

SERVICE SPECIFICATION

Service Specification No.	
Service	EHC Services
Authority Lead	Jeanette Crabbe
Sub-Contractor Lead	Cliff Dunbavin
Provider Lead	
Period	1st April 2018 – 31st March 2019
Date of Review	1st Jan 2019

1. Population Needs

1.1 National/local context and evidence base

The supply of emergency hormonal contraception (EHC) through community pharmacists has a crucial role in preventing unwanted pregnancies by providing fast, convenient, local access to EHC without an appointment, often out of hours, maximising the effectiveness of EHC by as much as 10% (1). The accessibility of the service will also contribute to reducing teenage pregnancy in Bradford.

1 Pharmaceutical Journal 2006; 276:583

2. Key Service Outcomes

2.1 The Emergency Hormonal Contraception Service (EHC Service) aims to:

- Increase access to Emergency Hormonal Contraception (EHC) and sexual health advice
- Increase choice of health care professionals who can provide EHC free of charge
- Reduce the rate of unintended pregnancies, in particular among women 19 years and under.
- Directing clients who fall outside the protocol or who need advice on ongoing contraception into mainstream contraceptive services and appropriate healthcare services.

3. Scope

3.1 Aims and objectives of service

- The aim of the service is to increase access to sexual health services in Bradford in order to reduce unintended pregnancies and improve sexual health. In addition the services will increase knowledge of the consequences of risky sexual behaviour by providing information and advice as appropriate on sexual health issues including STIs, avoiding unplanned pregnancy, contraception and delaying sex (as appropriate). The service will also improve awareness of the range of sexual health services available in the area.
- Specifically, the services will comprise: a consultation, information and advice, signposting to other services, provision of emergency hormonal contraception (EHC) and pregnancy testing.
- Females aged 19 and under who present within 120 hours of unprotected sexual intercourse will be provided with emergency hormonal contraception (subject to circumstances) free of charge
- The Contract allows the Provider to supply Levonorgestrol or Ulipristal emergency hormonal contraception to appropriate clients in line with relevant guidance and patient group directions, by accredited pharmacists from the accredited Provider.
- Increase the Public Health role of the community pharmacist and promote multidisciplinary working in relation to sexual health.

3.2 Service description/pathway

- The Provider will ensure that the Service offered is user-friendly, non-judgemental, client-centred, young people-friendly and confidential.
- Pharmacies will ensure that staff refer clients requesting EHC to the accredited pharmacist discreetly and as soon as practicable. See Accessibility section for action to be taken if accredited pharmacist not available
- Pharmacists can be proactive in offering EHC under the scheme for clients who present for over-the-counter (OTC) EHC and fit the criteria outlined

Consultation

- The complete sexual health consultation must be carried out within a private consultation room separate to the main area of the premises to ensure privacy
- The EHC consultation must be carried out by a pharmacist who is considered competent to provide; see section below.
- Ulipristal will be given within its licensed indication in line with national guidance. Where levonorgestrel is given, this will be under PGD
- The pharmacist will assess the need and suitability for a client to receive EHC, in line with the PGD and/or service specification
- If EHC is not justified or there is minimum risk – i.e. presented day before regular cycle or followed missed pill guidelines - offer Levonelle only (instead of Ullipristal acetate) if client is adamant of taking EHC
- Inclusion and exclusion criteria detailed in the PGD and service specification will be applied during the provision of the service
- Where appropriate supply of EHC will be made free of charge to the client
- The choice of EHC should be guided by the Decision Tree (Appendix G). Cu-IUD should be offered first line to all clients as it is the most effective form of emergency contraception.
- Pregnancy tests can only be used as part of an EHC consultation to exclude pregnancy, if required
- Supply must be labelled if not taken immediately at the pharmacy and should be recorded on the patients PMR. The consultation then needs to be recorded onto PharmOutcomes
- The pharmacist will normally supervise the administration of the EHC, unless a valid reason is given not to administer the EHC at that time, in which case the EHC will be dispensed and needs to be labelled and the client informed to take EHC as soon as it is possible
- The commissioner supports the RPS guidance that states that *if a pharmacist thinks that EHC is not required but the female perceives risk, and despite the pharmacist's advice still wishes to take EHC the pharmacist can consider making a supply*. Supply in this instance is covered and will be paid under this agreement.

- Although the RPS has issued guidance regarding advance supply of EHC this is not covered by the service therefore pharmacists are unable to make an advanced supply using this service. If a request is made for advance supply a pharmacist can offer OTC purchase if they feel it is appropriate

Advice to be provided

The pharmacist will provide support and information to clients accessing the service including:

- The avoidance of pregnancy and sexually transmitted infections through safer sex and condom use
- How to use condoms
- The use of regular contraceptive methods
- Where and how to access services that provide long-term contraceptive methods
- Where and how to access STI services
- Where and how to access further advice and care

NB this advice is to be provided whether or not EHC is provided

Information to be provided

Clients should receive an age appropriate information covering sexual health, on-going contraception and services.

NB This information is to be provided whether or not EHC is provided.

The Sexual Health (EHC) Consultation

A consultation under the Sexual Health (EHC) service must include:

- Being clear about confidentiality with the client
- Discussion of all three options for emergency contraception:
 - Cu-IUD
 - ellaOne
 - Levonelle
- Assessment of the client's suitability to receive EHC in line with the relevant PGD and service specification (including pregnancy test where appropriate).
- Supply of EHC (as appropriate)
- Consideration of, and if necessary managing, any safeguarding issues
- Advice on the avoidance of pregnancy and sexually transmitted infections through safer sex and condom use (including how to use condoms and a supply of condoms where appropriate)
- Providing information about long-term contraceptive methods including information
- about LARCs
- Providing details of where and how to access
 - services that provide long-term contraceptive methods
 - services that provide sexual health advice and STI services (including screening)
 - further advice and care

Referrals

- Clients who have exceeded the time limit for EHC must be informed about the possibility of use of an IUCD and should be referred to a local service such as Locala Integrated Sexual Health Services or GP as soon as possible
- Providers must refer any client who is identified as unsuitable for the supply of EHC under the PGD or service specification to Locala Integrated Sexual Health Services or a GP
- If a referral is made the pharmacist should make every effort to contact the GP/ Sexual Health Service direct, book an appointment for the client and inform the client of the time and location of the appointment.
- Pharmacists should link into existing networks for community contraceptive services so that clients who need to see a doctor or appropriate healthcare professional can be rapidly referred
- Referrals should be recorded on PharmOutcomes.

Excluded clients

- Clients excluded from the PGD criteria or service specification will be referred by the Provider to another local service that will be able to assist them as soon as possible e.g. Locala Integrated Sexual Health, GP or will be invited to purchase the medicine product if the exclusion from supply is for an administrative reason e.g. not resident in Bradford.
- If the client is excluded from accessing EHC due to a service specification exclusion (eg an authorised pharmacist is not available, not resident in Bradford) the pharmacist cannot claim a consultation fee as this exclusion should have been identified before the consultation
- If following consultation, a client is excluded or otherwise unable to access EHC, the Provider can claim the usual fee for the consultation as long as the advice, information and referral has been provided to the client as outlined in the PGD and service specification

Accessibility

- The expectation is that the Service will be available throughout the Provider's opening hours. The Provider should endeavour to ensure an authorised member of staff is present at all times.
- Where the Provider is unable to provide the Service, the Provider has a duty to signpost any potential clients to another provider of EHC and sexual health services, convenient to the client. This may be another provider of this Service, a GP or Local Integrated Sexual Health. Checks should be made if referral is made to another Provider of this Service that an authorised member of staff is available before the client leaves the premises.
- The pharmacy must ensure that the service to which the client chooses to be referred to is able to provide the service in terms of opening times, availability of suitable staff etc. In the case of referral to another pharmacy this would include phoning the pharmacy to check that an accredited pharmacist will be available to provide the EHC service for the client
- These checks must be made before the client leaves the pharmacy
- The pharmacy should also consider whether it is appropriate to provide clients being referred or signposted with information leaflets regarding emergency contraception, ongoing contraception and sexual health
- All staff working at the premises should be aware of the procedure for dealing with a client who presents at a time when an authorised pharmacist is not available. The procedure should be documented and accessible to all staff.

Formulary

- The pharmacy will hold adequate stocks (taking into consideration the possibility of an unexpected increase in demand) of EHC to ensure that clients can immediately access the necessary treatment
 - Levonorgestrel - Upostelle (Consilient Health)
 - Ulipristal - Ellaone (HRA)
- It is expected that the pharmacies will supply the most cost effective treatment

Staff

- Providers operating the Service must have a contract in place with Locala Community Partnerships CIC, the Co-ordinating Commissioner to provide the Service. This is the Public Health Contract which must be signed by both the Co-ordinating Commissioner and the Provider.
- It is the duty of the Provider to ensure that all individual pharmacists delivering this Service from their premises are fit to practise, suitable to deliver the Service and can demonstrate they are competent to deliver the Service.
- The Service can only be provided by a pharmacist who has demonstrated they are competent to provide the Service by completion of the emergency contraception Declaration of Competence (DoC) (to be completed at least every 3 years). The Declaration of Competence is available on the CPPE website: <https://www.cppe.ac.uk/doc>. Signing the DoC whilst not meeting the competencies may constitute or be treated as a fitness to practise issue. The pharmacy contractor must keep on the pharmacy premises copies of each DoC completed by pharmacists that they employ/engage to deliver the service.
- Each individual pharmacist providing the service must ensure they are competent to provide the service and demonstrate this by:
 - Complete the Declaration of Competence (DoC) for EHC process (at least every 3 years) <https://www.cppe.ac.uk/services/declaration-of-competence>
 - DoC must be confirmed on PharmOutcomes prior to any submission
- The pharmacy contractor must ensure that all pharmacy staff, including part-time staff and locum pharmacists, receive appropriate training and are aware of the service, how it operates including relevant signposting information and referral procedures, to ensure the pharmacy offers an effective, sensitive and non-judgemental service

Core competencies

- Competencies are listed within the DoC framework
- **For any enquiries related to training or Declaration of Competence, please contact <https://www.cppe.ac.uk/services/declaration-of-competence>**
- In order to comply with **legal requirements** each pharmacist who wishes to work under the contract **must**
 - Ensure they have the correct knowledge required to work under the PGD and service specification (this is likely to be met by undertaking CPD relevant to the service, Levonorgestrel and Ulipristal). Pharmacists must be familiar with the PGD for Levonorgestrel and licensing of Ulipristal, their place in EHC provision and their SPCs.
 - Sign the Levonorgestrel PGD in each pharmacy where they work/ will provide the EHC service to ensure the authorisation process for working under the PGD is completed.

- Only provide the service from a pharmacy that has completed, signed and returned all contractual documentation to provide EHC under the contract to Locala

Fitness to Practise

- It is the duty of the pharmacy commissioned to provide this service to ensure that all individual pharmacists delivering this from their premises are: -
 - Fit to practise
 - Suitable to deliver the service
 - Can demonstrate they are competent to deliver the service.

Premises

- The Service must be carried out in the consultation room, not over the counter or in another open area of the premises.
- The Pharmacy will advertise that they provide the service

Support for delivery of the service

- Locala Community Partnerships will utilise PharmOutcomes via Community Pharmacy West Yorkshire to collate activity, document consultation and facilitate payment
- Locala will support and advise on the promotion and publicity of the service locally and across the district.
- Locala will provide up-dated information about new or developing sexual health services and any service changes that may occur in order to continue effective signposting and referrals.
- Formal review meetings are not required for this Contract however where there are concerns from either commissioner or provider, ad hoc meetings will be arranged.

Storage of records

- The record of consultation must be retained for a minimum of 8 years from the consultation date and for under 18s until the client's 25th birthday or 26th if the young person was 17 years at the time of consultation.
- If the PGD is superseded, the superseded PGD should be retained, along with a list of those authorised to work under the PGD, until any client who had a supply made under the PGD reaches 25 years old (i.e. retain for a minimum of 12 years).
- Activity data must be recorded on PharmOutcomes.

Quality indicators

- Providers will report in writing, not more than annually, on the findings of their self-assessment using the quality outcomes indicators in when requested (see Appendix A)

- The service must maintain an effective compliments, concerns and complaints procedure and a critical incident log.
- The Provider must give users of the service the opportunity to feedback on level of satisfaction with the service. The Co-ordinating Commissioner may request a standard form to be used for this purpose. Any concerns raised or scope for improvement in the service should be reported back to the Co-ordinating Commissioner and Community Pharmacy West Yorkshire.

3.3 Population covered

- Residents of Bradford.

3.4 Any acceptance and exclusion criteria and thresholds

- EHC can only be provided to women of 19 years or under.

3.5 Interdependencies with other services

- Pharmacists providing the service must be familiar with and have up to date contact details of other sexual health services in the district, both to signpost clients on where necessary and to make users of the service aware of the choice of sexual health services available locally
- Key services are Locala Integrated Sexual Health, GPs including practices fitting LARCs and GPs providing specialist sexual health services, providers of community testing of HIV.

3.6 Any activity planning assumptions

None

4. Applicable Service Standards

4.1 Applicable national standards

Pharmacists must adhere to relevant professional standards associated with EHC supply and pregnancy testing.

4.2 Applicable local standards

The process for registering pharmacist's Declaration of Competence is managed by Community Pharmacy West Yorkshire.

5. Location of Provider Premises

The Provider's Premises are located at:

[Insert address of Provider's Premises]

6. Required Insurances

See standard terms and conditions, section B34

APPENDIX A

QUALITY OUTCOMES INDICATORS

Quality Outcomes Indicators	Threshold	Method of Measurement	Consequence of breach
The Provider is making full use of the promotional material for the Service	100%	Self-assessment	
The Provider has appropriate information leaflets and ensures that relevant written information is offered at each consultation	100%	Self-assessment	
The Provider ensures that it is delivering the Service in line with the service specification and PGD and reviews its internal processes on an annual basis	100%	Self-assessment	
The Provider can demonstrate that all pharmacists and staff involved in the provision of the Service have the required competencies, signed the declaration of competence and undergone CPD relevant to this Service in order to ensure competence is maintained	100%	See Authorisation section Self-assessment	
The Provider will take part in annual audit of service provisions when requested	100%	Return of all audit forms within the timescales requested by Locala Community Partnerships	
The Provider will co-operate with any locally agreed assessment of service-user experience and implement recommendations / respond where practicable	100%	Evidence of Provider's consideration of all client suggestions to enhance the service and investigation of feasibility with justified decisions for taking forward or not.	
The Provider will keep records of the use of the Service on PharmOutcomes which is auditable	N/A	Record service provided	N/A

APPENDIX B

CHARGES

Consultation Fee:	£15.00	
Pregnancy Test:	£5.00	can only be claimed in relation to an EHC consultation
EHC:	Treatment is reimbursed at cost price (based on the drug tariff or wholesalers list price) plus VAT at the appropriate rate	

Payment will be made retrospectively by Community Pharmacy West Yorkshire on a monthly basis on receipt of claims via PharmOutcomes.

APPENDIX C

SAFEGUARDING POLICIES

Please append safeguarding children and vulnerable adults policy/ SOP of Provider

APPENDIX D

INCIDENTS REQUIRING REPORTING PROCEDURE

*Procedure for reporting, investigating, and implementing and sharing Lessons Learned from:
(1) Serious Incidents (2) reportable Patient Safety Incidents; and (3) Non-Service User incidents]*

APPENDIX E

Protocol for Pregnancy Testing

The Medicines and Healthcare Products Regulatory Agency (MHRA) in conjunction with the Department of Health have developed a 'Top Tips' guide for pregnancy testing (March 2008). Access to the full document is available at www.mhra.gov.uk. There had been reports of false results with pregnancy test kits, the following points should be followed to prevent problems occurring:

1. Always follow the manufacturer's instructions that are on the pregnancy kit being used.
2. Ensure that all pregnancy testing kits are stored as per the manufacturer's instructions. Any Pregnancy test kit that is not stored correctly is at risk of damage or may deteriorate and may produce a false result.
3. It is important that care and attention is made to ensure that any samples are not exposed to contamination.
4. A separate room must be used for the purpose of pregnancy testing (see Royal Pharmaceutical Guidelines). This room must be maintained to the highest standards of cleanliness and have adequate lighting so that all results can be seen clearly. A separate sink should also be available.
5. Appropriate protocols and procedures must be in place and followed to ensure that there is no confusion between samples.
6. Pregnancy tests and results should be available on the day of the request.
7. Pharmacies must advertise that they offer a Free and Confidential Pregnancy Testing Service.

Performing the Pregnancy Test

1. All staff must obtain written consent/requests to undertake the pregnancy Test.
2. Clients must be made aware of the possible limits in accuracy of the pregnancy test; this may be in writing on the form for written consent.
3. Any questions regarding the test asked by a member of staff must be recorded in writing appropriate questions by the client may also need recording.
4. A pregnancy test must not be performed before the date of the clients expected period, even in the case of differing cycle lengths.
5. For clients that have consistently irregular or unpredictable cycles pregnancy tests must not be performed until 3 weeks after unprotected sexual intercourse. Clients that have a negative result and amenorrhea continues should be referred to their GP or other appropriate service.
6. Ensure that you can clearly see that the control line appears, this could be before or after the result. If the control line does not appear discard and use a new test.
7. The result time differs between pregnancy tests it is important to read the test at the time stated on the manufacturer's instructions, if the test is read before or after this may lead to a false result.

Pregnancy Test Result

1. All results should be given in a private consultation room to ensure confidentiality.
2. All results must be provided in writing and record kept by the pharmacy. In the event that a result has to be given over the phone staff must have obtained prior consent and an appropriate contact number, they must also ensure that they are speaking to the person that has requested the test. All telephone results must also be followed up in writing.

3. You must ensure that all results have been read correctly by a trained member of staff. If the result is not what the client expected it may be necessary to repeat the test or refer to another appropriate primary care service.
4. Women under 25 should be offered Chlamydia screening. All clients should be made aware of the STI risks of unprotected sex and signposted to appropriate sexual health services.
5. Clients should also be provided with further information around sexual health promotion.

Positive result:

1. All women that wish to continue with a pregnancy must be advised to book an appointment with their GP, or other appropriate health care provider as soon as possible and provided with information about the importance of antenatal care and how to stay healthy during pregnancy.
2. If a woman has any medical concerns, conditions or is taking medication it may be appropriate to advise them on their options or refer them to another appropriate health care provider.
3. In the case of a positive result for an unplanned pregnancy the client should be advised of their options and signposted/referred to appropriate services that can offer counseling and medical advice.

Negative Result:

1. In the case of a negative result the woman should be advised to re-take a pregnancy test within two weeks.
2. For all women that receive a negative result and do not want to conceive information should be provided around contraceptive methods, in particular Long Acting Reversible Contraception.
3. Young women should be provided with information about delaying sex.
4. Women who express that they have been trying to conceive should be referred to services that can provide information and address issues around infertility.
5. In cases of concern for the health or emotional wellbeing of the client or if they are experiencing any other health concerns, such as abdominal pains, discharge, have missed more than 2 consecutive cycles etc. they must be referred to their GP or other appropriate health care provider.

Staff Training:

1. All pharmacists and staff involved in the service must have undergone the appropriate training, which will include:
 - Training on all the pregnancy tests used by the pharmacy.
 - Training updates whenever new Pregnancy Tests are available.

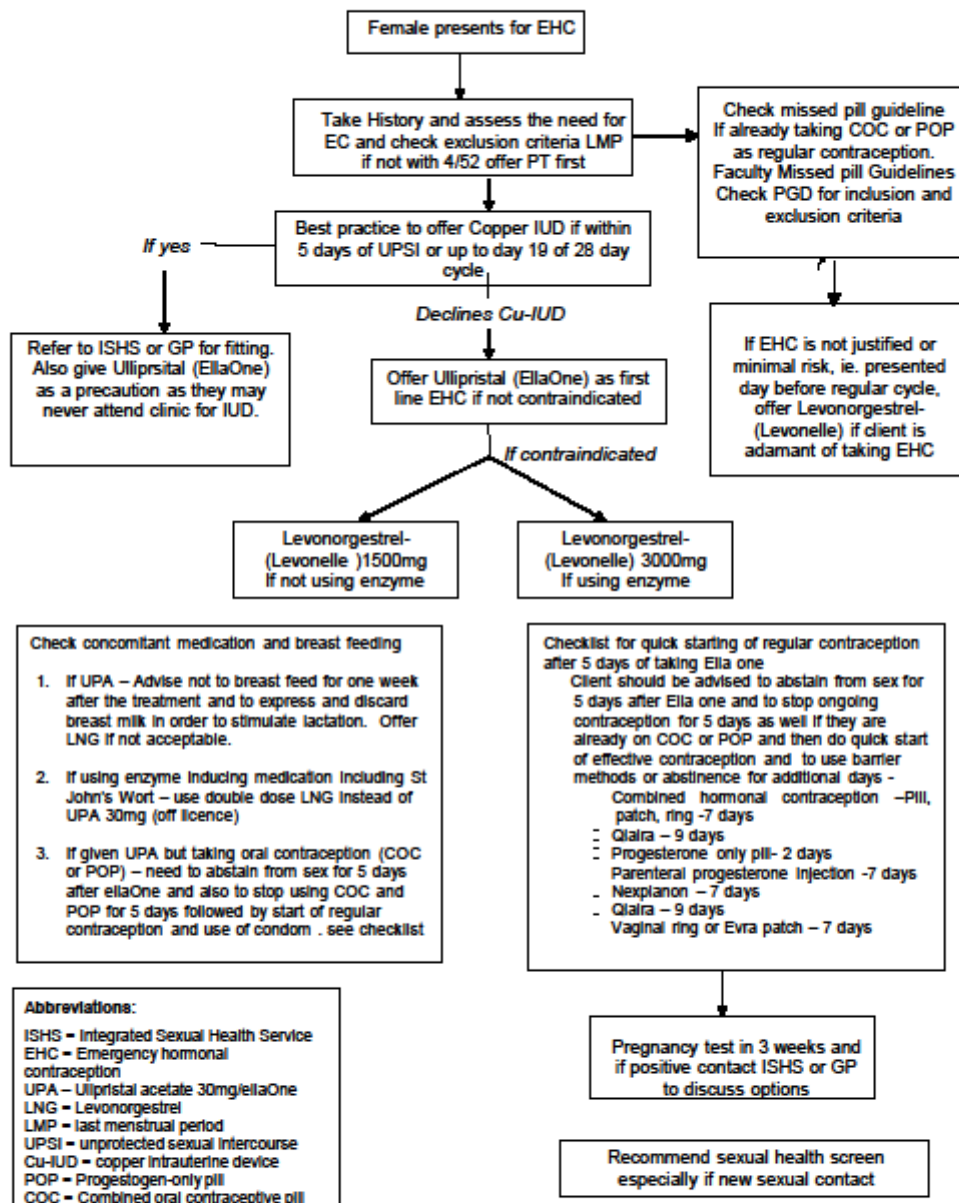
APPENDIX F

INFORMATION PROVISION

Information	Frequency	Consequence of non-provision of information
Number of women prescribed EHC	As part of quarterly monitoring returns	Payment cannot be made to Provider
Number of women given a pregnancy test	As part of quarterly monitoring returns	Payment cannot be made to Provider
Number of users of the service returning to the service	As part of quarterly monitoring returns	N/A
Number of people signposted to other sexual health services and details	As part of quarterly monitoring returns	N/A
Record service provided and demographics of service users to be submitted with quarterly monitoring returns	As part of quarterly monitoring returns	Payment cannot be made to Provider
Record which pharmacist carried out consultation to ensure competency is maintained	As part of quarterly monitoring returns	Payment cannot be made to Provider

APPENDIX G

Emergency Contraception- Decision tree



Locala Sexual Health Services, Locala Community Partnerships CIC, 1st Floor Beckside Court, Bradford Road, Batley, WF17 5PW