmacists should explain to the individual that their symptoms could be a sign of something more serious and that they must get checked out by their GP.
- The patient should be followed up in general practice as per locally agreed processes. These processes will be agreed by the Cancer Alliance with local general practices ahead of patients being engaged
in the service. The pharmacist should reassure the person and encourage them to write down their symptoms for review by the GP.

- If the person is not registered with a GP, the pharmacist should encourage them to register. Participating pharmacies must have enrolment forms for GP practices in their area who are accepting new patients. If the person is reluctant to register with a GP, follow locally agreed processes.

c) The individual meets the referral criteria for referral to secondary care/RDS

- The pharmacist should explain that they would like to refer the individual for further tests to rule out the possibility of something more serious like cancer. Tell the patient this will usually mean they will get an appointment within 2 weeks.
- A referral should be made through the NHS e-Referral Service (e-RS) or via NHSmail, flagging the suspected cancer symptoms that require further investigation.
- Be aware that individuals may react differently to the information they are being referred. This includes feeling scared, feeling shocked or feeling resistant to being referred. It is important to minimise people’s fears whilst providing support to achieve referral.
- Support can be offered by addressing barriers to referral, asking the person to let you know how they got on, and helping them to have a meaningful conversation during their referral appointment by writing down worrying symptoms and their duration.

1.8. The pharmacist submits a claim for payment for the service.

1.9. An evaluation of the service will be undertaken to facilitate a robust review and financial appraisal for NHS commissioners. The evaluation will examine the role of community pharmacists in referring individuals with suspected cancer symptoms and carry out a qualitative assessment of patient experience and pharmacy staff experience. It will also look at the wider service model and outcomes of referrals made.

2. Aims and intended outcomes

2.1. The aim of this project is to test a model whereby community pharmacists directly refer people with suspected cancer symptoms into secondary care/RDS and assess the extent to which this service can:

- Improve early diagnosis
- Impact health inequalities
- Impact on General Practitioners
- Increase patient choice

2.2. The outcomes that the pilot aims to achieve include:

- Establishing the benefits and barriers to community pharmacies making suspected cancer referrals.
- Improving access to early diagnosis of cancer symptoms within primary care.
- Evaluating learning for pharmacists’ training and professional development.
- Evaluating the funding model

2.3. This pilot will be subject to a full evaluation. Further development or extension of the pilot will be dependent on the results of this evaluation and cannot be guaranteed.
3. Service Sign-up – Pharmacy contractors

3.1. Registration is via the NHS Business Services Authority (BSA) website. Pharmacies wishing to provide this service should register for the service via the dedicated web page.

3.2. Pharmacies will need to sign up to the Data Processing Agreement (DPA) at the point of registration, via the BSA website.

3.3. This sign up is for pharmacies within the Peninsula Cancer Alliance geography only.

4. Service Sign-up – Pharmacist self-declaration

4.1. Registration for the pilot will involve making a self-declaration of readiness to provide the Supporting Early Diagnosis of Cancer (Community Pharmacy Pilot).

4.2. This self-declaration will require that you confirm that you:

- Have read this service specification and can comply with all the elements laid out therein
- Have read the clinical protocol and understand all the elements laid out therein
- Are aware of the escalation process and how to seek Healthcare Professional support should this be required
- Will provide this service from a consultation room, where possible
- Have access to e-RS and/or shared NHSmail account specific to the pharmacy premises
- Have completed the required self-directed online learning associated with the service. (list in Annex A of this document)

5. Model of Care (See also service pathway in Annex B)

5.1. Patient presents at Community Pharmacy

5.1.1. Community pharmacy staff are well placed to identify people who may be showing early signs of cancer. For example:

- People who seek advice for potential cancer symptoms/health conditions
- People who repeatedly buy or report repeated use of over-the-counter medicines such as cough syrup, throat lozenges, proton pump inhibitors, anti-diarrhoea medication and mouth ulcer medication.
- People who describe potential cancer symptoms during routine conversations as part of a “Pharmacy Only” medicine request or when using any other pharmacy services such as the Community Pharmacist Consultation Service or smoking cessation service

5.1.2. Community pharmacy staff should escalate people they suspect of having cancer signs and symptoms or people who are concerned their symptoms could be a sign of cancer to the pharmacist.

5.1.3. People meeting these criteria should be invited to continue the conversation in the pharmacy consultation room. If this is not possible, or the person does not wish to use the consultation room, make sure the conversation takes place in a quiet area.

5.1.4. It can be difficult to initiate conversations with people about potential cancer symptoms. Training and resources are available to support community pharmacy staff who may want to refresh skills in order to undertake these conversations (see Annex A).
5.1.5. Medicine taking behaviour can be a prompt for discussing cancer signs and symptoms with people. The table below gives examples of medicine taking behaviour that could trigger a discussion with a person about symptoms (see table 1. below):

Table 1. Medicine taking behaviour that can be a red flag for cancer

<table>
<thead>
<tr>
<th>Category</th>
<th>Medicine taking behaviour that might suggest cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>Regular or increasing repeat purchase/use of cough medication</td>
</tr>
<tr>
<td>Upper GI</td>
<td>Regular or increasing repeat purchases/use of:</td>
</tr>
<tr>
<td></td>
<td>- Antacid preparations for reflux/indigestion</td>
</tr>
<tr>
<td></td>
<td>- Proton pump inhibitors</td>
</tr>
<tr>
<td></td>
<td>- Histamine 2 receptor antagonists</td>
</tr>
<tr>
<td>Lower GI</td>
<td>Regular or increasing repeat purchases/use of:</td>
</tr>
<tr>
<td></td>
<td>- Haemorrhoid medicine without diagnosis</td>
</tr>
<tr>
<td></td>
<td>- Medicines indicative of a change in bowel habit such as loperamide or other medicines to manage diarrhoea</td>
</tr>
<tr>
<td>Gynaecological</td>
<td>Regular or increasing repeat purchases/use of:</td>
</tr>
<tr>
<td></td>
<td>- Medicines to manage diarrhoea/other Irritable Bowel Syndrome (IBS) symptoms</td>
</tr>
<tr>
<td></td>
<td>- Medicines or products to manage post-menopausal bleeding</td>
</tr>
<tr>
<td>Head and neck</td>
<td>Regular or increasing repeat purchases/ use of:</td>
</tr>
<tr>
<td></td>
<td>- Throat lozenges or medicine</td>
</tr>
<tr>
<td></td>
<td>- Mouth ulcer medication</td>
</tr>
<tr>
<td>Skin</td>
<td>Regular or increasing repeat purchases/ use of medication to treat skin complaints, with no skin condition present</td>
</tr>
<tr>
<td>Non-specific symptoms</td>
<td>Regular or increasing repeat purchase/ use of analgesic medications for persistent pain</td>
</tr>
</tbody>
</table>

5.2. Pharmacist Clinical assessment of the patient

5.2.1. The pharmacist will conduct a face-to-face consultation, where possible, in the pharmacy consultation room and use the online MS Forms tool and e-RS/NHSmail during that consultation to record the consultation notes.

5.2.2. The pharmacist must conduct a clinical assessment of the patient using the referral criteria (see Annex C) to determine whether a person does not need further intervention, or whether a person either meets the threshold for referral to secondary care/RDS for diagnosis or for onward investigation by their GP. The criteria have been developed to reflect NICE NG12 Suspected Cancer: Recognition Referral Guidelines, NHSE/I Cancer Faster Diagnosis pathways and the British Oncology Pharmacy Association training modules on communicating cancer.

5.3. Referral decision is made

5.3.1. If the clinical assessment indicates that the patient is not eligible for referral:
• If a person does not meet the referral threshold and the pharmacist does not think they need to be seen by another health professional, pharmacists should provide general advice and information about managing their symptoms.
• Pharmacists may wish to signpost people to the GP for support with symptoms unrelated to cancer or because the pharmacist suspects they may have a health condition other than suspected cancer. These individuals should be managed in accordance with any locally established arrangements and professional obligations.
• People should always be advised to see their GP if their symptoms persist or get worse.

5.3.2. If the clinical assessment indicates that the patient is eligible for onward investigation by their GP:
• Pharmacists should explain to the person that their symptoms could be a sign of something more serious and that they must get checked out by their GP.
• The pharmacist should reassure the person and encourage them to write down their symptoms for review by the GP.

5.3.3. If the clinical assessment indicates that the patient is eligible for referral to secondary care/RDS:
• The pharmacist should explain that they would like to refer the patient for further tests to rule out the possibility of something more serious like cancer. Tell the patient this will usually mean they will get an appointment within 2 weeks.
• NICE (National Institute for Health and Care Excellence) recommends:
  ▪ Explaining to people who are being referred with suspected cancer that they are being referred to a cancer service. Reassure them, as appropriate, that most people referred will not have a diagnosis of cancer and discuss potential alternative diagnoses with them.
  ▪ The information you give to people with suspected cancer and their families and/or carers should include:
    • where the person is being referred to
    • how long they will have to wait for the appointment
    • who to contact if they do not receive confirmation of an appointment
    • other sources of support and information about their referral appointment, such as the NHS website, Cancer Research UK and Macmillan Cancer Support.

• Cancer Alliances can support pharmacies to provide information that is appropriate for the person in terms of language, ability, and culture, recognising the potential for different cultural meanings associated with the possibility of cancer.
• Be aware that people may react in a variety of ways to this information. This includes feeling scared, feeling shocked or feeling resistant to being referred. It is important to address people’s fears, whilst providing support to achieve successful referral.
• Support can be offered by addressing barriers to referral, asking the person to let you know how they got on, and helping them to have a
meaningful conversation during their referral appointment by writing down worrying symptoms and their duration.

- Further information should be collected to fill out the relevant referral proforma.
- Once the decision to refer has been made, make sure that the referral is sent within 1 working day.
- If after 24 hours the pharmacy has not been notified by secondary care/RDS that the referral has been received, then the pharmacy should complete a repeat referral.
- The person’s GP will be contacted to inform them of the outcome of the referral.

5.3.4. For all scenarios the pharmacist who carried out the consultation will request permission from the patient for participation in evaluation. If the patient refuses to take part in data collection, this does not stop the patient from receiving the service.

5.3.5. The pharmacist will record the consultation on the provided online data collection tool (MS Form), if possible in the consultation room.

5.3.6. The e-RS/NHSmail referral (if needed) may be made during or after the consultation in the consultation room.

5.3.7. The emphasis of the service is on the consultation and referral, however should minor illness medication be required for the presenting condition, then private sale of an OTC (Over the Counter) or Pharmacy Only product may be used depending on local commissioning arrangements. The pharmacist is professionally accountable for the clinical judgement and treatment decisions made.

5.3.8. The patient must not be charged for the consultation.

6. Advice and Information

6.1. Every patient who accesses the service will be provided with verbal and written advice and information on their symptoms and details of the discussion with the pharmacist. All patients will be offered a patient information leaflet.

6.2. Any verbal advice should be appropriate for the person in terms of language, ability, and culture, recognising the potential for different cultural meanings associated with the possibility of cancer.

6.3. All patients who consent to being part of the evaluation, will be given the evaluation patient information sheet.

7. Core Competencies

7.1. Pharmacy teams will be able to:
   a) Communicate with, counsel, and advise patients appropriately and effectively on suspected cancer symptoms.
   b) Assess the clinical needs of patients including the identification of patients that require onward referral.
   c) Signpost to other professions in healthcare appropriate to the needs of the patient.
   d) Explain the provision of the service and give appropriate self-care advice.

8. Records and Documentation
8.1. The pharmacy will maintain a record of the consultation. This will be recorded on the online form.
8.2. Patients will be asked to consent to a follow up patient survey or interview as part of the evaluation.
8.3. All relevant records must be managed in line with Records Management Code of Practice for Health and Social Care.

9. Available Training and Premises

9.1. All Community Pharmacy staff will want to ensure they have an up to date understanding of the service specification. In addition, all staff are expected to have completed Module 1 of ‘Let’s Communicate Cancer’ online learning outlined in Annex A prior to delivery of the service.
9.2. To provide the service, pharmacies must have access to the online MS Form, e-RS (if applicable), and NHSmail within the pharmacy. Pharmacies must have a shared NHSmail mailbox for each pharmacy premises.
9.3. The pharmacy contractor must have a standard operating procedure (SOP) in place covering the provision of the service (or services generally). This must include key contact details that are set out in Annex E. Your LPC (Local Pharmaceutical Committee) may be able to support with this.
9.4. Prior to providing the service, the pharmacy contractor should review and make any necessary amendments to their business continuity plan to incorporate appropriate content on the service within the plan.
9.5. Prior to provision of the service, the pharmacy contractor must be satisfactorily complying with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (terms of service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.
9.6. The pharmacy contractor must ensure that all pharmacy staff involved in provision of the service are appropriately trained on the operation of the service, including relevant sections of the SOP for the service. It is of importance that locum pharmacists are made aware of the service and understand the SOP so that they can provide the service, including at weekends and Bank Holidays.
9.7. Pharmacy owners and pharmacists should make their insurers aware of the provision of the new service.

10. Service availability

10.1. The pharmacy contractor must ensure that the service is available throughout the pharmacy’s core and supplementary opening hours.
10.2. The pharmacy contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible patient shall be excluded or experience difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.
10.3. Ensure all pharmacy team members, including locums and relief pharmacists, are aware of the procedures to be followed, including the training to deliver the service and have easy access to the key contact numbers for the service (they need to be recorded in the local SOP for the Service).
10.4. Ensure all pharmacy team members, including locums and relief pharmacists, are aware of how to contact the support team for e-RS (if applicable) in the event that there is a problem with the system. **Include the contact details in the local SOP for the Service.**

10.5. When locums are being booked to work at the pharmacy, make sure the locum is made aware that the Service is being provided and ensure they are able to provide the Service.

10.6. If the Service must be temporarily withdrawn by the pharmacy due to unforeseen circumstances, the pharmacy contractor will ensure the elements of their business continuity plan related to the service are activated.

10.7. If the pharmacy contractor wishes to cease to provide this service, they must notify NHS England via **england.pharmacyintegration@nhs.net** that they are no longer going to provide the service via email. At least one month’s notice must be provided prior to the cessation of service provision.

11. **Governance**

11.1. The pharmacy governance lead (nominated individual in the pharmacy) will provide feedback about any incidents related to patient safety, the referral process, or operational issues with respect to the service via **england.pharmacyintegration@nhs.net**

11.2. The pharmacy is required to report any patient safety incidents in line with the Clinical Governance Approved Particulars for pharmacies - i.e. follow your existing incident reporting mechanisms.

12. **Evaluation**

12.1. The service will be evaluated independently. The pilot pathway will take place over three stages with the evaluation being used to develop and iterate the pilot depending on findings; ensuring referrals are appropriate, to the right setting and there are good systems for safeguarding and safety netting. The three stages are:

   12.1.1. Pre-step – testing referral processes in a small number of pharmacies
   12.1.2. Phase 1 – small scale testing to understand effectiveness and safety and non-inferiority when compared with usual care
   12.1.3. Phase 2 – roll out to more pharmacies and iterate based on learning from Phase 1

12.2. Specifically, we would like to understand the benefits and limitations, including the appropriateness and safety of the model, of using community pharmacy services for cancer referrals from the perspective of:

   - Community Pharmacists, Primary Care, Patients and Secondary Care
   - The impact of the pilots on health inequalities of cancer referrals and diagnoses
   - The impact of the pilots on early detection of cancer
   - The impact of the pilots on non-cancer diagnoses
   - The cost / cost-effectiveness of the clinical service offer running in the pilot, including the funding model
   - All participating pharmacies and pharmacy staff must participate in the evaluation.

13. **Payment**
13.1. Remuneration will be made to the pharmacy as per funding model (Annex D).
13.2. A further payment, part way, through the pilot will be made for taking part in the evaluation.
13.3. Payments will be made based on the information recorded on the online MS Form for each consultation. This information will be automatically transferred to the NHS England local primary care pharmacy contract team. Pharmacies do not need to do anything to secure payment except in exceptional circumstances or for audit or post payment verification purposes.
13.4. Payment will be made to pharmacies on a monthly basis, within 2 months of the end of the month, by NHS England via the local payments’ application process.
13.5. Pharmacists must record information onto the online MS Form during the consultation with the patient present.
13.6. Claims submitted which relate to provisions over 3 calendar months old will not be paid.
13.7. Any information supplied to NHS England must be anonymised and not contain any patient identifiable information.
14. **Annexes**

**Annex A – Available training relevant to providing the service**

**Online resources**

A number of packages and online resources have been identified for this pilot. Prior to commencing the service, pharmacy teams must complete module 1 of BOPA’s Let’s Communicate Cancer e-learning if they have not already done so as part of the 2022/23 Pharmacy Quality Scheme. Other training is optional and for the pharmacy team to decide based on their existing knowledge and competence.

<table>
<thead>
<tr>
<th>Online learning</th>
<th>Staff Group</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHSE/I film series: Learning from the experience of BME cancer patients</td>
<td>All patient-facing CP staff</td>
<td><a href="https://www.youtube.com/watch?v=BDSurHtFtZA">https://www.youtube.com/watch?v=BDSurHtFtZA</a></td>
</tr>
<tr>
<td>CPPE Cancer Resources</td>
<td>Community Pharmacist</td>
<td><a href="https://www.cppe.ac.uk/gateway/cancer">https://www.cppe.ac.uk/gateway/cancer</a></td>
</tr>
<tr>
<td>CPPE Cancer: supporting people with early diagnosis e-learning</td>
<td>Community Pharmacist, Pharmacy Technician, trainee pharmacist</td>
<td><a href="https://www.cppe.ac.uk/programmes/l/cancer-e-03/">https://www.cppe.ac.uk/programmes/l/cancer-e-03/</a></td>
</tr>
<tr>
<td>CPPE Clinical history taking: what a good consultation looks like</td>
<td>Community Pharmacist</td>
<td><a href="https://www.cppe.ac.uk/programmes/l/consult-e-00/">https://www.cppe.ac.uk/programmes/l/consult-e-00/</a></td>
</tr>
</tbody>
</table>
Annex B – Service pathway

Individual asks for advice
- regarding potential cancer symptom
t or
- medication not resolving their health complaint

Individual describes potential symptoms during routine questioning, e.g.
- as part of a pharmacy
- or when using other pharmacy services such as smoking cessation services

Pharmacy staff become aware of repeat CYC medication purchase
- For example cough syrup, throat lozenges, proton pump inhibitors, mouth ulcer medication

Clinical Protocol

- Escalate individual to Community Pharmacist
- Ask individual if they can discuss this further in a quiet confidential space, e.g., consultation room
- Questions for individual
  - Ask about any medication
  - Use referral criteria to prompt for specific symptoms
  - Ask if this is normal for you?

Next steps

Referral into Secondary Care/RDS
- Explain next steps and offer reassurance
- Signpost to other information/services
- Fill out referral proforma

Refer individual to GP
- Explain next steps and offer reassurance
- Use local processes/Pathway to refer to GP

Offer symptom management advice/safety netting
- Signpost individual to GP or 111 if symptoms persist/worsen
Annex C – Clinical protocol

People are eligible for a referral if they have the below specified symptoms. The referral route (to secondary care/RDS or for onward investigation in primary care) is indicated with an X. In some cases, marked as optional, local areas can decide on which referral route to use.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Action</th>
<th>Suspected Cancer referral to secondary care/RDS</th>
<th>Onward investigation in primary care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lung</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults, 40 years and over and unexplained coughing up blood</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smokers (including shisha users), 40 years and over with 2 or more of the following unexplained symptoms:</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o persistent cough</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o shortness of breath</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o chest pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o finger clubbing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults 40 years and over with any of the following:</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>o persistent or recurrent chest infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o persistent cough</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o shortness of breath</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o chest pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o weight loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o appetite loss.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o finger clubbing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gynaecological</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women 55 years and over, with post-menopausal bleeding (unexplained vaginal bleeding) with more than 12 months after menstruation has stopped because of the menopause. Excluding women on systemic HRT (hormone replacement therapy) or who have had a hysterectomy.</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women 55 years and over, with post-menopausal bleeding (unexplained vaginal bleeding) with more than 12 months after menstruation has stopped, who are on systemic HRT.</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women over the age of 50 with 2 or more of the following symptoms</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Persistent abdominal distension (or ‘bloating’) – happening several times a month</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Feeling full (early satiety) and/or loss of appetite</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Pelvic or abdominal pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Increased urinary urgency and/or frequency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women 50 years and over who have experienced symptoms within the last 12 months that suggest IBS (irritable bowel syndrome)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Skin – Optional Secondary Care/RDS Route</strong></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Adults with:</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
New suspicious pigmented skin lesion mole with a weighted 7-point checklist score of 3 or more.

<table>
<thead>
<tr>
<th>Major features of the lesions (scoring 2 points each):</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>• change in size</td>
<td></td>
</tr>
<tr>
<td>• irregular shape</td>
<td></td>
</tr>
<tr>
<td>• irregular colour</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minor features of the lesions (scoring 1 point each):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• largest diameter 7 mm or more</td>
<td></td>
</tr>
<tr>
<td>• oozing</td>
<td></td>
</tr>
<tr>
<td>• change in sensation</td>
<td></td>
</tr>
<tr>
<td>• inflammation</td>
<td></td>
</tr>
</tbody>
</table>

Referral route optional depending on local pathways and accessibility of GPDA (GP direct access) pathways

**Head and Neck**

Adults with any of the following:
- Mouth ulcers lasting 3 weeks or more, or that do not heal
- A lump in the lip or mouth lasting 3 weeks or more

**Kidney and Bladder – Optional Secondary Care/RDS Route**

Adults 45 years and over with:
- Self-reported visible haematuria (blood in urine) without any signs of urinary tract infection such as pain when urinating or a temperature.

Referral route optional depending on local pathways and accessibility of GPDA (GP direct access) pathways

Adults over the age of 45 with unexplained hoarse voice, lasting 3 weeks or more.

**Upper GI - Optional Secondary Care/RDS Route**

Adults 55 years and over with dysphagia (trouble swallowing)

Referral route optional depending on local pathways and accessibility of GPDA pathways

Adults 40 years and over with jaundice
### Referral route optional depending on local pathways and accessibility of GPDA pathways

<table>
<thead>
<tr>
<th>Adults 55 years and over with both the following symptoms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Persistent reflux / indigestion</td>
</tr>
<tr>
<td>- Upper abdominal pain</td>
</tr>
</tbody>
</table>

### Lower GI – Optional Secondary Care/RDS Route

<table>
<thead>
<tr>
<th>Adults 60 years and over who are not registered with a GP, with blood in stools and any of the following unexplained symptoms or findings:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- abdominal pain</td>
</tr>
<tr>
<td>- change in bowel habit</td>
</tr>
<tr>
<td>- weight loss</td>
</tr>
</tbody>
</table>

Patient to be issued a FIT (faecal immunochemical test) kit by the pharmacy. Referral may be downgraded based on FIT result.

<table>
<thead>
<tr>
<th>Adults with two or more of the following symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>- blood in stool</td>
</tr>
<tr>
<td>- abdominal pain</td>
</tr>
<tr>
<td>- change in bowel habit</td>
</tr>
<tr>
<td>- weight loss</td>
</tr>
</tbody>
</table>

### Haematological

<table>
<thead>
<tr>
<th>People with any of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Unexplained bruising</td>
</tr>
<tr>
<td>- Unexplained bleeding</td>
</tr>
<tr>
<td>- Unexplained petechiae (clustered small purple, red, or brown spots on the skin)</td>
</tr>
<tr>
<td>- Persistent back or bone pain</td>
</tr>
</tbody>
</table>

### Breast

<table>
<thead>
<tr>
<th>Adults 30 years and over with a self-reported, unexplained breast lump</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Adults 50 years and over with any of the following symptoms in one nipple only:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- discharge</td>
</tr>
<tr>
<td>- retraction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adults 70 years and over with any self-reported breast change</th>
</tr>
</thead>
</table>
### Annex D – Funding model

<table>
<thead>
<tr>
<th>Activity</th>
<th>Fee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot Set Up</td>
<td>£390.00</td>
<td>One off</td>
</tr>
<tr>
<td><strong>Submission of complete and accurate dataset</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Dataset submitted which provides:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 1a Assurance that the initial assessments identified red flag symptoms appropriately.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 1b How many consultations took place for patients in the 1a cohort.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 1c Assurance the clinical protocol was followed for each patient.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 1d What the outcome was for each patient.</td>
<td>£260.00</td>
<td>Monthly</td>
</tr>
<tr>
<td>2. Data sharing as per specification and evaluation plan.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Quality assurance checks.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Service Delivery</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1 to 5 consultations per month</td>
<td>£68.62</td>
<td>Monthly</td>
</tr>
<tr>
<td>• 6 to 10 consultations per month</td>
<td>£137.23</td>
<td>Monthly</td>
</tr>
<tr>
<td>• 11 or more consultations per month</td>
<td>£150.96</td>
<td>Monthly</td>
</tr>
<tr>
<td><strong>Total for delivering service</strong></td>
<td>£328.62 to £410.96</td>
<td>Monthly</td>
</tr>
<tr>
<td><strong>Fee for supporting evaluation</strong></td>
<td>To be determined</td>
<td>One off</td>
</tr>
</tbody>
</table>
Annex E – Key Contacts to be included in a Standard Operating Procedure

GP Practice Contact details
[Insert NHSmail addresses and contact numbers]

Cancer Alliance Supporting Early Diagnosis of Cancer (Community Pharmacy Pilot) Scheme Contact Details:
[Insert email address and contact number]

NHS England contact:
england.pharmacyintegration@nhs.net