

**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

HQ Building

58 Nicholas Street

Chester

CH1 2NP



**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 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 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 Cheshire West and Chester women who require the service.

**2.2 Objectives**

2.2.1 The objectives of the service are:

* To increase the availability of Emergency Hormonal Contraception (EHC) and sexual health advice to those who require it;
* To raise awareness of the risks associated with unprotected sexual intercourse (UPSI);
* To provide information on the full range of contraception options available and enable swift and seamless transition into community sexual health services;
* To carry out a pregnancy test, if required, and take appropriate actions following the result;
* To strengthen the local network of contraceptive and sexual health services to help ensure easy and swift access to advice; and
* To 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 accredited 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 1) 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](https://www.nice.org.uk/guidance/lifestyle-and-wellbeing/sexual-health).
* **Verbal and written advice** on the avoidance of STIs and the use of regular contraceptive methods, safer sex and the use of condoms (Appendix 2).
* **Onward signposting to local sexual health services** and services for diagnosis and treatment of STIs (Appendix 2)
* **Patients aged 15 to 24** must be advised of the rise in 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, Appendix 2).
* **Appropriate health promotion materials** **and three free condoms** (Appendix 2) 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.

2.5.2 All consultations should be carried out in a consultation room which is separate from the general public areas of the pharmacy. The client 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. Women 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.

* + 1. **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.
  + 1. All community pharmacy contractors for the EHC service must provide details of an **authorised signatory** who is responsible for:
* Holding the signed SLAs of the pharmacy branches delivering the service;
* Holding the signed PGDs of their accredited pharmacists and ensuring that pharmacists provide copies of these to [commissioningandcontracts@cheshirewestandchester.gov.uk](mailto:commissioningandcontracts@cheshirewestandchester.gov.uk) ;
* Notifying the commissioned back office IT supplier (appendix 3) of any changes to the accredited pharmacist list;
* Ensuring pharmacists (who must also be registered with the General Pharmaceutical Council) are appropriately accredited to deliver the EHC service and providing to Cheshire West and Chester details of accredited pharmacists to [commissioningandcontract@cheshirewestandchester.gov.uk](mailto:commissioningandcontract@cheshirewestandchester.gov.uk)
* Ensuring that any locum pharmacists delivering the service comply with all requirements of the specification
  + 1. **Safeguarding**

2.4.1 The accredited pharmacist must operate within the [Local Safeguarding Children Board](http://cheshirewestlscb.org.uk/training/) and the [Local Safeguarding Adult Board](http://westcheshirelsab.co.uk/) guidance and make this available within the pharmacy.

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.](https://www.cppe.ac.uk/programmes/l/safegrding-e-01)

2.4.3 The authorised signatory must ensure that any serious untoward incidents are reported through the process attached at Appendix 6.

**3 Data, monitoring and quality**

**3.1 Service User Data**

3.1.1 A mandatory set of anonymised data from each consultation will be entered onto the commissioned IT programme for EHC to support the audit trail, recording of numbers and payment procedure. Where possible the consultation should be recorded in the patient’s pharmacy PMR record.

3.1.2 The service provider must keep all completed consultation and Fraser ruling pro-forma for a period of 8 years (in adults) or until 25th birthday in a child (age 26 if entry made when the young person was 17) or eight years after death in line with [NHS Document and Records Management Policy](https://www.england.nhs.uk/?s=document+and+recors) 2014 and [NHS Records management policy 2009](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200139/Records_Management_-_NHS_Code_of_Practice_Part_2_second_edition.pdf)

3.1.3 Electronic records must also be kept and available for this period. Records will be kept by the service provider in a secure and confidential manner. Records must be destroyed in a confidential manner.

3.1.4 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.

3.1.5 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. For further advice on disclosing patient information please refer to the General Pharmaceutical Council’s (GPhC) guidance documents:

* Consent 2012
* Raising Concerns 2012
* Confidentiality 2012

3.1.6 In exceptional circumstances information can be disclosed without the patient’s consent, if in the pharmacists professional opinion disclosure will prevent serious injury or damage to the health of the patient, a third party or public health. For further advice on disclosing patient information refer to GPhC guidance documents: Consent 2012, Raising Concerns 2012 and Confidentiality 2012.

3.1.7 Records maintained in association with this service must be available to Cheshire West and Chester Council on request.

* 1. **Service quality** 
     1. The service provider will provide a non-judgemental patient centred confidential service that complies with most up to date [NICE guidance](https://www.nice.org.uk/guidance/lifestyle-and-wellbeing/sexual-health) and [standards.](https://www.nice.org.uk/Standards-and-Indicators/Developing-NICE-quality-standards-/Quality-standards-topic-library)
     2. The service provider must be registered with the GPhC and fully comply with the National Pharmacy Contract regulations for delivery of Essential and Advanced Services.
     3. Cheshire West and Chester Council retains the right to audit any part of the service provided by the service provider or the accredited pharmacist at any time to ensure continued quality.
     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.
     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.
     6. Cheshire West and Chester reserves the right to evaluate other health professionals’ perception of the overall quality of the service.
     7. 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 / accreditation**

3.3.1 The Pharmacy’s designated authorised signatory 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 Self Declaration of Competence for Community Pharmacy 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](https://www.cppe.ac.uk/services/docs/emergency%20contraception.pdf)”, complete a self-assessment of core competencies at least every two years and print and sign their “Personal Declaration of Qualifications and competence to deliver Emergency Contraception Services”. This certificate must be submitted to the Pharmacy’s designated authorised signatory to maintain inclusion on its accredited pharmacist list

3.3.3 The Pharmacist should also have achieved the competency levels specified in the [NICE Competency Framework for Health Professionals using Patient Group Directions](https://www.nice.org.uk/guidance/mpg2)

3.3.4 All pharmacists involved in providing this service must adhere to their professional code of conduct and at no point does this service abrogate 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.

3.3.5 It is the pharmacy’s responsibility to ensure that 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.

3.3.6 The service provider will be required to 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.

3.3.7 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.

3.3.8 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.

3.3.9 A staff training log which deals specifically with this service must be maintained and should be available to Cheshire West and Chester Council on request. The training log must be updated to reflect the review the SOP / protocol.

3.3.10 In addition to the standard termination clause listed in the standard terms and conditions of contract for the purchase of services (clause D1), 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.

3.3.11 All community pharmacists providing an EHC service for Cheshire West and Chester council must have signed and returned to the Pharmacy’s designated authorised signatory a copy of the signatures page of the latest version of the PGD before providing the service. (see clause 2.3.7)

**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.  If this is a neighbouring pharmacy, 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 |

4.1.1The 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).

**5. Monitoring and Payment schedule**

5.1 The service provider will enter consultation details onto the EHC Module of the approved IT system. Consultation details must be submitted in a timely manner, as required by the IT provider. 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.

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

5.3 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.

5.4 **Post payment verification check** - It is the service provider’s responsibility to verify quarterly payments by downloading and printing invoices from the EHC module.

5.5 Invoices should be signed as correct and filed in the pharmacy for reference/post payment verification check. The Pharmacy must not send invoices for payment as this may result in duplicate payments.

5.6 Payment will not be made to the Pharmacy if the Pharmacist conducting the consultation is not registered on the IT system. Pharmacists can only be registered on the system once accredited and the commissioner has been notified.

5.7 Cheshire West and Chester Council reserve 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.

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

**Appendix 1**

**Patient Group Directive – attached separately**

**Appendix 2**

**Ordering Supplies**

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

Contact: Stephanie Rumsey

Email: [stephanierumsey@nhs.net](mailto:stephanierumsey@nhs.net)

Tel: 01244 389245

**Leaflets: Contraception and Sexually Transmitted Infections**

[FPA – Leaflets and booklets downloads](http://www.fpa.org.uk/resources/leaflet-and-booklet-downloads)

**Local Sexual Health Services**

[Go Sexual Health](https://www.gosexualhealth.co.uk/) – Tel: **0300 323 1300**

[NHS Service Search](http://www.nhs.uk/Service-Search/Sexual-health-services/LocationSearch/1847)

**Appendix 3**

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](mailto:cpcwnw@gmail.com) or 07828 832782.

**Appendix 5**

**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.

1. During 2014 in Cheshire West and Chester there were 894 abortions in women of which 424 were in women aged under 25 and 470 in those aged 25 and over (Department of Health, 2015). Typically, in England and Wales, 21% of all conceptions and 51% of conceptions to under 18s led to an abortion (ONS, 2015 based on 2012 conception data). Access to effective contraception, including emergency hormonal contraception, is needed by women throughout their reproductive years.
2. During 2014, there were 112 under 18 conceptions in Cheshire West and Chester, a rate of 19.9 per 1000 female population aged 15-17, lower than the England rate (22.8). In 2013 the under 16 conception rate was 5.1 conceptions per 1,000 females aged 13 to 15, slightly higher than the England rate (2013).
3. 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.

1. 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.
2. 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 recent report](https://www.gov.uk/government/publications/developing-pharmacys-contribution-to-public-health) (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.
3. 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.

1. 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 6**

****