

Service specification for the supply of emergency hormonal contraception

This service is supplied by Community Pharmacists under a Patient Group Direction (PGD)

Commissioned by:

Commissioning People
Cheshire West and Chester Council
Nicholas House
1 Black Friars
Chester
CH1 2NU



1 Purpose

1.1 The purpose of this Agreement is to:

- Specify how the service will be delivered;
- Agree reporting and invoice submission protocols;
- Provide clarity as to the respective responsibilities of the Cheshire West and Chester Council and the Provider in the delivery of the service.

2 Aim of the Service

2.1 To enable any suitable patients to be prescribed free Emergency Hormonal Contraception (EHC) under a Patient Group Direction (PGD) in community pharmacies in Cheshire West and Chester. This will contribute to better reproductive health and wellbeing outcomes for women in West Cheshire who require the service. For the evidence base see appendix 1.

2.2 Objectives

2.2.1 The objectives of the service are to:

- Increase the availability of EHC and sexual health advice to those who require it;
- Raise awareness of the risks associated with unprotected sexual intercourse (UPSI);
- Provide information on the full range of contraception options available and enable swift and seamless transition into community sexual health services:
 - Virgin Care Sexual Health Service - 0300 247 0020
- Carry out a pregnancy test, if required, and take appropriate actions following the result;
- Strengthen the local network of contraceptive and sexual health services to help ensure easy and swift access to advice; and
- Be vigilant with regard to safeguarding issues and to act immediately if there are any concerns.

2.3 Service Description

2.3.1 This service includes the following:

- **1:1 consultation** - All females requesting EHC will be referred to the providing pharmacist for a confidential consultation to take place in an area that is fit for purpose. Assessment of the need and suitability of a patient to receive EHC, in line with the PGDs (Appendix 2) must be undertaken by an accredited pharmacist.
- **Provision of EHC** - Where appropriate EHC will be supplied; where a supply of EHC is not appropriate, advice, provision of information and referral to another source of assistance will be provided.
- **Provision of a pregnancy test** - If there is the possibility that a patient may be pregnant from a previous instance of unprotected intercourse then supply of EHC cannot be made until pregnancy is ruled out. Performance of a pregnancy test will be undertaken as outlined in the PGD. Where appropriate a home pregnancy test should be supplied if a test cannot be done in-store.
- **Consultation** - For each consultation the pharmacist must complete the consultation pro-forma in discussion with the patient at the time of the consultation, which will include date and time of supply and patient details in line with [NICE guidance](#).

- **Verbal and written advice** on the avoidance of STIs and the use of regular contraceptive methods, safer sex and the use of condoms (see Appendix 3 for information on resources).
- **Onward signposting to local sexual health services** and services for diagnosis and treatment of STIs (Appendix 3).
- **Patients aged 15 to 24** must be advised of the risk of Chlamydia infection and advised to have a Chlamydia test two weeks after the episode of unprotected sex and whenever they change their partner. These patients should be given local service information and a Chlamydia postal testing kit (available to pharmacies free of charge from the local Integrated Sexual Health Service).
- **Appropriate health promotion materials** must be available to those accessing the service. Pharmacists must actively promote uptake and be able to discuss the contents of the material with the patient, where appropriate.
- **Pharmacists to work with existing local provision** for community contraceptive services so that women who need to see a doctor can be referred on rapidly.

2.3.2 All consultations should be carried out in a consultation room which is separate from the general public areas of the pharmacy. The patient and the pharmacist should be able to sit down together and be able to talk at normal speaking volume without being overheard.

2.3.3. **Referral criteria and sources** - Women may self-refer or may be referred from any other health professional.

2.3.4 **Exclusion criteria** - Inclusion and exclusion criteria detailed in the PGD will be applied to the provision of the service. Patients excluded from the PGD criteria will be provided with information on other local services that will be able to assist them as soon as possible.

2.3.5 **Response time** - The service should be provided for a **minimum** of 80% of the total hours the pharmacy is open unless otherwise directed by Cheshire West and Chester Council.

2.3.6 **Fraser Guidelines** - based on a House of Lords Ruling, a health professional can give advice or treatment to a person under 16 without parental consent providing they are satisfied that:

- The young person will understand the advice;
- The young person cannot be persuaded to tell his or her parents/carer or allow the doctor to tell them that they are seeking advice;
- The young person is likely to begin or continue engaging in risk-taking activities which could be detrimental to their health with or without treatment; and
- The young person's physical or mental health is likely to suffer unless he or she receives advice or treatment.

2.3.7 All community pharmacy contractors for the EHC service must have an **authorised signatory** who is responsible for:

- Holding the signed SLAs/contracts of pharmacy branches delivering the service;
- Holding the signed PGDs of their providing pharmacists.

2.4 Safeguarding

- 2.4.1 The accredited pharmacist must operate within the [Local Safeguarding Children Board](#) and the [Local Safeguarding Adult Board](#) guidance and make this available within the pharmacy. A local safeguarding children flow chart must be available for reference in the pharmacy providing the service.
- 2.4.2 The accredited pharmacist is required to undertake basic awareness training in child and adult safeguarding. The pharmacist must have completed an accredited learning package for example, the [Centre for Pharmacy Postgraduate Education \(CPPE\) 'Safeguarding Children and Vulnerable Adults' e-learning and assessment.](#)
- 2.4.3 The authorised signatory must ensure that any serious untoward incidents are reported through the process attached at Appendix 4.

3 Data, monitoring and quality

3.1 Service User Data

- 3.1.1 Production of an appropriate record, submitted via the defined IT platform commissioned by the local authority (Appendix 5).
- 3.1.2 A mandatory set of anonymised data from each consultation will be entered onto the IT platform commissioned and defined for data recording by the Commissioner. This will allow support to the audit trail, recording of numbers and payment procedure. Where possible the consultation should be recorded in the patient's pharmacy PMR record.
- 3.1.3 The service provider must keep all completed consultation and Fraser ruling pro-forma for a period of 8 years (in adults) or until turning 25 years of age in a child (age 26 if entry made when the young person was 17), or eight years after death in line with [NHS Records Management Policy 2009](#)
- 3.1.4 Records will be kept by the service provider in a secure and confidential manner and in line with new GDPR regulations. Records must be destroyed in a confidential manner.
- 3.1.5 In accordance with the pharmacist's Code of Ethics and other regulatory requirements, the pharmacist must not disclose to any person other than authorised by Cheshire West and Chester Council, any information acquired by them in connection with the provision of the service, the identity of a service user or the medical condition or any treatment received by any service user.
- 3.1.6 Pharmacists may need to share relevant information with other health care professionals and agencies including local safeguarding teams in line with locally determined confidentiality arrangements, including, where appropriate, the need for the permission of the patient to share the information.
- 3.1.7 For further advice on disclosing patient information, please refer to the General Pharmaceutical Council's (GPhC) guidance documents:
- Consent (revised 2018)
 - Guidance on maintaining clear sexual boundaries (revised May 2017)
 - Raising Concerns (revised 2017)
 - Confidentiality (revised 2018)

Pharmacies must also adhere to the revised 2017 guidance related to the mandatory requirement to report Female Genital Mutilation

https://www.pharmacyregulation.org/sites/default/files/female_genital_mutilation_mandatory_duty_for_pharmacy_professionals_to_report_may_2017.pdf

- 3.1.8 In exceptional circumstances information can be disclosed without the patient's consent, if in the pharmacist's professional opinion disclosure will prevent serious injury or damage to the health of the patient, a third party or public health.
- 3.1.9 Records maintained in association with this Service must be available to Cheshire West and Chester Council on request.

3.2 Service quality

- 3.2.1 The service provider will provide a non-judgemental patient centred confidential service.
- 3.2.2 The service provider will have an NHS dispensing contract with NHS England and must fully comply with the National Pharmacy Contract regulations for delivery of Essential Services.
- 3.2.3 Cheshire West and Chester Council retain the right to audit any part of the service provided by the Service Provider or the providing pharmacist at any time to ensure continued quality.
- 3.2.4 Cheshire West and Chester Council reserves the right to ask for evidence from the Service Provider that it is following the procedures and requirements outlined in this specification.
- 3.2.5 The Service Provider will co-operate with any Cheshire West and Chester Council led assessment of service user experience or audit of the service in order to evaluate service provision and identify areas for service improvement.
- 3.2.6 Changes to the level or quality of the service will not be introduced without prior agreement with Cheshire West and Chester Council. Changes will be authorised in writing.

3.3 Training

- 3.3.1 The Service Provider has a responsibility to ensure that all staff provide the service strictly in accordance with the service specification. This will include the provision of Levonorgestrel (Levonelle, Upostelle) and Ulipristal Acetate (Ella One) as defined in the Patient Group Direction (PGD) by Pharmacists that have satisfied the requirements of The Centre for Pharmacy Postgraduate Education (CPPE) Declaration of Competence for Emergency Contraception.
- 3.3.2 The pharmacist must satisfy the requirements of the CPPE 'Self-declaration of Competence for Community Pharmacy for Emergency Contraception', complete a self-assessment of core competencies and print and sign their 'Personal Declaration of Qualifications and competence to deliver Emergency Contraception Services'.
- 3.3.3 NICE Competency Framework: The Pharmacist must have achieved the competency levels specified in the NICE Competency Framework for Health Professionals using Patient Group Directions
<http://www.nice.org.uk/mpc/medicinespracticeguidelines/MPG2.jsp>

- 3.3.4 All community pharmacists providing an EHC service for Cheshire West and Chester Council must also have signed a copy of the signatures page of the latest version of the PGDs before providing the service. As part of this, the pharmacist will be required to include their name and registration number in block capitals for ease of recording. This may then be held in the relevant place as evidence of authorisation and submitted for audit purposes if requested by the Council.
- 3.3.5 Maintenance of Self-assessment Declaration of Competency – It is the pharmacists responsibility to maintain a regular Self-assessment Declaration of Competency. It is the responsibility of the pharmacist to undertake Continuing Professional Development and to make this information available on request.

Self-assessment Declaration of Competency must be reviewed at least every two years, this is in the form of a self-declaration of competency (Appendix 6).

It is expected that pharmacists will allow the information in their CPPE record to be shared directly with the commissioned IT provider (presently PharmOutcomes, as at April 2019) and the Commissioner. In order to do this the pharmacist must have ticked the box on their CPPE profile page to allow data from their learning and assessment record to be shared with the Commissioner.

- 3.3.6 All pharmacists involved in providing this service must adhere to their professional code of conduct and at no point does this service revoke their professional responsibility, professional judgement must be used at all times. It is the professional's responsibility to practice only within the bounds of their own competence.
- 3.3.7 The responsible pharmacist on each given day has overall responsibility for ensuring the service is delivered in accordance with the service specification.
- 3.3.8 The Service Provider will have a Standard Operating Procedure (SOP) / protocol which specifically details the operational delivery of this service. The Service Provider must ensure that all staff including those other than pharmacists, involved in the provision of the service, have relevant knowledge, are appropriately trained and operate within protocols / SOPs; this includes sensitive patient centred communication skills.
- 3.3.9 The SOP/protocol should be reviewed at least every two years or before if circumstances dictate. Each review should be documented and the SOP/protocol subject to version control. Staff must read, date and sign the SOP/protocol after a review.
- 3.3.10 Changes to procedure must be highlighted within the SOP/protocol for special attention. The SOP/protocol must be available to Cheshire West and Chester Council if required.
- 3.3.11 In addition to the standard termination clauses listed in **Schedule/clause** of the contract, the service will be terminated if the individual pharmacist and/or service provider acts outside the ethical governance framework for the profession, brings the profession into disrepute, is subject to an NHS or professional disciplinary process, or the pharmacist is unable to demonstrate maintenance of competence.
- 3.3.12 **It is the pharmacy's responsibility to ensure that all staff they employ are trained and competent to provide the service. Staff should not provide the service until they have satisfied the requirements of Self- Declaration of Competence for Community Pharmacy for Emergency Contraception.**

The pharmacy must ensure that there are systems in place to make locum pharmacists aware of this locally commissioned service.

3.4 Provider to Provider referrals

- 3.4.1 If the pharmacy cannot for any reason provide the service, then patients must be signposted to the next nearest provider that can. It is advisable to contact the pharmacy to ensure an accredited pharmacist is on duty before signposting the patient.

4. Pricing schedule

4.1 Currency and Price

Service	Rate
Consultation (including supply of Chlamydia postal testing kit to 15-24 year olds)	£10
Per pack of Levonorgestrel 1500 supplied	Drug tariff Price + VAT
Per Pack of Ulipristal Acetate	Drug tariff Price + VAT
Pregnancy test performed as part of the EHC consultation	£5

4.1.1 The service covers the cost of the consultation (including supply of Chlamydia postal testing kit to 15-24 year olds), EHC, condoms and pregnancy test (if required).

4.1.2 The Service Provider must be able to access the web based pharmacy IT programme that is commissioned by the Council for the monitoring of enhanced sexual health services.

4.1.3 The Service Provider will enter consultation details onto the EHC Module. Consultation details must be submitted in a timely manner. The IT provider will collate the data and generate an invoice on behalf of the Service Provider. The IT provider will direct the invoice to Cheshire West and Chester Council for payment on the Service Provider's behalf.

4.1.4 Payments will be made to pharmacies on a quarterly basis.

4.1.5 **Post Payment Verification Check** - It is the Service Provider's responsibility to verify and check invoices each quarter.

4.1.6 Cheshire West and Chester Council reserves the right to carry out post payment verification checks. In the event of any underpayment or overpayment made by the purchaser, the amount is recoverable within 3 months by prior arrangement with the Provider.

4.1.7 Cheshire West and Chester Council reserve the right to ask for a forecast of activity in the final quarter of the year.

5. Monitoring Schedule

5.1 The activity levels of individual Pharmacies will not be capped due to the numbers involved within the scheme and the nature of the service.

5.2 The programme is however subject to an overall cap based on the total budget allocated to this service by Cheshire West and Chester Council. The Council reserves the right to reduce or ration the service by giving the Provider six weeks' notice or to terminate the contract using the termination clauses as outlined in the contract.

Appendix 1

Evidence Base

1. The Department of Health's *'Making it work: A guide to whole system commissioning for sexual health, reproductive health and HIV'* (revised March 2015) provides an insight into the financial impact of unintended pregnancy:
 - In 2010 unintended pregnancies cost the NHS an estimated £193m in direct medical costs; and
 - It has been estimated that £1 invested in contraception saves £11.09 in averted outcomes.
2. Indeed, a BMJ report (2014) found that the NHS spent almost £4 billion on pregnancy healthcare in 2011. Inclusion of child health costs during the first year of life brings the total NHS healthcare costs to £4.5 billion. It is estimated that unintended pregnancies cost the NHS over £1 billion.
3. Under 18s conceptions have decreased in Cheshire West and Chester and nationally over the last few years. However there are wards in Cheshire West and Chester that have a significantly higher rate of teenage conceptions than the England average and these areas are all within the most deprived neighbourhoods in the borough.
4. The latest data (2016) shows a rate of 18.7 per 1,000 under 18 conceptions in Cheshire West and Chester which is similar to the England average of 18.8 per 1,000.
5. In Cheshire West and Chester the percentage of conceptions leading to abortion has shown some variation in recent years. During 2016 57 per cent of teenage pregnancies led to abortion, this is statistically similar to the England average of 51.8 per cent.
6. During 2016, 14.9 per 1,000 (n=891) women aged 15 to 44 in Cheshire West and Chester had an abortion. This is significantly lower than the England average of 16.7 per 1,000, however, improved access to EHC (along with robust signposting to planned contraceptive options), is needed to continue to improve the situation.
7. The Department of Health's *'Framework for Sexual Health Improvement in England'* (2013) includes a specific ambition to *"reduce unwanted pregnancies among all women of fertile age"*. It reports that in 2010, England was in the bottom third of 43 countries in the World Health Organization's European Region and North America for condom use among sexually active young people; previously, England was in the top ten. In addition to this, the Framework cites the findings of other research reports:
 - Some young people struggled to use their preferred methods of contraception effectively (principally condoms and the pill, which are user dependent);
 - Some young people continue to have unprotected sex when they are fully aware of the possible consequences and when they do not want to become pregnant; and
 - In a recent study, around 20% of young people said that they had recently had unprotected sex with a new partner and only one-third said that they always used a condom.
8. The local pharmacy has a vital role in meeting the needs of diverse communities, particularly the needs of young people who may be anxious about approaching

contraceptive services (NICE Guidelines, PH51, 2014). Furthermore, the evidence review to inform these guidelines cites the importance of trust in services; accessible locations and opening hours; choice; walk-in services; respectful and non-judgemental staff; and a comfortable and welcoming atmosphere. All of these requirements can be provided in a community pharmacy setting.

9. Comprehensive and open access provision for women of child bearing age to control their fertility is a key element of any local sexual health service provision. [Public Health England's report](#) (2014) recognises that there is good evidence that community pharmacy based EHC services provide timely access to treatment and are highly rated by women who use them. However, currently there does not appear to be any hard evidence about outcome, i.e. reduction of rates of teenage pregnancy as a result of access to EHC services from community pharmacy, although it would seem to be a reasonable assumption.
10. The supply of EHC through community pharmacies therefore has a crucial role to play in preventing unwanted pregnancies by providing fast, convenient, local access to EHC without an appointment and extended out-of-hours.
11. The provision of free Emergency Hormonal Contraception in Cheshire West and Chester is in line with best practice and women can be directed into clinical services for further advice and provision of contraception including long acting reversible contraception.

Appendix 2

Patient Group Directive – attached separately (current PGD expires May 2019, refreshed PGD currently being written by a CHAMPS led working group)

Appendix 3

Ordering Supplies

Condoms and Chlamydia Postal Testing Kits can be ordered from the Integrated Sexual Health Service:

Main contact number: 0300 247 0020
Fountains Health Centre Sexual Health clinic
Fountains Health,
Delamere Street,
Chester,
CH1 4DS

[NHS Service Search](#)

Leaflets: Contraception and Sexually Transmitted Infections

[FPA – Leaflets and booklets downloads](#)

Appendix 4



CWC Public Health
Procedure for Incident

Appendix 5

EHC provisions will be recorded on PharmOutcomes which can be accessed via <https://www.pharmoutcomes.org/pharmoutcomes/>

For any problems with the system there is extensive help available from the Help tab on the home screen. Here you have an opportunity to send a support email, request your password, look at FAQ and user guides as well as requesting an activation code.

Alternatively assistance is available from CPCW at cpcwnw@gmail.com or 07828 832782.

Appendix 6 – Self- declaration of competence process



Pharmacy Workforce
NW - EC DoC (Exam