

Northumbria Healthcare NHS Foundation Trust

SERVICE SPECIFICATION

Service	Emergency Hormonal Contraception and Chlamydia / GC Screening Service in Community Pharmacies
Commissioner Lead	Helen Mason, Service Manager Integrated Sexual Health Service
Provider	_____ Pharmacy
Period	1st April 2020 to 31st March 2021

1. Purpose

1.1 Aims of the service

The purpose of this service is to ensure equitable and timely access to emergency hormonal contraception for under 25 year old women. The service will also provide Chlamydia and Gonorrhoea screening (15-24yrs) and C Card from the community pharmacy. The purpose of this service is also to ensure referrals are made to sexual health services for ongoing contraception and further advice (imperative for all under 16 year olds)

1.2 Evidence Base

The cost of buying emergency hormonal contraception (EHC), approximately £27 per course, excludes many clients from accessing EHC via the community pharmacy. The product licence for over the counter sale further restricts access for this target group, as sales are restricted to those 16 years of age or over. The Copper IUD is the most effective method of EHC and should be offered as first line treatment if the timing is suitable and the woman is medically eligible.

There is evidence to suggest that young people want to be offered Chlamydia / Gonorrhoea Screening by health professionals and that those screened in core services including pharmacies are more likely to test positive for these infections. Offering screening via community pharmacies will ensure the scheme is accessible and targeted at those most likely to benefit from screening. Dual testing of chlamydia screening programme specimens was introduced in March 2012 as part of a range of outbreak control measures to tackle an increase in Gonorrhoea infection amongst young adults in the region. Following the successful detection of cases via this route it has been agreed that dual testing of CSP specimens will continue.

This service will reduce the barriers to access to EHC and contribute to a reduction in unintended pregnancies. Also, the service will raise the overall health benefits which screening for and treatment of sexual transmitted infections (STIs) provides by offering direct referral to local Contraception and Sexual Health Clinics (CASH) services / GPs.

NICE Guidance Prevention of sexually transmitted infections and under 18 conceptions PH3 (2007) recommends all clinicians working in primary and community care including pharmacists should provide one to one sexual health advice on:

- How to prevent and/or get tested for STIs and how to prevent unwanted pregnancies
- All methods of reversible contraception, including long-acting reversible contraception (LARC) (in line with NICE clinical guideline 30)
- How to get and use emergency contraception
- Other reproductive issues and concerns.

1.3 General Overview

Within a community pharmacy setting this service will provide;

- Access to free emergency hormonal contraception for women up to 25 years old)
- Chlamydia and Gonorrhoea screening (for 15-24yrs olds)
- Free condoms to 13-24 year olds
- Pregnancy testing
- Evidence based sexual health materials
- Referral to sexual health services for ongoing contraception and further advice (imperative for all under 16 year olds)

This service does not extend to the provision of any NHS England agreements with pharmacies.

1.4 Objectives

The service objectives are:

- To reduce health inequalities in harder to reach groups.
- To improve services, providing fast and convenient access and plurality of provision for patient choice
- To provide advice on sexual health as appropriate, including onward signposting and referrals
- To increase referrals, particularly of hard to reach young people, into mainstream sexual health services

1.5 Expected Outcomes

- Reduction in under 18 conception rate
- Reduction in unintended pregnancies
- Reduction in rate of terminations of pregnancies
- Increase number of Chlamydia / Gonorrhoea screens and positive diagnoses
- All under 16 year olds will be referred to sexual health services / GP for further contraception and advice
- All safeguarding concerns will be identified and referred appropriately

2. Scope

2.1 Service Description

The service will offer:

- Provision of emergency hormonal contraception (for women under 25 years old)
- Discussion of emergency contraceptive options including informing women that an intrauterine device is more effective than an oral method¹
- Provision of dual test for Chlamydia and Gonorrhoea screening
- Referral to sexual health services for ongoing contraception, further advice or where there are treatment contraindications
- Free condoms to 13-24 year olds
- Pregnancy testing
- Provision of evidence based sexual health materials

The service will be provided by one or more pharmacists or locum pharmacists that are appropriately skilled and knowledgeable.

The pharmacist(s) will:

- Assess clients for suitability of treatment at the time of presentation.
- Obtain and record informed consent for treatment from the client consistent with Department of Health guidance.

¹ NICE quality standard QS129, published September 2016

2.2 Accessibility / acceptability

The service and related training will support community pharmacies in working towards the Access Standards contained in the Department of Health's "You're Welcome" criteria.

In particular all pharmacists are required to maintain the confidentiality of client data in line with Caldicott principles. Pharmacists are reminded of their obligation within the code of ethics, in particular the maintenance of confidentiality²

The pharmacist and their staff must not disclose to any person any information acquired by them in connection with the provision of the services hereunder which concerns

- The identity of any client
- The medical condition of or the treatment received by any client.

The pharmacy is required to display latest information for local sexual health services including the QR code, downloadable app and website details³.

Pharmacy staff are encouraged to access further sexual health training with Northumbria Healthcare NHS Foundation Trust.

2.3 Whole System Relationships

This service contributes to the provision of a comprehensive and accessible sexual health service in North Tyneside.

2.4 Interdependencies

- Integrated sexual health service in North Tyneside and Northumberland
- Primary care

² [GPhC.org: Code of Ethics for Pharmacists and Pharmacy Technicians](https://www.gphc.org/)

³ www.northumbria.nhs.uk/sexualhealth

3. Service Delivery

3.1 Service Model

The pharmacist will provide sexual health advice and guidance to clients as well as assessing suitability of women for EHC. This will be in accordance with the Patient Group Directions (PGD) named in Appendix 1. The pharmacist offering this service will:

- Undertake a comprehensive sexual health history and risk assessment, including competence assessment
- Provide verbal and written information about all future contraceptive options to inform choice about future choices including verbal and written information on effectiveness, duration of use, side effects and those symptoms that require urgent assessment to increase client understanding.
- Give information on safer sex practices, information on effective condom use, a pack of condoms and information on where to obtain condoms via the C-card scheme.
- Provide Emergency Hormonal Contraception (EHC) to anyone under the age of 25 as appropriate offering referral for a Copper IUD as a first line treatment in all suitable cases.
- Supply a Chlamydia / Gonorrhoea Screening pack to those aged 15-24 indicating a desire to undertake screening.
- Produce an appropriate clinical record. Adequate recording should be made regarding the client's clinical, reproductive and sexual history, the counselling process. Any follow up consultations should be documented.
- Record a range of data relating to clients on the PharmOutcomes system including
 - Age of client (Fraser guidelines for under 16s)
 - Postcode
 - Details of intervention provided to each client
 - Previous form of contraception used
- All clients are advised regarding referral directly to their nearest Sexual Health Clinic at all stages of the consultation for STI advice, or for a robust contraception method, or where there are contra-indications.
- Identify any Safeguarding concerns and if appropriate refer to Children Social Care services.
- Offer pregnancy testing
- Provide evidence based sexual health materials

3.2 Pathways

Chlamydia / Gonorrhoea screening pathway.

Patient Group Directions for EHC named in Appendix 1.

3.3 Monitoring arrangements

The pharmacy will ensure that appropriate clinical governance arrangements are in place in line with Department of Health guidance. Any clinical governance breaches including serious clinical incidents in relation to this service will be notified to the clinical lead for sexual health Northumbria Healthcare Trust (One to One Centre / sexual health service).

The pharmacy must maintain appropriate records on each woman treated to ensure effective ongoing service delivery, clinical audit and reporting of activity and invoicing for payment.

The Pharmacy will be monitored on the number of consultations completed and number of supplies of EHC made. The number of pregnancy tests, condom packs and Chlamydia screening kits supplied will also be monitored.

The pharmacy must allow access by the Clinical Lead for sexual health services and other nominated auditors to all or any papers relating to this Agreement for the purposes of audit. The pharmacy must fully co-operate to carry out service evaluation audits as required.

3.4 Information Technology and Information management

The Provider will:

- Ensure that the case management system (and any other electronic record management system used) complies with the relevant security and data protection standards and those records are regularly backed up.
- Have a clear confidentiality and data handling policy, which is understood by all members of staff. The policy should be presented and clearly explained to Service Users before assessment for treatment begins.
- Ensure effective data monitoring mechanisms and systems are in place to demonstrate the identified outcomes (utilising PharmOutcomes system), to include all nationally mandated data systems and locally agreed Quality Outcome Indicators.
- Have policies in place to manage any loss of data, accidental or otherwise. The Provider must notify Northumbria of any information security incidents relating to Service Users within 24 hours of such an incident occurring.
- Demonstrate that they have information governance policies in place to ensure that records are held securely and Staff are appropriately trained in how to handle and store records.

3.5 Accommodation and equipment

Buildings and areas from which the Provider delivers all elements of the Service need to demonstrate appropriate clinical quality standards and be fit for purpose.

The Provider must inform the Trust in writing of any change in premises during the term of the Contract.

Premises from which the Services is delivered must be registered appropriately with the CQC and comply with their standards i.e. Outcome 10 Safety and Sustainability of Premises. Premises and facilities must also comply with DoH guidance regarding Sexual and Reproductive Health clinics⁴.

3.6 Medicines

All prescribers employed directly by the Service or working in an element of the Service which the Provider sub-contracts (in accordance with the terms of this contract) must:

- Adhere to both legal and good practice guidance on prescribing and medicines management in line with the Medicines Act 1968 and all associated legislation and regulations.
- Engage in quality and cost effective prescribing in the context of overall use of NHS resources.

Prescribed contraceptives will be provided free at the point of access to the Service Users under 25 years old.

The Provider must work to its own specific formulary to ensure that all drug prescribing is cost effective.

The Provider will:

- Ensure that an impact assessment is performed in relation to prescribing costs and procurement of medicines.
- Ensure that medicines procured for the purpose of supply to Service Users is purchased from a provider with the necessary Medicines and Health Care Products Regulatory Agency (MHRA) authorisation, labelled and supplied in accordance with the European Labelling and Leaflet Direction 92/27,2001/83/EC Directive and the Medicines Act.
- Ensure that prescribers comply with all the statutory regulatory requirements for the safe and secure management of controlled drugs.
- Ensure that prescribers employed directly by the Pharmacy implement National Patient Safety Alerts and Drug Alerts within the time frame specified in the alerts.
- ensure that prescribers comply with the Health Care Commission Standards for Better Health Core Standard C4(d); medicines are handled safely and securely; and C4(e); the prevention, segregation, handling, transport and disposal of medicines is properly managed so as to minimise the risks to the health and safety of staff, patients, the public and the safety of the environment.
- Ensure that PDGs are authorised for use and comply with the Provider's PGD Policy and the Health Service Circular (HSC) 2000/026.

⁴ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/142892/HBN_12-01_SuppA_DSSA.pdf

The circumstances in which PGDs can be used and the healthcare professionals, who are allowed to administer medicines under PGD, are set out in legislation. The Medicines and Healthcare Products Regulatory Agency (MHRA) offers a guide to the legislation at:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheNHS/index.htm>

The Provider must comply with the NICE guidance for individual and organisations developing PGDs. The NICE guidance recommends that governance arrangements should include the process for reporting patient safety incidents relating to PGD use, such as medication errors, near misses and suspected adverse events. These arrangements should be included in existing local processes, but not replace national patient safety reporting systems, including the yellow card scheme.

4. Referral, Access and Acceptance Criteria

4.1 Geographic coverage/boundaries

The service is provided in Community Pharmacies participating in the scheme North Tyneside.

4.2 Location(s) of Service Delivery

On the premises of the community pharmacy.

4.3 Days/Hours of operation

The service is offered during the opening hours of the community pharmacy when the pharmacist is present.

4.4 Referral sources & criteria

Clients may refer themselves or be referred for assessment by other professionals. All women, under 25, requesting EHC from the pharmacy must be informed of the free service and signposted to an alternate service provider if the pharmacy is unable to provide this. Clients may attend solely for Chlamydia / Gonorrhoea screening and / or condoms.

4.5 Exclusion Criteria

This agreement is strictly limited to specifically trained specialised pharmacists. The pharmacists must have completed the approved training course and supportive training material, undertaken mandatory Basic Life Support and Anaphylaxis training within the previous 12 months, have had a DBS check within the previous three years and have signed up to patient group directions for EHC.

Clinical exclusions to EHC are outlined in the Patient Group Direction, but clients may prefer to seek advice from, or be referred to one of the local specialist sexual health services if clients have chronic medical conditions or disorders that cause concern.

Women aged 25 and over are excluded from the provision free Emergency Hormonal Contraception. However pharmacies are required to advise clients that free provision is available at Sexual Health Services / GPs.

4.6 Response time and prioritisation

Clients attending the Community Pharmacy for this service will be considered a high priority and will be seen promptly.

5. Discharge Criteria & Planning

N/a

6. Self-Care and Patient and Carer Information

The pharmacist will ensure that clients are given details of local services for future use, e.g. Contraception and Sexual Health Clinics (CaSH), and Genito-urinary (GUM) services. This should also include promotion of the Integrated Sexual Health website a brief description of what each service provides and leaflets as well as information on effective condom use, a pack of condoms and information on where to obtain condoms via the C-card & Chlamydia Screening and treatment schemes.

7. Quality and Performance Indicators

7.1 Quality Indicators

The pharmacy must employ one or more pharmacists or locum pharmacists who have been accredited to deliver the scheme.

- The accredited pharmacist must work within the agreed Patient Group Directions named in Appendix 1.
- A private consultation area must be available which meets the criteria for advanced service provision, as a minimum.
- Whilst participating in delivery of the service the pharmacy will designate space for marketing material advertising the service and must display leaflets that signpost other Sexual Health and Contraception Services available to patients within the local health community.
- The accredited pharmacist and/or pharmacy staff lead will complete all necessary paperwork and collect data as agreed, to enable monitoring and evaluation of the service.
- The service will be provided in compliance with Fraser Guidelines and Department of Health guidance on confidential sexual health advice and treatment for young people aged under 16yrs.
- The service protocols should reflect national and local child and vulnerable adult protection guidelines.
- Verbal and written advice on the avoidance of STIs and the use of regular contraceptive methods, including advice on the use of condoms, will be provided to the client. This should be supplemented by the offer of a referral to a service that can provide treatment and further advice and care.
- The pharmacy must maintain appropriate records to ensure effective ongoing service delivery and audit. Records will be confidential and should be stored securely and for the length of time expressed in local NHS record retention policies.
- Pharmacists may need to share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements, including, where appropriate, the need for the consent of the client to share the information.
- In the absence of an accredited pharmacist the pharmacy support staff and/or non-accredited pharmacists, e.g. locums, must signpost patients to either an alternative pharmacy providing EHC, the client's GP or local specialist sexual health service when the service cannot be provided free of charge via the PGD. Having discussed the patient's preferred alternative location, staff must telephone that location to ensure the service is available before the patient leaves the pharmacy.

Accreditation is conditional on the following:

- Training and education has been completed by the Pharmacist
- Commitment to ensure continuous professional development pertaining to EHC

- Adhering to Patient Group Directions named in Appendix 1
- Completion of the CPPE pack 'Emergency Contraception'.
- DBS clearance

The pharmacist is accredited to work only in pharmacies registered as part of the scheme. Should the pharmacist leave the employ of the premises owner and not be replaced immediately by an accredited pharmacist, the commissioner must be informed and the pharmacy will no longer participate in the scheme.

7.2 Applicable Service Standards

The service is underpinned by the following:

1. Service Standards for Sexual and Reproductive Healthcare (FSRH, 2016)
2. Research Governance Framework for Health and Social Care (Health Research Authority 2016)
3. Quality Standard for Contraceptive Services (FSRH, 2016)
4. CG30 Long-acting reversible contraception (NICE, 2016)
5. Clinical Guidance – Emergency Contraception (FSRH, 2016)
6. PH51 Contraceptive services with a focus on young people up to the age of 25 (NICE, 2016)
7. Male and Female Sterilisation (FSRH, 2014)
8. The Care of Women Requesting Induced Abortion, Evidence-based Clinical Guideline Number 7 (RCOG, 2011)
9. Standards for the Management of STIs (BASHH & Medfash, 2017)
10. UK National Guidelines on Safer Sex Advice (BASHH & BHIVA, 2012)
11. National Chlamydia Screening Programme Standards (7th Edition, 2014)
12. BASHH Statement on Partner Notification for Sexually Transmissible Infections (2012)
13. SSHA Guidance on Partner Notification (SSHA, 2015)
14. Hepatitis B and C: Ways to promote and offer testing to people at increased risk of infection. NICE Public Health Guidance 43 (NICE, 2012)
15. British HIV Association Standards of Care for People Living with HIV (BHIVA, 2016)
16. Standards for psychological support for adults living with HIV (British Psychological Society, BHIVA & MEDFASH, 2011)
17. UK Guidelines for the use of Post-Exposure Prophylaxis for HIV following Sexual Exposure (BASHH, 2016)
18. Public health services contract 2015 to 2016 (Public Health England 2015)

8. Activity

Activity will be recorded on the quarterly claim form submitted for payment via PharmOutcomes.

9. Continual Service Improvement Plan

The service will be updated in line with national guidance and in response to new evidence.

The service will use complaints and service evaluations as an opportunity to improve service delivery.

10. Prices & Costs

A fee of £10.00 will be paid for each consultation which takes place between the pharmacist and the client in relation to EHC requests.

Levonelle 1500 and EllaOne will be reimbursed at £5.20 and £16.95 respectively. These payments will only be made in respect of clients who are 24 years or younger.

Pregnancy tests may be provided to clients where pregnancy status cannot be established from the medical history. Reimbursement will be at £4.88.

A fee of 60p per bag of condoms will be paid for each consultation which takes place between the pharmacist and the client in relation to free condoms.

Payment will be paid quarterly in arrears on receipt of a completed claim form submitted via PharmOutcomes by the pharmacy to Northumbria Healthcare NHS Foundation Trust.

Appendix 1 Patient Group Directions

A Patient Group Direction is a written instruction for the supply and/or administration of medicines by named health care professionals to groups of patients who meet the criteria specified in the PGD.

PGDs, can be used in *“limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability”*.

PGDs were introduced as a facilitative measure to allow some registered health care professionals to take a decision to supply or administer a POM to a patient with an identified clinical condition without the patient needing to see a prescriber. Because they are, in effect, giving someone without the legal ability to prescribe the right to supply or administer prescription only medication, they are instruments that should be subject to monitoring and checks.

The pharmacist will provide sexual health advice and guidance to clients as well as assessing suitability of women for EHC. This will be in accordance with the Patient Group Directions (PGD) developed and maintained by the Northumbria Healthcare NHS Foundation Trust Pharmaceutical Committee namely:

1. Patient Group Direction for the supply and oral administration of Levonorgestrel 1500mcgs (Levonelle 1500) by registered pharmacists for women requesting emergency contraception.
Ref No: CP-01 Version 02 Northumbria Healthcare NHS Foundation Trust Patient Group Direction for the administration or Supply of Levonorgestrel 1500micrograms as Emergency Hormonal Contraception by Community Pharmacists (2017)

2. Patient Group Direction for the supply and oral administration of Ulipristal Acetate 30mg Tablet (ellaOne) by registered pharmacists for women requesting emergency contraception in.
Ref No: CP02 Version 02 Northumbria Healthcare NHS Foundation Trust Patient Group Direction for the administration or Supply of ULIPRISTAL ACETATE (EllaOne®) as Emergency Hormonal Contraception by Community Pharmacists (2017)

Which can be found on the North of Tyne LPC website (<http://www.northoftynelpc.org/>) and Pharmoutcomes.

Faculty Guidelines <https://www.fsrh.org/site-search/?keywords=emergency+contraception>