

## SPECIFICATION

<b>Service</b>	Provision of Emergency Hormonal Contraception (EHC) through Community Pharmacy
<b>Council Lead</b>	Colleen Briton ( <a href="mailto:colleenbriton@gateshead.gov.uk">colleenbriton@gateshead.gov.uk</a> )
<b>Provider Lead</b>	Pharmacist
<b>Period</b>	1 <sup>st</sup> April 2023 – 31 <sup>st</sup> March 2024

### 1. Purpose

#### 1.1 Introduction

The Service is the free provision of Emergency Hormonal Contraception (EHC) to Service Users, specifically the dispensing of Levonorgestrel 1500 mcg tablet and Ulipristal 30mg tablet under PGD (see **Appendix 1** for PGDs). The Service is to be delivered alongside the signposting and/or referral of Service Users into other local sexual health services and or General Practice and the potential provision of dual screening (chlamydia and gonorrhoea) kits and condoms for under 16 to 24 year olds.

Throughout this Specification, the term Pharmacist or Practitioner refers to pharmacists registered with the General Pharmaceutical Council to practice in Great Britain and providing the Service as employee/agent of the Provider.

#### 1.2 Background

Sexual health is an important area of public health. The Government set out its ambitions for improving sexual health in its publication, *A Framework for Sexual Health Improvement in England*.<sup>1</sup>

Sexual health needs vary according to factors such as age, gender, sexuality and ethnicity, and some groups are particularly at risk of poor sexual health, especially young people, Men who have sex with men (MSM) and BME groups. Strong links exist between deprivation and sexually transmitted infection (STI's), teenage conceptions and abortions.

Local authorities commission HIV Prevention, open access genitourinary medicine (GUM) and contraception and sexual health services (CASH) for all age groups. This includes services commissioned from general practice and pharmacy, such as long-acting reversible contraception (LARC), Emergency Hormonal Contraception (EHC) and chlamydia screening.

<sup>1</sup> Department of Health (2013). *A Framework for Sexual Health Improvement in England*. (<http://www.dh.gov.uk/health/2013/03/sex-health-framework/>)

### 1.3 Evidence Base

Equitable access to EHC is an important step in the drive to reduce teenage and unplanned pregnancies. The broad coverage that pharmacies offer ensures good geographical accessibility.

Between 1998 and 2020, there was a 71 % reduction in Gateshead for under 18 conceptions,<sup>2</sup> however data pertaining to percentage of Gateshead births to mothers under 18 was 1.1% during 2020/21, worse than the 0.6% for England overall.<sup>3</sup> Whilst data for that period is to be considered in light of COVID restrictions and the effect on sexual behavior and health service provision, it highlights a need to ensure equitable EHC access, delivered in light of the particular sensitivities of the younger Service User (provision of a confidential and anonymous service in an environment that respects the dignity and confidentiality of the Service User is key).

## 2. Key Service Outcomes

### 2.1 Aims and outcomes of the Service

The overall aim of the Service is to improve access to EHC for individuals aged 13 years and above assessed as having capacity to consent (for under 16s, an assessment based on the use of Fraser Guidelines to assess Gillick competence must be made and documented) and to develop and enhance the EHC Service to contribute to reducing unplanned pregnancies and incidences of STIs.

The intended outcomes of this Service are:

- To improve access to emergency contraception and sexual health advice.
- To contribute to a reduction in the number of unintended pregnancies in the Service User group.
- To increase the knowledge of risks associated with STIs relative to the type of contraception chosen and sexual and reproductive health awareness.
- To signpost Service Users, especially those from high-risk groups (Young people, BME), to available mainstream sexual health services.
- To contribute to the local network of contraceptive and sexual health services to help ensure easy and swift access to advice and services.
- To increase the knowledge, especially among young people, of the availability of free emergency contraception from local pharmacies.

The overarching Service objectives are to:

- Reduce health inequalities in sexual health
- Develop a wide network of community pharmacies offering an easily accessible, free emergency hormonal contraception to Service Users.

<sup>2</sup> Office for National Statistics

<sup>3</sup><https://fingertips.phe.org.uk/profile/sexualhealth/data#page/13/gid/8000057/ati/402/iid/90742/age/1/sex/4/cat/-1/ctp/-1/yr/1/cid/4/tbm/1>

- Improve convenience of access and convenient access and plurality of provision for Service User choice
- Increase referrals, particularly of higher risk groups, into mainstream sexual health services

### 3. Service Scope and Delivery

#### 3.1 Service Description and Delivery

The Service is the provision of (Levonorgestrel 1500 mcg tablet and Ulipristal 30mg tablet) to Service Users according to the approved local Patient Group Directions (PGDs), the most recent versions effective from 1<sup>st</sup> April 2023 Direction Number GCP 20231/01C (FRSH v2.0) and GCP 20231/02C (FRSH v2.0) (**see Appendix 1**).

The Provider must have a Standard Operating Procedure in place which covers the supply of Levonorgestrel 1500mg tablet(s) or a Ulipristal 30mg tablet via the PGDs.

The Service must be provided in compliance with Fraser guidelines and Department of Health guidance for the provision of confidential sexual health advice and treatment for young people aged under 16. Providers are to ensure ready access to the following link:

<https://learning.nspcc.org.uk/child-protection-system/gillick-competence-fraser-guidelines>

**Should the exclusion criteria for the PGD(s) apply, Pharmacists MUST take all practicable steps to provide the Service User with a same day referral appointment to their GP or the sexual health service** (see 3.2 Care Pathways and Safeguarding and 4.3 Referral Process and Access, below). Records must be kept regarding excluded Service Users, reasons for exclusion and subsequent actions or advice given.

The Service is to be delivered by **accredited** Community Pharmacists (see Schedule 1 – Training and Qualifications below), **free of charge** to the Service User.

When delivering the Service, the Provider/Pharmacist must:

With appropriate underpinning knowledge, competently undertake the clinical assessment of Service Users leading to treatment according to the indications listed in the accompanying PGDs.

Ensure that the various contraceptive protection and sexual health service options are discussed in conjunction with or without supplied medication. All women asking for emergency contraception **must** be told that a copper intrauterine device is more effective than an oral method.<sup>4</sup>

<sup>4</sup> NICE Quality standard [QS129] and Faculty of Sexual and Reproductive Healthcare [www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/](http://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/)

Actively signpost Service Users to the Integrated Sexual Health Service to encourage full sexual health screening.

Provide a professional, confidential and anonymous Service in an environment that respects the dignity and confidentiality of the Service User. The Provider must have and use an accredited consultation area. The consultation area must:

- Enable both the Service User and the pharmacist to sit down together.
- Enable the Service User and pharmacist to talk at normal speaking volumes without being overheard by other visitors to the pharmacy, or by staff undertaking their normal duties.
- Be clearly designated as a private consultation area, distinct from the public areas of the pharmacy.
- Have suitable equipment to enable live input of data into the EHC PharmOutcomes template.

Record each consultation using PharmOutcomes as it occurs as a live service (all fields must be completed to ensure prompt payment). The Service User **must** be present at the point of EHC supply. No third party EHC supplies are permissible.

Provide support and advice to Service Users on the avoidance of pregnancy, STIs through safer sex and condom use. Information will should also be given on the use of long-acting reversible contraception along with other regular contraceptive methods including the provision of information on how to access free condoms, either supplied by the Pharmacy as part of the Condom Distribution Scheme (see below) or referral to the Integrated Sexual Health Service (see 4.3 Referral Process and Access below).

Free Dual Screening (chlamydia and gonorrhoea) kits can also be supplied by the Provider to Service Users aged 16 to 24 years (attracting a £1 supplement paid by the Council for each kit supplied, to be claimed PharmOutcomes), as well as signposting to free Condom Distribution Scheme providers. This is strongly encouraged by the Council, see **Appendix 3** for details. Should Providers wish to offer this additional provision, please contact the Gateshead Integrated Sexual Health Service to discuss further and facilitate;

- [www.gatesheadsexualhealth.co.uk](http://www.gatesheadsexualhealth.co.uk)
- telephone: 0191 283 1577
- secure email inbox: [stsft.sexualhealthreferrals@nhs.net](mailto:stsft.sexualhealthreferrals@nhs.net)

Requests to restock Dual Screening kits can be made to Dan Dobson at the Integrated Sexual Health Service, using the same details above.

Information advertising the Service must be made prominent at the Provider premises. The Provider is strongly encouraged to promote other local sexual health services and sexual health campaigns and must ensure relevant written information in relation to the EHC Service is readily and freely available to the public. As a minimum the Provider must actively advertise the Gateshead Integrated Sexual Health Service and its clinic location and opening times.

See [www.gatesheadsexualhealth.co.uk/](http://www.gatesheadsexualhealth.co.uk/) for access to Gateshead Integrated Sexual Health service information, including clinic times and locations.

See also [www.ourgateshead.org/oneyou](http://www.ourgateshead.org/oneyou) for general health wellbeing local information.

The Provider is expected, upon request, to support programme developments across all Sexual Health Services in Gateshead.

All medicines supplied must be labelled to comply with the Medicines Act 1968.

### **3.2 Care pathways and Safeguarding**

The Service standard or standard operating procedures set by the Provider must reflect national and local child and vulnerable adult safeguarding procedures. A full guide to local arrangements can be found here: [www.gatesheadsafeguarding.org.uk/](http://www.gatesheadsafeguarding.org.uk/)

**Please refer to Appendix 2 for local safeguarding contact details.**

**Whenever the exclusion criteria apply**, or the Service User wishes to use the option of copper intra-uterine device for emergency contraception, the Provider **must** refer the Service User onto a specialist sexual health service [www.gatesheadsexualhealth.co.uk/](http://www.gatesheadsexualhealth.co.uk/) or their GP if necessary (see 4.3 Referral Process and Access, below). It is recommended that Service Users requesting IUD as emergency contraception are also given EHC unless contraindicated. Providers are advised to keep an anonymous record of all these referrals.

**All practicable steps should be taken by the Provider to ensure the Service User is provided with a same day referral before they leave the consultation.**

When an accredited Pharmacist is not available to make a supply of EHC under the PGD, or in the event a supply cannot be made for whatever reason, the Service User is to be actively referred to or advised of alternative sources of supply, including other pharmacies that supply EHC under PGD and other local contraception and sexual health services, including General Practice. The Provider must telephone the referral to the service to which they are directing the Service User, to ensure that the service is available to the Service User that day and an appointment is confirmed and supplied to the Service User. See 4.3 Referral Process and Access below.

### **3.3 Interdependencies and relationships**

The Provider should maintain efficient working relationships with allied services, agencies and stakeholders to enhance the quality of care delivered and ensure the holistic nature of the Service. Specifically, links are to be maintained with, GPs, the Gateshead Integrated Sexual Health Service, Council Public Health Commissioners, and any other sexual health and secondary health service provider, for use when relevant.

The Service cannot work in isolation and the Provider is required to have an awareness of the wider needs of Service Users and increase the opportunity for Service Users to achieve optimum sexual health outcomes. Providers should be mindful of organisations delivering the following services:

- Abortion Providers
- Safeguarding Team
- Antenatal and post-natal services
- Cervical Screening Programme
- Child and adolescent mental health services
- Drug, alcohol, obesity and smoking intervention services
- General practice
- Gynaecology
- HIV treatment and care services
- Male and female sterilisation services
- Mental health services
- Other healthcare service areas including voluntary sector
- Pathology and laboratory services
- Prisons and youth offender's institutions
- School and education services
- Sexual Assault Referral Centre
- Social Care
- Youth services

## 4. Service Location, Availability and Referral

### 4.1 Service location.

The Service is to be provided within the locality of Gateshead, within the full opening hours of the community pharmacy contract.

### 4.2 Equality, Accessibility, Acceptability

All policies and services, including those relating to sexual health, should be designed to meet the needs of the entire target population. This should include action to address inequalities, wherever relevant<sup>5</sup>.

### 4.3 Referral process and access.

Referral into the Gateshead Integrated Sexual Health Service for further sexual health care, including LARC Referral, is:

Email the secure referral inbox: [stsft.sexualhealthreferrals@nhs.net](mailto:stsft.sexualhealthreferrals@nhs.net)  
 Telephone: **0191 283 1577**  
 Visit: [www.gatesheadsexualhealth.co.uk](http://www.gatesheadsexualhealth.co.uk)  
 for further Accessing Services details

<sup>5</sup> Department of Health (2010). *Equality Impact Assessment for National Sexual Health Policy*  
[http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_111231.pdf](http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_111231.pdf)

All referrals into the Gateshead Integrated Sexual Health Service will be directed to an appropriate sexual health clinician to make contact with the Service User.

A full range of local sexual health care provided by Gateshead Sexual Health Service can be found by visiting the following link to support signposting and referral <https://bit.ly/3ZRGOr8>

Service Users may self-refer or be referred via appropriate professionals from a range of organisations.

Following the consultation, whether medication is supplied, the accredited Pharmacist may decide it is relevant to provide onward signposting to sexual health services that provide long-term contraception methods and diagnosis and management of STIs.

Providers are to give guidance and signpost Service Users to community contraceptive services and GPs as appropriate.

Providers are to inform the Service User of other health and social care providers and support organisations, such as Service User groups, when appropriate.

Service Users are to be actively referred to the local specialist sexual health website, to access clinic times, locations, and the option to remotely request dual screening (chlamydia and gonorrhoea) testing kits. [www.gatesheadsexualhealth.co.uk/](http://www.gatesheadsexualhealth.co.uk/)

## 5. Training & Qualifications

### 5.1 Training & Qualifications

Please refer to Schedule 1 (Conditions Precedent) for a comprehensive description of Training and Qualification requirements to enable Pharmacist delivery of the Service.

### 5.2 Patient Group Direction (PGD)

It is an absolute requirement under this Contract for the Provider to apply the PGDs GCP 20231/1C (FSRH V2) and GCP 20231/02C (FSRH V2) (Appendix 1). Both PGDs are downloadable via the LPC website (link in Appendix 1) and the PharmOutcomes template module.

## 6. Contract Monitoring and Quality Framework

**6.1** The Provider must complete **all fields** as appropriate within the PharmOutcomes module template as a live service.

Other quality indicators that must be evidenced upon request:

- Women asking for emergency contraception are told that a copper intrauterine device is more effective than an oral method.
- The Provider actively advertising the Service within the Provider's premises, together with related sexual health information and the main sexual health service clinic location and opening times which can be downloaded -see [www.gatesheadsexualhealth.co.uk/](http://www.gatesheadsexualhealth.co.uk/)

- The Provider reviewing its Standard Operating Procedures (SOPs) and referral pathways for the Service on a regular basis.
- The Provider ensuring that the Service is delivered within a private consultation area.

**6.2** A quality audit assessment can be arranged at any point within the Term of the Contract. To minimise the administrative burden, the Council would accept from Providers, (where applicable), existing quality audit information generated for the purposes of other principal stakeholders, for example NHS England (NHSE), General Pharmaceutical Council (GPhC), Care Quality Commission (CQC) etc.

The Council will endeavour to give the Provider 28 days' notice that it is carrying out the assessment, however if concerns or issues are raised regarding the Service, the Council can carry an unplanned assessment without any notice.

## 7. Performance Indicators

**7.1** Performance of the Service is monitored by the completion of all required fields appropriate to the EHC Service consultation via the PharmOutcomes platform.

**7.2** The Provider must complete any national statistics as and when required at the request of the Council. The Provider must supply information in relation to any other relevant Service outcome indicators requested by the Council.

**7.3** As delivery of the Service consultation is recorded live using PharmOutcomes, performance data is captured via PharmOutcomes and automatically presented to the Council as auto-generated reports.

Please see Schedule 2, KPIs

## 8. Pricing

Please see Schedule 3, Pricing



**Appendix 1 Gateshead EHC PGDs –**

**These are available to download via the PharmOutcomes Gateshead EHC module and the LPC website <http://www.gandstlpc.net> 'services' tab**

## Appendix 2 – Local Safeguarding Arrangements

**Comprehensive information and guides are available at**  
[www.gatesheadsafeguarding.org.uk/](http://www.gatesheadsafeguarding.org.uk/)

<b>Gateshead Safeguarding Team Details</b>		
<b>Last update March 2023</b>		
Integrated Referral & Assessment Team (IRT) (Children Services)	Gateshead Council	Civic Centre, Gateshead Office Hrs Tel No: <b>0191 433 2515/2653</b> Email: <a href="mailto:R&amp;ADuty@Gateshead.Gov.UK">R&amp;ADuty@Gateshead.Gov.UK</a> Out of Hours Tel No: <b>0191 4770844</b> Email: <a href="mailto:EDT@Gateshead.Gov.UK">EDT@Gateshead.Gov.UK</a> Online referral form (child Protection) <a href="https://www.gatesheadsafeguarding.org.uk/article/9298">https://www.gatesheadsafeguarding.org.uk/article/9298</a>
Safeguarding Unit	Gateshead Council	Civic Centre, Gateshead Tel No: <b>0191 433 3565</b> Email: <a href="mailto:SafeguardingChildrenUnit@Gateshead.Gov.UK">SafeguardingChildrenUnit@Gateshead.Gov.UK</a>
Dr. Neelmanee Ramphul	Designated Doctor (QE)	Queen Elizabeth Hospital Tel No: <b>0191 482 0000</b> Email: <a href="mailto:n.ramphul@nhs.net">n.ramphul@nhs.net</a>
Trina Holcroft	Designated Nurse, Safeguarding Children (ICB)	North East & North Cumbria ICB, Riverside House Tel No: <b>0191 217 2552</b> Mob No: <b>07585403072</b> Email: <a href="mailto:tholcroft@nhs.net">tholcroft@nhs.net</a>
Maxine Duffy	Named Nurse (safeguarding children) (QE)	Paediatric Department - Queen Elizabeth Hospital Tel No: <b>0191 445 2049</b> Safeguarding Admin Tel No: <b>0191 445 2248</b> Mob: <b>07970261784</b> Email: <a href="mailto:maxineduffy@nhs.net">maxineduffy@nhs.net</a>
Rachael McDougall	Named Nurse Child Protection (HDFT)	0-19 Service Gateshead - Harrogate and District NHS Foundation Trust Tel No: <b>07741700425</b> Email: <a href="mailto:rachael.macdougall@nhs.net">rachael.macdougall@nhs.net</a>
Linda Hubbucks	Designated Nurse for Looked After Children	Tel No: <b>0191 2172828</b> Mob: <b>07769362016</b> Email: <a href="mailto:Linda.hubbucks@nhs.net">Linda.hubbucks@nhs.net</a>
Dr A Liddle	Named GP (Children Protection)	Newcastle/Gateshead ICB Tel No: 07584 162366 Email: <a href="mailto:alexander.liddle@nhs.net">alexander.liddle@nhs.net</a>
Claire Brunskill	Named Midwife	Gateshead Health NHS Foundation Trust Tel No: <b>0191 445 8186</b> Mob: <b>07769307715</b> Email: <a href="mailto:Claire.brunskill1@nhs.net">Claire.brunskill1@nhs.net</a>

## Appendix 3 – Dual Screening Kits and Condom Pack Offer



### Grab & Go Kits: Chlamydia, Gonorrhoea & Condom Pack Offer: EHC

#### Background & Overview

Free Dual Screening (Chlamydia and Gonorrhoea) kits can be supplied by the provider to service users aged under 25 (attracting a £1 supplement paid by the Council for each kit supplied and claimed using Pharmoutcomes template). Free condom packs are also supplied as part of this offer to further support service delivery.

Requests to restock dual screening & condom kits can be made to Dan Dobson at the Integrated Sexual Health Service by emailing: [dan.dobson2@nhs.net](mailto:dan.dobson2@nhs.net)

Chlamydia & Gonorrhoea are the most common sexually transmitted infections (STIs) in England, especially amongst people under 25 years old. But most people with infections will not have any noticeable signs or symptoms of the infection. Chlamydia & Gonorrhoea are both easy to treat and cure. Anyone who's sexually active can get the infections and pass it on. Young people do not need to have lots of sexual partners.

Gateshead Sexual Health are offering free, confidential dual testing (Chlamydia & Gonorrhoea) and free condom kits as part of the National Chlamydia Screening Programme (NCSP). Testing kits and condom packs are being routinely offered to under 25 year olds in England. Chlamydia in females can cause inflammation and pain in the pelvis, an ectopic pregnancy (a pregnancy in the fallopian tubes) and infertility, this risk is increased if a person contracts the infection again and again. For males an untreated infection can cause swelling the epididymis (the tubes that carry sperm from the testicles) and the testicles. This could affect a person's fertility.

The UK Health Security Agency (UKHSA) have introduced new guidance regarding target audience for dual screening offer to young people under the age of 25. Aims of the National Chlamydia Screening Programme (NCSP) is to focus on reducing the harms from untreated chlamydia infection in women and other people with a womb or ovaries including transgender men, and non-binary people assigned female at birth, and intersex people with a womb or ovaries.

The harmful effects of Chlamydia occur predominantly in women and other people with a womb or ovaries. Opportunistic screening should focus on sexually active females attending for emergency contraception with the proactive offer of a dual screening and condom pack alongside EHC consultations. Dual screening/condom offer and pathway process can be found here: <https://bit.ly/3YRrglN>


Gateshead Sexual Health are encouraging all community partners to routinely offer, where appropriate opportunistic dual screening and free condom kits for service users attending pharmacy for emergency contraception. Kits will be supplied free of charge to all requesting services and delivered within 10 working days.

UK Health Security Agency (UKHSA) collects data on all chlamydia tests undertaken in England from NHS laboratories, local authorities and NHS commissioned laboratories, to measure screening activity. Personal details are not shared or collected.

For more information about our services please visit:

[www.gatesheadsexualhealth.co.uk](http://www.gatesheadsexualhealth.co.uk)

Services Provided by:

  
South Tyneside and Sunderland  
NHS Foundation Trust



**GATESHEAD  
SEXUAL  
HEALTH**

**Chlamydia  
& gonorrhoea  
Screening**

**Grab & Go Kits:  
Chlamydia, Gonorrhoea & Condom Pack Offer: EHC**

#### What is the Chlamydia & Gonorrhoea test?

The test is free & confidential and involves the patient providing a urine sample in a container provided, completing a short form and posting the test in the free post envelope included back to the laboratory (full instructions for patients are included in the kits). Patients complete the test themselves by taking kits of site following EHC consultation or requesting in store, without the need for an examination.

Please see the following link for example of patient instruction. Full instructions and local sexual health information are also included in the packs for service users to follow and support completion of test kit <https://bit.ly/3LtnhZx>

Chlamydia & Gonorrhoea can be easily treated with antibiotics. The antibiotic treatment is **FREE** on the NHS and available from Gateshead Sexual Health. If a patient has the infection following completion/posting of the test kit, Gateshead Sexual Health will inform the patient by text or letter, arrange an appointment, provide antibiotic treatment and will manage the patients sexual health care. All patients who complete and post the test will be informed of results within 8 days of posting the kit. There is nothing clinical or administrative for community partners (pharmacy) to complete other than issuing the kits for service users to complete themselves at home. Testing kits will be delivered pre made and ready to issue. Pharmacy can then issue to eligible service users alongside EHC and act as a collection points for testing in community settings. Gateshead Sexual Health will manage all results, treatments and patient sexual health care from kits issued in community settings. Condom kits will also be delivered pre made ready to issue and include local sexual health service provision and condom demonstration information including what to do in the event of a contraceptive failure.

#### Referral Information and Signposting

For service users attending EHC that require further sexual health care including LARC Referral: Please refer direct to Gateshead Sexual Health by emailing the secure referral inbox below:

[stsft.sexualhealthreferrals@nhs.net](mailto:stsft.sexualhealthreferrals@nhs.net)

**All referrals will be directed to an appropriate sexual health clinician to make contact with patient.**

Or contact by telephone 0191 283 1577 or visit [www.gatesheadsexualhealth.co.uk](http://www.gatesheadsexualhealth.co.uk)

A full range of local sexual health care provided by Gateshead Sexual Health care can be found by visiting the following link to support signposting and referral <https://bit.ly/3ZRGOr8>

Printed promotional materials to advertise will also be made available to all services.

For more information about our services please visit:

[www.gatesheadsexualhealth.co.uk](http://www.gatesheadsexualhealth.co.uk)

Services Provided by:

**NHS**  
South Tyneside and Sunderland  
NHS Foundation Trust

## SCHEDULE 1

### CONDITIONS PRECEDENT

#### 1. GPhC

Upon request, provide the Council with the General Pharmaceutical Council Registration Number for the Pharmacy premises along with details of a Pharmacy Superintendent and their GPhC Number.

#### 2. Insurance

Upon request, provide the Council with a copy of the insurance policies to illustrate that the Required Insurances (as detailed in the Terms and Conditions and Invitation to Tender) are in place.

#### 3. Training and Qualifications

##### 3.1 **Accreditation to enable delivery of the EHC Service is via annual CPPE Declaration of Competence (DoC) for Emergency Hormonal Contraception, including safeguarding. The declaration remains the professional responsibility of the Practitioner.**

Practitioners shall demonstrate competency in the use of PGDs (see NICE competency framework for health professionals using patient group directions). <https://www.nice.org.uk/guidance/mpg2/resources>

**Practitioners MUST also attend a 'local EHC update' training session regarding this Service within 2 years of a consultation claim.** Local EHC updates will be advertised to Practitioners.

**In the event that a local EHC update training event is unavailable, Practitioners MUST demonstrate the studying of the online resources ([gandstlpc.net/ehc-training.html](http://gandstlpc.net/ehc-training.html)) If you have studied the online update, this should also be reflected on within your DoC at CPPE.**

Practitioners must take all practicable steps to attend local EHC updates or study online resources or action may be taken to withhold payments, suspended or terminate the Service upon ongoing failure to do so.

##### 3.2 Practitioners must meet and evidence upon request declared competencies for the purposes of audit and quality checks.

##### 3.3 Providers must retain copies of their own or Staff's evidence of accreditation and training at the premises where they offer the Service and provide copies to the Council upon request. This remains an enrolled service. Ensure CPPE viewer is enabled to allow commissioners the option to audit competency status.

- 3.4 The Provider will be required to comply with General Pharmaceutical Council Standards of Conduct, Ethics and Performance and demonstrate maintenance of knowledge, skills and competencies, with evidence of Continuing Professional Development, ideally via the professional registration and revalidation process on the General Pharmaceutical Council website [www.mygphc.org/home](http://www.mygphc.org/home)
- 3.6 The Provider shall ensure that each Practitioner ensures their skills and knowledge are kept up to date prior to supplying under the PGD. Each Practitioner supplying under the PGDs **must** sign and date the Authorisation section of each PGD to demonstrate that they accept personal responsibility for working under them, understand the legal implications and will work within the scope of the PGD.
- 3.7 The Provider must ensure locums also sign and date the current PGD for each shop they work in.
- 3.8 The Provider must ensure that supporting Pharmacy Staff are trained in dealing with Service Users in a patient-centred, user-friendly, confidential, and non-judgmental manner when requesting EHC. Providers are expected to work towards implementing the Department of Health paper 'You're Welcome' Quality Standards<sup>6</sup>.
- 3.9 Pharmacists must, with appropriate underpinning knowledge, competently undertake the clinical assessment of patients leading to treatment according to the indications listed in the accompanying PGDs.
- 3.10 Each Provider pharmacy must have a Standard Operating Procedure in place which covers the supply of Levonorgestrel 1500mg tablet(s) or a Ulipristal 30mg tablet via the PGDs.
4. **Patient Group Direction(s):** See above, Appendix 1

## SCHEDULE 2

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<sup>6</sup> <https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services>

## PERFORMANCE INDICATORS & SERVICE REQUIREMENTS

Performance Indicator / Service Requirement	Threshold	Method of Measurement	Consequence of breach
Standard Operating Procedure (SOP) is in line with the Service Specification and reviews this SOP and the referral pathways for the Service on a regular basis.	100% compliance	Contract Assurance process	Appropriate action under Clause 24 of the Terms and Conditions ( <i>Defaults and Suspension</i> )
Evidence of Fraser guidelines fulfilled for Service Users under 16.	100% compliance	Contract Assurance process	As above
Records kept regarding excluded Service Users, reasons for exclusion and subsequent actions or advice given.	100% compliance	Contract Assurance process	As above
Pharmacists and Staff involved in the provision of the Service have undertaken CPD and / or training relevant to the Service.	100% compliance	Contract Assurance process	As above
All women asking for emergency contraception are told that a copper intrauterine device is more effective than an oral method (NICE Quality standard [QS129] Published date: September 2016 & FSRH Emergency contraception March 2017)	100% compliance	Contract Assurance process	As above
Records of all drugs supplied in relation to this Service for audit purposes.	100% compliance	Contract Assurance process	As above
Use of and compliance with Pharmoutcomes module to input/monitor delivery of the Service (live input at point of consultation)	100% compliance	Contract Assurance process	As above
Evidence of advice given to Service Users, future contraception needs explored, STI testing undertaken, treatment (if necessary) and risk	100% compliance	Contract Assurance process	As above

discussion and any details of onward referral.			
Full use is made of the promotional material available for the Service and promotes its uptake via window displays or similar	100% compliance	Contract Assurance process	As above

A quality audit assessment can be arranged at any point within the Term of the Contract. To minimise the administrative burden, the Council may accept from Providers existing quality audit information generated for the purposes of other principal stakeholders, for example NHS England (NHSE), General Pharmaceutical Council (GPhC), Care Quality Commission (CQC).

The Council will endeavour to give the Provider 28 days' notice that it is carrying out the assessment, however if concerns or issues are raised regarding the Service, the Council reserves the right to carry an unplanned assessment without any notice.



**SCHEDULE 3****PRICING**

In consideration of the Provider delivering the Service the Council will pay the Provider the following Price:

<b>Element to be Delivered</b>	<b>Amount</b>
Consultation	£11.26
Dual (chlamydia and gonorrhoea) Screening kit	£1.00
Levonorgestrel per dose	£5.20 drug tariff unit price as of April 1 <sup>st</sup> 2023 plus VAT
Ulipristal per dose	£14.05 drug tariff unit price as of April 1 <sup>st</sup> 2023 plus VAT

Claims are to be submitted by Providers/Practitioners during each consultation using PharmOutcomes as it occurs as a live Service (all fields must be completed to ensure prompt payment). PharmOutcomes will then auto-generate such claims as monthly invoices to the Council.

The Council shall pay the Provider the Price following verification of the PharmOutcomes monthly invoice, within 30 days of receipt.

Practitioners must include their full name next to each claim for consultation and/or supply of medication. The monthly invoice will only be paid so long as Practitioners have complied with the PGD, 'Qualifications Required' and the inclusion criteria of the PGD.

There is a 3-month grace period for submission and payment of historical claims. For the avoidance of doubt, any claim made outside of the 3-month grace period (claims for activity undertaken more than 3 months previously) will not be paid by the Council.

The Price shall remain as set out during the financial year 2023/24. If the Contract is extended in accordance with Clause 2.4 of the Terms and Conditions the Price shall continue at the same rate unless a variation is agreed with Council.

## SCHEDULE 4

### DATA SHARING FOR EHC SERVICE

#### DEFINITIONS

**Agreed Purposes:** The performance by each party of its obligations under this Contract and in order to deliver the Service under the provisions of the National Health Service Act 2006 with the Localism Act 2011 providing the incidental powers to share data in order to allow for payment to be made for the provision of the Service.

**Controller, data controller, processor, data processor, data subject, personal data, processing and appropriate technical and organisational measures:** as set out in the Data Protection Legislation in force at the time.

**Data Protection Legislation:** (i) the Data Protection Act 1998, until the effective date of its repeal (ii) the General Data Protection Regulation ((EU) 2016/679) (**GDPR**) and any national implementing laws, regulations and secondary legislation, for so long as the GDPR is effective in the UK, and (iii) any successor legislation to the Data Protection Act 1998 and the GDPR, in particular the Data Protection Bill 2017-2019, once it becomes law.

**Permitted Recipients:** The parties to this agreement, the employees of each party, and the PharmOutcomes system.

**Shared Personal Data:** the personal data to be shared between the parties under clause 1.1 of this agreement. Shared Personal Data shall be confined to the following categories of information relevant to the following categories of data subject:

- a) Unique identifier for Service User
- b) Date of service provision to Service User
- c) Initials, age and postcode district of Service User
- d) Triage assessment of Service User (including referral or not, if so where from, reason for presentation to Service, alcohol involvement, time since UPSI, liver enzyme medication being taken, cycle length, last period date, point in cycle, period normal, other UPSI, breastfeeding, exclusion criteria applied, counselling given, previous use of EHC, EHC supplied or not, medicine batch number, expiry date, where taken, second dose required, chlamydia test and condoms supplied and any other relevant information); and
- e) Name of Provider and practitioner

## 1. DATA PROTECTION

- 1.1 **Shared Personal Data.** This clause sets out the framework for the sharing of personal data between the parties as data controllers. Each party acknowledges that one party (the Data Discloser) will regularly disclose to the other party (the Data Recipient) Shared Personal Data collected by the Data Discloser for the Agreed Purposes and shared via the PharmOutcomes system.
- 1.2 **Effect of non-compliance with Data Protection Legislation.** Each party shall comply with all the obligations imposed on a controller under the Data Protection Legislation, and any material breach of the Data Protection Legislation by one party shall, if not remedied within 30 days of written notice from the other party, give grounds to the other party to terminate this agreement with immediate effect.
- 1.3 **Particular obligations relating to data sharing.** Each party shall:
- (a) ensure that it has all necessary notices and consents in place to enable lawful transfer of the Shared Personal Data to the Permitted Recipients for the Agreed Purposes;
  - (b) give full information to any data subject whose personal data may be processed under this agreement of the nature such processing. This includes giving notice that, on the termination of this agreement, personal data relating to them may be retained by or, as the case may be, transferred to one or more of the Permitted Recipients, their successors and assignees;
  - (c) process the Shared Personal Data only for the Agreed Purposes;
  - (d) not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients;
  - (e) ensure that all Permitted Recipients are subject to written contractual obligations concerning the Shared Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this agreement;
  - (f) ensure that it has in place appropriate technical and organisational measures, reviewed and approved by the other party, to protect against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
  - (g) not transfer any personal data received from the Data Discloser outside the EEA unless the transferor:
    - (i) complies with the provisions of Articles 26 of the GDPR (in the event the third party is a joint controller); and

- (ii) ensures that (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 GDPR; (ii) there are appropriate safeguards in place pursuant to Article 46 GDPR; or (iii) one of the derogations for specific situations in Article 49 GDPR applies to the transfer.

1.4 **Mutual assistance.** Each party shall assist the other in complying with all applicable requirements of the Data Protection Legislation. In particular, each party shall:

- (a) consult with the other party about any notices given to data subjects in relation to the Shared Personal Data;
- (b) promptly inform the other party about the receipt of any data subject access request;
- (c) provide the other party with reasonable assistance in complying with any data subject access request;
- (d) not disclose or release any Shared Personal Data in response to a data subject access request without first consulting the other party wherever possible;
- (e) assist the other party, at the cost of the other party, in responding to any request from a data subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;
- (f) notify the other party without undue delay on becoming aware of any breach of the Data Protection Legislation;
- (g) at the written direction of the Data Discloser, delete or return and delete Shared Personal Data and copies thereof to the Data Discloser on termination of this agreement unless required by law to store the personal data;
- (h) use compatible technology for the processing of Shared Personal Data to ensure that there is no lack of accuracy resulting from personal data transfers;
- (i) maintain complete and accurate records and information to demonstrate its compliance with this Schedule 4 and allow for audits by the other party or the other party's designated auditor; and
- (j) provide the other party with contact details of at least one employee as point of contact and responsible manager for all issues arising out of the Data Protection Legislation, including the joint training of relevant staff, the procedures to be followed in the event of a data

security breach, and the regular review of the parties' compliance with the Data Protection Legislation.

- 1.5 **Indemnity.** Each party shall indemnify the other against all liabilities, costs, expenses, damages and losses (including but not limited to any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by the indemnified party arising out of or in connection with the breach of the Data Protection Legislation by the indemnifying party, its employees or agents, provided that the indemnified party gives to the indemnifier prompt notice of such claim, full information about the circumstances giving rise to it, reasonable assistance in dealing with the claim and sole authority to manage, defend and/or settle it. The liability of the indemnifying party under this clause shall be subject to the limits set out in 22 of the Terms and Conditions of this Contract.