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NHS Pharmacy Contraception Service Tier 1 – Ongoing supply of oral contraception

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Community Pharmacy advanced service specification

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1. Service background

1.1 <u>The NHS Long Term Plan (LTP) Chapter 2</u> (https://www.longtermplan.nhs.uk/online-version/chapter-2-more-nhs-action-on-prevention-and-health-inequalities/) highlights the importance of NHS services complementing the action taken by local government to support the commissioning

of sexual health services. The LTP also facilitates exploration of the future commissioning arrangements to widen access and create capacity where it is needed.

- 1.2 A <u>Public Health England resource for commissioners (2019)</u> (https://www.gov.uk/government/publications/pharmacy-offer-for-sexual-health-reproductive-health-and-hiv) also highlights the role community pharmacy can play in supporting ongoing contraception.
- 1.3 In response to this, and in line with the <u>Community Pharmacy Contractual Framework (CPCF) 2019-2024</u>
 (https://www.gov.uk/government/publications/community-pharmacy-contractual-framework-2019-to-2024) commitment to "test a range of prevention services", a tiered pharmacy contraception service has been designed. The tiered approach will be as follows:
 - Tier 1 Ongoing monitoring and supply of repeat oral contraception (OC) prescriptions
 - Tier 2 Initiation of OC via a Patient Group Direction (PGD)
 - Tier 3 Ongoing monitoring and management of repeat long-acting reversible contraception (LARC), excluding intrauterine systems (IUS) and intrauterine devices (IUD)
 - Tier 4 Initiation of LARCs.
- 1.4 This service specification covers tier 1 of the service only, allowing routine monitoring and supply of repeat OC via a PGD.
- 1.5 The aim of the Pharmacy Contraception Service (PCS) is to offer greater choice from where people can access contraception services and create additional capacity in primary care and sexual health clinics (or equivalent) to support meeting the demand for more complex assessments.
- 1.6 This service will support the important role community pharmacy teams can play to help address health inequalities by providing wider healthcare access in their communities and signposting service users to local sexual health services in line with NICE guideline NG 102 (https://www.nice.org.uk/guidance/ng102).

2. Service objectives

- 2.1 The objectives of tier 1 of the service are:
 - To provide a model for community pharmacy teams to continue the provision of

- OC supplies initiated in primary care or sexual health clinics (or equivalent). This will be undertaken using PGDs to support the review and supply process.
- To establish an integrated pathway between existing services and community pharmacies that provides people with greater choice and access when considering continuing their current form of OC.

3. Requirements for service provision

- 3.1 Prior to provision of the service, the pharmacy contractor must:
 - be satisfactorily complying with their obligations under Schedule 4 of the NHS (pharmaceutical and local pharmaceutical services) Regulations (Terms of Service of NHS pharmacists) in respect of the provision of Essential services and an acceptable system of clinical governance
 - 2. notify NHS England that they intend to provide the service by completion of an electronic registration declaration through the NHS Business Services Authority (NHSBSA) Manage Your Service (MYS) platform.
- 3.2 The consultation must be provided by a pharmacist, except for body mass index (BMI) and blood pressure measurements, which may be conducted by a suitably trained pharmacy technician in advance of the pharmacist consultation (see 4.17).
- 3.3 The service can be offered directly to people presenting in the pharmacy with NHS prescriptions for OC or by receiving signposted referrals from local general practices and sexual health clinics (or equivalent).
- 3.4 A member of the pharmacy team will agree with a referred person, the date and time of their consultation.
- 3.5 The pharmacy contractor must have a standard operating procedure (SOP) in place covering the provision of the service. The SOP must include the process for escalation of issues identified, signposting details, equipment maintenance and validation, and staff training.
- 3.6 The pharmacy contractor must ensure that all pharmacy staff involved in the provision of the service, are familiar with and adhere to the SOP. The SOP should be reviewed regularly, including following any significant incident or change to the service.
- 3.7 Pharmacies must have a consultation room that will be used for the provision of the service which meets the requirements of the terms of service. Where a face-toface consultation is the preferred access model for the person, these consultations

must be delivered from the consultation room at the pharmacy.

3.8 Remote consultations are also permitted to be used to provide the service. When undertaking remote consultations, the contractor must ensure that there are arrangements in place at the pharmacy which enable staff to communicate confidentially with the person receiving the service by telephone or another live audio link or a live video link. https://www.england.nhs.uk/publication/remote-and-video-consultations-guidance-for-community-pharmacy-teams/) can help to plan for this.

Equipment

- 3.9 Before ongoing supply of an OC can be made, a blood pressure reading and, in some cases a BMI, will need to be recorded, according to the PGD protocol. Blood pressure and a BMI reading provided by the person may be accepted where the pharmacist feels this is clinically appropriate.
- 3.10 The pharmacy contractor must use equipment that is validated by the British and Irish Hypertension Society (BIHsoc), as recommended by NICE, to measure a person's blood pressure. The clinic blood pressure monitor used must be listed on one of the following lists:
 - <u>BIHsoc Validated blood pressure monitors for home (https://bihsoc.org/bp-monitors/for-home-use)</u> or
 - <u>BIHsoc Validated blood pressure monitors for specialist use</u> (<u>https://bihsoc.org/bp-monitors/for-specialist-use/</u>).
- 3.11 The NHS website provides an online <u>BMI calculator (https://www.nhs.uk/live-well/healthy-weight/bmi-calculator/)</u>.
- 3.12 Where IT solutions which meet the minimum digital requirements of the service (as specified within the NHS technical toolkits) are available, contractors must utilise these solutions to support the PCS. This will ensure that data is captured consistently, that all elements of the service are completed where appropriate, and the contractor is correctly reimbursed.

3. Service description

4.1 The pharmacy contractor must ensure the service is accessible, appropriate, and sensitive to the needs of all service users. No eligible person shall be excluded or experience particular 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.

People will access the service by one of the following routes:

- identified as clinically suitable by the community pharmacist and accept the offer of the service
- self-refer to a community pharmacy
- referred by their general practice as they have requested a repeat prescription and a review is needed
- referred from a sexual health clinic (or equivalent) or
- referred from other NHS service providers, eg urgent treatment centres or NHS 111.

NB for the purposes of this tier 1 service, a referral includes active signposting to attend the pharmacy to receive the service.

4.3 When a person attends the pharmacy to collect an NHS repeat prescription for OC, the service can be highlighted to them to consider when they need their next supply.

Inclusion criteria

- 4.4 To be eligible to access this service a person must:
 - be an individual seeking a repeat supply of their ongoing OC in line with the PGD protocol, and as follows:
 - combined oral contraceptive (COC) age from menarche to up to 50 years.
 - progestogen only pill (POP) age from menarche to 55 years
 - have already been supplied with OC by their general practice or a sexual health clinic (or equivalent) and a subsequent supply is needed. Their current supply of OC should still be in use.

People who have had a gap (of any duration in length) in their OC cycle, cannot be re-initiated on their original prescription as part of this service.

Exclusion criteria

- 4.5 A person will not be eligible for this service if:
 - They are considered clinically unsuitable, or are excluded for supply of OC

according to the PGD protocols, including, but not limited to:

- Individuals under 16 years of age and assessed as not competent using <u>Fraser Guidelines (https://learning.nspcc.org.uk/child-protection-system/gillick-competence-fraser-guidelines)</u>
- Individuals 16 years of age and over and assessed as lacking capacity to consent

Consultation

- 4.6 The pharmacy must respond to anybody requesting a repeat supply of their ongoing OC as soon as is reasonably possible. Following discussion, if the pharmacy is unable to offer a consultation within the time needed to meet the person's ongoing contraception need, they should be signposted to an alternative pharmacy or other service for a consultation.
- 4.7 Please refer to Annex A for a flow diagram describing the service.
- 4.8 Verbal consent to receive the service must be sought from the person and recorded in the pharmacy's clinical record for the service.
- 4.9 If the person provides consent to share the outcome of the consultation with their general practice, a notification should be sent via NHSmail or other secure digital mechanism. This message must clearly prompt general practice staff to add details of the consultation to the person's clinical record upon receipt. The information to be sent to the general practice can be found in <u>Annex B</u>.
- 4.10 The person should also be advised of the following information sharing that will take place:
 - The sharing of information about the service with NHS England as part of the service monitoring and evaluation; and
 - The sharing of information about the service with the NHSBSA and NHS England for the purpose of contract management and as part of post-payment verification (PPV).
- 4.11 The clinical appropriateness of a further supply of OC will be determined by the pharmacist, as part of a consultation with the person, following the guidelines in the PGD.
- 4.12 During the consultation, if the pharmacist is concerned about a potential safeguarding issue, then appropriate action should be taken, where necessary, in line with local safeguarding processes.

4.13 Either party may request / offer a chaperone to be present during the consultation.

More information regarding use of a chaperone can be found in the Clinical Governance section of the Pharmaceutical Services Negotiating Committee (PSNC)) website (https://psnc.org.uk/quality-and-regulations/clinical-governance/).

- 4.14 The consultation must include a conversation with the person regarding alternative and more effective forms of contraception, eg LARC.
- 4.15 For a combined oral hormonal contraception, repeat supply will require BMI and a blood pressure measurement taken in line with NICE guideline 136
 (hypertension). A person accessing the service may also offer their own weight, height and blood pressure measurements. Any self-reported measurements will need to be recorded as such.
- 4.16 Where BMI and blood pressure measurements are performed within the pharmacy, these can be conducted by the pharmacist as part of the consultation or by a suitably trained pharmacy technician in advance of the pharmacist consultation.

Outcomes and next steps

- 4.17 If the assessment criteria are met, supply of the ongoing OC can be made.
- 4.18 Repeat supplies of up to 12 months duration can be made, and unless there are reasons not to, such a duration of supply should be considered in line with the Faculty of Sexual and Reproductive Healthcare (FSRH) guidance (https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/). Restricting the length of supply could result in unwanted discontinuation of the method and an increased risk of pregnancy for the person.
- 4.19 Repeat supplies should be made in line with the person's previous supply, e.g. in the instance that a branded product has been supplied for clinical reasons such as an allergy to product constituents, the repeat supply should be made from an equivalent brand/generic equivalent of OC, that follows any medicines formulary requirements of the local integrated care board.
- 4.20 If a supply of the ongoing OC is not deemed clinically appropriate, the pharmacist should explain why this is the case to the person and refer them to their general practice or sexual health clinic (or equivalent) where they were initially provided with OC.

4.21 The pharmacy is required to report any patient safety incidents in line with the <u>Clinical governance approved particulars for pharmacies</u> (https://www.gov.uk/government/publications/clinical-governance-approved-particulars).

5. Clinical skills and knowledge

Competency requirements

5.1 Before commencement of the service, the pharmacy contractor must ensure that pharmacists and pharmacy staff providing the service are competent to do so in line with the specific skills and knowledge in paragraph 5.4 and the relevant PGDs. This may involve completion of training.

Competency evidence

- 5.2 The pharmacy contractor will keep documentary evidence that all pharmacists and pharmacy staff involved in the provision of the service are competent with regards to the specific skills and knowledge below.
- 5.3 Pharmacists providing the service will be personally responsible for remaining up to date with the skills and competencies identified in paragraph 5.4.

Accessible training modules

- 5.4 To deliver this service, the pharmacist should have evidence of competence in the clinical skills and knowledge covered in the following training modules on the Centre for Pharmacy Postgraduate Education (CPPE) and/or the Health Education England e-learning for healthcare (elfh) websites:
 - <u>CPPE Emergency contraception (https://www.cppe.ac.uk/gateway/ehc)</u>
 - <u>CPPE contraception (https://www.cppe.ac.uk/programmes/l/contra-e-01)</u>
 including <u>contraception e-assessment (https://www.cppe.ac.uk/programmes/l?</u>
 <u>t=CONTRA-A-13&evid=</u>) **or** the following four subsections of module 3 –
 <u>Contraceptive choices of the FSRH sexual and reproductive health e-learning (e-SRH) (https://www.e-lfh.org.uk/programmes/sexual-and-reproductive-healthcare/</u>) on elfh:
 - 03 01: Mechanism of action, effectiveness and UKMEC
 - 03_02: Choosing contraceptive methods
 - 03_03: Combined hormonal contraception
 - 03 04: Progestogen only methods (oral and injectable).

- <u>CPPE consultation skills for pharmacy practice</u>
 (https://www.cppe.ac.uk/gateway/consultfound) and e-assessment
 (https://www.cppe.ac.uk/programmes/l/consult-a-06)
- <u>CPPE Sexual health in pharmacies</u>
 (https://www.cppe.ac.uk/programmes/l/sexual-e-01) and e-assessment
 (https://www.cppe.ac.uk/programmes/l?t=Sexual-A-14&evid=) or the following four subsections of module 9 STIs of the FSRH e-SRH (https://www.e-lfh.org.uk/programmes/sexual-and-reproductive-healthcare/) on elfh:
 - 09_01: Epidemiology and transmission of STIs
 - 09_02: Sexually transmitted infection (STI) testing
 - 09_03: STI management
 - 09_04: Partner notification.
- and one subsection in the External resources module of the <u>Sexual Health</u>
 (<u>PWP</u>) (<u>https://portal.e-lfh.org.uk/Component/Details/546276</u>) e-learning on
 elfh:
 - FSRH Contraception counselling eLearning.

6. Data and information management

- 6.1 The pharmacy contractor should maintain appropriate patient records to ensure effective ongoing service delivery and audit.
- 6.2 With explicit consent, information relating to the consultation set out in <u>Annex B</u> will be shared with the person's general practice. However, if the person does not consent to sharing information with their general practice or they are not registered with a general practice, the consultation can still proceed, and a notification to the practice will not need to be sent.
- 6.3 Records of the reimbursement data reported to the NHSBSA's MYS portal should be retained for 3 years for post payment verification purposes (See Annex C).
- 6.4 Data recorded via electronic clinical records systems may be shared with the NHSBSA as part of normal payment arrangements (see section 7 below). An application programming interface (API) is being developed to facilitate automatic transfer of this data into the NHSBSA MYS platform and to improve payment claim accuracy. Details of the API and the data to be reported from clinical systems to MYS are listed in <u>Annex C.</u>
- 6.5 Data recorded via electronic clinical records systems may be shared with NHS England for service monitoring and evaluation purposes.

6.6 All relevant records must be managed in line with the <u>Records management</u> code of practice for health and social care (https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care).

7. Payment arrangements

- 7.1 Claims for payments for this service should be made monthly, via the NHSBSA's MYS platform, in accordance with the usual Drug Tariff claims process.
- 7.2 Pharmacies providing this service will be eligible for the following payments:

Item	Payment
Consultation fee	Payment of £18 per consultation
Pharmacy set up costs	 £900 per pharmacy premises paid in instalments as follows: £400 paid on signing up to deliver the service via the NHSBSA MYS portal £250 paid after claiming the first 5 consultations £250 paid after claiming a further 5 consultations (ie 10 consultations completed).

- 7.3 Reimbursement will be paid on the condition that the pharmacy has provided the service in accordance with the service specification.
- 7.4 If the pharmacy contractor is commissioned to deliver any related services, eg the Hypertension Case-Finding Service (incorporating BP clinic measurement), the contractor may not claim twice for the same activity.
- 7.5 The product price for the OC supplied will be reimbursed in accordance with the Drug Tariff determination. An allowance at the applicable VAT rate will be paid to cover the VAT incurred when purchasing the product supplied. Any purchase margin

by pharmacies relating to contraceptives supplied as part of this service would be included in the calculation of allowed purchase margin that forms a part of agreed NHS pharmacy funding.

- 7.6 Where a price concession has been granted for specific strengths of a product, this concession will apply to those specific strengths of products supplied as part of this service. Concessions will only apply to the month in which they are granted according to the usual Drug Tariff arrangements.
- 7.7 Out of pocket expenses cannot be claimed as part of this service.
- 7.8 Prescription charges are not relevant to the provision of this service and an appropriate patient declaration is not required.
- 7.9 Claims for payment should be submitted within one month of, and no later than three months of providing the chargeable activity. Claims which relate to work completed more than three months after the consultation will not be paid.

8. Withdrawal from the service

- 8.1 If the pharmacy contractor wishes to stop providing the service, they must notify the Commissioner that they are no longer going to provide the service via the MYS platform, giving at least one month's notice prior to the cessation of the service. The pharmacy contractor may be asked for their reason for withdrawal from the service.
- 8.2 If a pharmacy contractor de-registers from the service or ceases trading within 30 days of registration, they will not qualify for the £400 set up fee. In this event, if the £400 fee has already been paid to the contractor, this money will be claimed back.

9. Monitoring and post payment verification

Monitoring

- 9.1 In addition to meeting the Essential services requirements, the pharmacy contractor shall ensure the pharmacy has the following and that these are available for inspection should the local NHS England or integrated care system (ICS) primary care commissioning team undertake a site visit:
 - A working and appropriately calibrated blood pressure monitor (see section 3.10).
 - Sexual health promotional media or evidence of an ability to signpost.

 A suitable quantity of OC products to enable efficient and direct supply to the person attending and ensure continuation of supply.

Post payment verification

9.2 The Commissioner reserves the right to audit or conduct PPV on the information and data held at the pharmacy in respect of this service.

Annex A: service pathway						

(<u>https://www.england.nhs.uk/wp-content/uploads/2023/01/Pharmacy-Contraception-Service-Patient-Pathway-900.jpg</u>)

Annex B: sending information to general practices

Where consent is provided, information on the consultation must be sent via NHSmail or other secure digital process to the person's general practice for entry into the patient record. The following information should be sent:

- full name
- · date of birth
- address
- postcode
- referrer organisation
- date of consultation
- systolic blood pressure
- diastolic blood pressure
- BMI (when applicable)
- medicine supplied
- quantity of medicine supplied
- consultation outcome
- no supply reason

Annex C: dataset to be reported to the NHSBSA's MYS portal

An application programming interface (API) will be available within pharmacy clinical record systems. This will support the below dataset being extracted from patient records with the data being submitted to the NHSBSA MYS portal for payment, monitoring and evaluation purposes:

- system ID
- NHS number
- GP practice identifier
- referral date
- referrer organisation type
- referrer organisation
- organisation identifier (pharmacy)
- date of service provision
- · service provided
- reason for service
- professional role (of staff member providing the consultation)
- professional identifier (of staff member providing the consultation)
- consultation method
- contraception method
- · medicine supplied
- quantity of medication supplied
- dose duration
- supply type
- · consultation outcome
- no supply reason

- referral to
- escalated to
- receiving organisation identifier
- onward referral date

Annex D: dataset to be recorded for the PGD

The following dataset must be recorded for the supply of oral contraception against the PGD for monitoring and evaluation purposes:

- full name
- · date of birth
- address
- postcode
- GP practice identifier
- · date of consultation
- professional identifier (of staff member providing the consultation)
- relevant past medical, surgical and mental health history
- consent for treatment record
- systolic blood pressure
- · diastolic blood pressure
- BMI (when applicable)
- allergies and adverse reactions
- medicine supplied
- quantity of medicine supplied
- dose amount
- supply type
- information and advice given
- referral to
- escalated to
- receiving organisation identifier
- · onward referral date

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