

**AGREEMENT FOR THE PROVISION OF SERVICES
COMMUNITY PHARMACY EMERGENCY HORMONAL CONTRACEPTION SERVICE**

THIS AGREEMENT IS DATED

This **Agreement** is made with effect from 1st December 2016 (the “**Effective Date**”)

BETWEEN: Calderdale & Huddersfield NHS Foundation Trust (CHFT) (the “**Commissioner**”)

AND: (the “**Provider**”)

together referred to as the “**Parties**” or individually a “**Party**”.

Term. This Agreement will commence on the 1st December 2016 and continue until 30th November 2017, unless extended by the Commissioner on giving the Provider not less than six months written notice prior to 30th November 2017 or terminated by agreement of the parties with not less than six months written notice to terminate or terminated in accordance with section 3 of the Conditions (“**Terminations**”).

Services. The services to be provided by the Provider to the Commissioner shall be as set out in Section 1 (“**the Services**”).

Entire Agreement. This Agreement comprises;

- (i) this signature page
- (ii) the attached Conditions
- (iii) Schedule 1 – Service Specification
- (iv) Schedule 2 - Finance and Payment

which in the event of any conflict shall take precedence in the order in which they appear above. The Agreement, effected by the signatures of the Parties below, constitutes the entire agreement between the Parties relating to the Services and supersedes all prior negotiations, representations or understandings whether written or oral. This Agreement may only be amended in writing in accordance with section 11 of the Conditions.

Signed on behalf of **Commissioner**

Signed on behalf of **Provider**

Name:.....

Name:.....

Title:.....

Title :

Date:.....

Date:.....

Section 1: The Services

The Provider is commissioned on a non-exclusive basis to provide the services specified in the schedule of services and described in the relevant service specification and appendices. The Provider will provide such services upon the terms and conditions set out below.

For the purposes of this agreement and in the provision of the services the Provider will be responsible to the Commissioner as stated within the Schedule of services to be provided.

In order to provide the services, the Provider must also provide all the essential services as stated in the NHS Pharmaceutical Services Regulations 2005 (as amended).

The suspension of the Enhanced Services will be considered in the following circumstances:

- Provider under investigation by regulatory body
- Provider subject of an NHS Tribunal
- Provider subject of a Fitness to Practice investigation

Both parties will ensure that the service conforms to professional and legal requirements.

Neither party shall discriminate unlawfully within the meaning and scope of any law, enactment, order, regulation or similar instrument relating to discrimination (whether in relation to age, race, gender, sexual orientation, gender reassignment, disability, religion, or any other non-medical characteristic) in employment or performance of the service.

Both parties shall take all reasonable steps to ensure the observance of this clause by all members of the parties' personnel.

The Provider shall not be required to provide or to continue to provide Services to Service Users who in the reasonable professional opinion of the Provider are unsuitable to receive the relevant Service, for as long as such unsuitability remains; or in respect of whom no valid consent has been given; or who display abusive, violent or threatening behaviour unacceptable to the Provider (provided that the Provider must act reasonably and take into account the mental health of such Service Users). Where this applies the Provider shall;

- Tell the service user that he/she has the right to challenge the Provider's decision through the Provider's complaints procedure
- Inform the Commissioner and the Service User's Referrer in writing, wherever possible in advance of taking such action, and in any event within 2 Operational Days of taking such action; and
- The Provider shall liaise with the Commissioner and the Service User's Referrer to resolve the issue of provision of the relevant care to the Service User in a way that minimises any disruption to the Service User's care

The Provider will allow the Commissioner to publicise, where appropriate, pharmacy contact details to the public, patients and relevant professionals as part of the promotion of the service.

The Commissioner will allow the Provider to publicise, where appropriate, details of the service to the public, patients and relevant professionals. The Provider will ensure that any materials are professional in appearance and content, in line with the aims and intended outcomes of the service.

No party shall assign transfer charge or deal in any other similar manner with this agreement or its rights or any part of them under this agreement, nor subcontract any or all of its obligations under this agreement without the prior written consent of the other party.

Nothing in this agreement shall be construed as or having effect as constituting the relationship of employer and employee between the Commissioner and the Provider (nor staff employed by the Provider).

Section 2: Duration

This Agreement will commence on the 1st December 2016 and continue until 30th November 2017, unless extended by the Commissioner on giving the Provider not less than six months written notice prior to 30th November 2017 or terminated by agreement of the parties with not less than six months written notice to terminate or terminated in accordance with section 3 of the Conditions.

The terms and conditions of the agreement may be varied in accordance with section 11.

Section 3: Termination

Notwithstanding the provisions of section 2 of this agreement, either party may terminate the agreement subject to providing six months' notice in writing.

Notwithstanding the provisions of section 2 of this agreement, the Commissioner shall be entitled (without prejudice to our rights and remedies for any breach of this agreement and without prejudice to any continuing obligations you have under this agreement) to terminate this agreement immediately if the Provider seriously breaches the terms of this agreement including by any act or omission which prejudicially affects or is likely so to affect the interests of the Commissioner.

For the avoidance of doubt and without prejudice to any other reason for invoking section 3, paragraph 2, any breach of section 6 paragraph 1 would constitute a serious breach of the terms of this agreement and constitute grounds for immediate termination of the agreement.

Upon termination of this agreement for whatever reason the Commissioner may request that the Provider delivers to the Commissioner books, documents, papers, memoranda notes, records (including any contained in magnetic media or other forms of computer storage) and any other property and materials relating to our business which may be in the Providers control. Such a request by the Commissioner must be reasonable and proportionate. The ownership of all such property shall at all times be vested in the Commissioner.

Section 4: Fees and Payment Mechanism

The Commissioner will only make payments where the Provider has signed and submitted the Schedule of services to be provided to the Commissioner.

The payments may be subject to revision dependant on any changes in fees following negotiations between Community Pharmacy West Yorkshire (CPWY) and Calderdale and Huddersfield NHS Foundation Trust and agreement between the Provider and Commissioner.

For Services that include the supply of medicines and appliances by dispensing an NHS prescription, the dispensing fee and cost of the medicines/ appliances supplied will be reimbursed via the usual route of the NHS Business Services Authority.

The Provider will levy a fee equivalent to the NHS prescription charges when applicable. The Provider will ensure patients exempt from prescription charges are asked for evidence of their prescription exemption status and sign the exemption declaration, in line with the checks made for NHS prescriptions using the Counter Fraud and Security Management Service / NHS Protect procedures. The Provider should only sign the declaration on behalf of a patient in exceptional circumstances.

The Commissioner will make payment for the services on a monthly basis, unless otherwise specified in the Service Specification. The payments will be managed by CPWY on behalf of Calderdale and Huddersfield NHS Foundation Trust providing the appropriate activity information has been recorded on PharmaOutcomes.

The Provider must use PharmaOutcomes for recording consultations and generating payments for Emergency Hormonal Contraception (EHC) enhanced services.

Patient identifiable information must not be submitted to the Commissioner

All service activity must be entered onto PharmaOutcomes before the end of each month to ensure payment by CPWY in or during the 1st week of the following month. CPWY will not be able to backdate claims without recourse to the commissioner. Backdated claims will only be considered in special circumstances.

Any subsequent payments made by the Provider to their employees are a matter for agreement between the Provider and their employee.

Section 5: Status and tax liabilities

The Provider shall be accountable to the proper authorities for any income tax liability, national insurance contributions, VAT and any other tax liability charge or duty arising out of any payment made to you under this agreement

It is agreed that nothing in this agreement shall constitute the Provider acting as an agent or employee of Calderdale and Huddersfield NHS Foundation Trust and the Provider shall have no right or power whatsoever to contract on the behalf of the Commissioner or bind the Commissioner in any way in relation to third parties except as specifically authorised in writing by the Commissioner.

Section 6: Confidential information

The Provider will ensure that the storage of patient records/ paperwork containing client details is as outlined in the NHS code of practice for records management and associated guidance. Equipment used to store records should provide storage that is safe and secure from unauthorised access and which meets health and safety, and fire regulations, but which also allow maximum accessibility of the information commensurate with its frequency of use.

The Provider will treat as confidential and restrict access to records and documents containing information relating to individual clients managed under the terms of the service to personnel authorised to participate in the service and, in the appropriate circumstances, other health care professionals and agencies, in line with local confidentiality arrangements, including where appropriate, the need for the permission of the client to share the information.

All parties will comply with the Data Protection Act, Caldicott and other legislation covering access to confidential client information. The requirement for confidentiality will be balanced with the needs of the service user. Other than the above circumstances the Provider agrees to treat as confidential and not disclose to any person, or otherwise make use of or permit to be made use of, the following information gained as result of providing this service,

- Any information relating to the health records of any client
- Any information relating to the prescribing habits or activities of any clinician or GP practice unless section 9 applies

This restriction shall continue to apply after the termination of this agreement without limit in time but will cease to apply to information which may come into the public domain otherwise than through unauthorised disclosure by the Provider

The Provider shall not be prevented by section 6 and its sub clauses from using any general knowledge experience or skill gained through the provision of these services

The restrictions of this agreement shall not apply to any disclosure or use authorised by the Commissioner in writing or required by law or by this agreement.

Section 7: Quality and Clinical Governance

The Provider will ensure that the service is underpinned by a system of clinical governance which ensures that the service is of a high quality, provided to the agreed standard and supports quality improvement which ensures the delivery of high quality patient care.

The Provider will provide and maintain a safe and suitable environment for service delivery and comply with all relevant statutory requirements, legislation, Department of Health Guidance and professional Codes of Practice.

The Provider shall comply with the Commissioner's policy for safeguarding and promoting the welfare of children and adults in vulnerable circumstances.

Safeguarding contacts are available at the following link: -

www.calderdale-scb.org.uk

The Provider will ensure that all internal policies, procedures and culture must ensure effective privacy, dignity and respect for service users.

The Provider and Commissioner shall comply with NHS Counter-fraud and Security Management regulations and guidance. The Provider will allow an authorised agent of Calderdale and Huddersfield NHS Foundation Trust to access to all documentation for audit/fraud protection and detection purposes, at any reasonable time. The Provider will ensure that all staff involved in the services are reminded that they are to be vigilant to the possible fraudulent use of the service by the public, patients, GP practices, pharmacies or any other health/ social care worker. If fraud is suspected the Provider must inform the Commissioner. The Commissioner will provide details of relevant referral points which pharmacy staff can use to signpost service users who require further assistance.

When relevant, the Commissioner will obtain, or produce, publicity and health promotion material relevant to the service and make this available to the Provider. The Provider must pro-actively use this information in the delivery of the service.

The Provider will ensure that the pharmacy maintains appropriate records to ensure effective ongoing service delivery.

Standard Operating Procedure

The Provider will produce a Standard Operating Procedure (SOP) for the service. The Provider will ensure that the SOP:

- Defines staff roles and responsibilities
- Includes any relevant signposting information
- Includes the processes for error and near miss reporting
- Is regularly reviewed and kept up-to-date
- Is signed and dated by all staff (including locums) operating under the SOP
- States the date of production
- States the date for review

Staff

The Provider will ensure that pharmacists and staff (including locums) involved in the provision of the service are familiar and operate within the Standard Operating Procedure (including associated procedures and documentation).

The Provider will ensure that pharmacists and staff (including locums) involved in the provision of the service have the relevant knowledge and competencies, are appropriately trained to provide the service as specified in the Service Specification and have access to relevant and up-to-date reference sources.

The Provider will promptly inform the commissioner of any change in pharmacy staff/ circumstances that mean that either more staff need training or the pharmacy is unable to participate in the service due to a lack of suitably trained and accredited staff

Complaints

The Commissioner and the Provider shall each operate and publicise a complaints procedure that complies with the Law. The Provider will effectively manage any complaints using the Providers own internal complaints procedures which must be consistent with the NHS and National Health Service Complaints (England) Regulations.

Incidents

The Provider will directly report any incidents or near misses relating to the service to the commissioner without delay. The Provider will identify themselves on the paperwork (i.e. the incident will not be submitted anonymously). This mechanism of reporting will be used by the Provider even if this is not the Providers usual route for incident reporting. In response to incidents or near-misses both the Commissioner and the Provider will reflect on current practice and, if appropriate, implement changes to reduce the risk of a similar event and improving the quality of care provided. The Provider will consider and respond to the recommendations arising from any audit, Serious Untoward Incident report or Patient Safety Incident report produced by the Commissioner.

The contractor acknowledges that they have acquainted themselves with the requirement of this service, as further outlined in the attached service specification and appendices.

The contractor therefore agrees that they will deliver the service as described the service specification and in line with the documentation provided on the website.

Section 8: Performance Management

The Provider shall meet the service targets and quality indicators where specified in each of the Service Specifications.

Where the Commissioner or the Provider has a query regarding the other's performance under this Agreement, it may issue a Contract Query to the other in writing setting out the nature of its query. The recipient is obliged to reply to it in writing, in a manner that satisfies the nature of the Contract Query, within 10 Operational Days unless otherwise agreed in writing.

Where the Commissioner has reasonable evidence that the performance of the Provider materially fails to meet the requirements of this Agreement (inclusive of the requirements within the relevant service specifications) then it may issue a Performance Notice to the Provider setting out the performance deficiency, a reminder of its implications and a timescale for the implementation of remedial actions. Failure of the Provider to rectify the performance as outlined in the Performance Notice will lead to the Commissioner suspending or terminating the service, as deemed suitable by the Commissioner and in line with the Department of Health Non-compliance and Dispute Resolution guidance.

Section 9: Restrictive covenants

The Provider agrees that throughout the term of this agreement services will only be provided by pharmacy staff accredited and trained as specified within the service specification.

Any registered pharmaceutical chemist providing the services and the registered pharmaceutical chemist signing the local public health services agreement on behalf of the Provider will follow the General Pharmaceutical Council *Standards of Conduct, Ethics and Performance*.

The Provider will provide evidence to the Commissioner that the services provided under this agreement are covered by adequate professional indemnity arrangements.

If the Provider becomes aware of any possible fraudulent activity, poor practice or professional misconduct on the part of an independent contractor, their employees or agents, or any employee of Calderdale and Huddersfield NHS Foundation Trust, they will communicate your concerns within one working day to the commissioner.

Section 10: Dispute Resolution Procedure

If any dispute arises out of this Agreement ("Dispute") the Parties will attempt to settle by negotiation addressed at the "lowest level".

Where this is not possible the named contacts to the agreement will meet to attempt resolution.

In the event of failure to resolve the matter as outlined above, negotiations will commence with each of the Parties represented by a person who is a Director (or of equivalent status with authority to settle the dispute) and whom ideally have no direct day to day involvement in the relevant matter.

If the Parties in Dispute are unable to settle the Dispute by negotiation, they must, within 5 Operational Days after the end of the Negotiation Period, submit the Dispute to mediation by CEDR or other independent body or organisation agreed between the Parties and set out in the Particulars, in all other cases.

Section 11: Variations

Written variations to local public health services and appendices must be signed off by the signatories to this agreement in consultation with the Commissioners and the Local Pharmaceutical Committee (LPC). The Commissioner will provide at least 28 days' notice for any changes or variations made.

Section 12: Signatories

This document constitutes the agreement between the Provider and the Commissioner in regards to local public health services. The Provider must immediately inform The Commissioner of any change in pharmacy personnel that means either the pharmacy is unable to provide the service or this agreement is no longer valid as the pharmacy contractor no longer employs the signatory.

Entire agreement

This agreement sets out the entire agreement of the parties and supersedes all prior agreements and understandings relating to its subject matter.

Neither party shall be liable to the other for any loss, damage, delay or failure to perform its obligations under this agreement, howsoever arising, caused by circumstances beyond its reasonable control (Force Majeure).

If provision of the service is delayed by Force Majeure, the Provider shall be allowed a reasonable time for completion. This notwithstanding, the Provider shall use the best endeavours to fulfil their obligations under this agreement for the duration of the force majeure or other circumstances.

The construction, validity and performance of this agreement is governed by the laws of England and the parties accept and agree to the jurisdiction of the English Courts.

If any part of this Agreement is declared invalid or otherwise unenforceable, it shall be severed from this Agreement and this shall not affect the validity and/or enforceability of the remaining provisions.

SCHEDULE of SERVICES TO BE PROVIDED

The Provider	(Name of Community Pharmacy)	<i>OSC code</i> (PPD number)	F
Address of Provider	(Insert pharmacy address)		
Commissioner:			
Local Public Health Services	Service Commissioner For and on behalf of Calderdale and Huddersfield NHS Foundation Trust (commissioner)	Pharmacy to provide service	to
EHC service	Gill Harries General Manager		
Authorisation (commissioner): I hereby authorise the above named pharmacy to provide the EHC Local Public Health Services			
For and on behalf of Calderdale and Huddersfield NHS Foundation Trust			
Signed		Date	
Name		Position	
Authorisation (provider): I hereby agree to provide the Local Public Health Services as specified above.			
For and on behalf of the above named <i>pharmacy</i> (service provider)			
Signed		Date	
Name		Position	
GPhC registration number			
Service agreement and Service specifications do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own code of professional conduct.			

SCHEDULE 1 – SERVICE SPECIFICATION

COMMUNITY PHARMACY EMERGENCY HORMONAL CONTRACEPTION SERVICE

Executive Summary

The supply of 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. Additionally, supply of EHC on the NHS from community pharmacists has been well received by service users².

The importance of improving sexual health is acknowledged by the inclusion of three indicators in the Public Health Outcomes Framework (PHOF) (DOH, 2013). These indicators are:

- Under-18 conceptions;
- Chlamydia diagnoses (15–24 year olds)
- People presenting with HIV at a late stage of infection.

Community pharmacies play an important role in improving these indicators.

Aims and intended service outcomes of the service

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 under 25 years of age
- Directing clients who fall outside the protocol or who need advice on ongoing contraception into mainstream contraceptive services and appropriate healthcare services.
- Improving Chlamydia diagnosis, particularly among 15-24 year olds and referral onto other sexual health services, as necessary for other screening and treatment.

Brief service description

Females between 13 and 25 years of age who present within 120 hours of unprotected sexual intercourse will be provided with emergency hormonal contraception (subject to clinical circumstances) free of charge.

Additionally, females who present within 120 hours of unprotected sexual intercourse who are in receipt of an income based prescription exemption (income support, income based jobseekers allowance or working families tax credit) will be offered emergency hormonal contraception (subject to clinical circumstances) free of charge.

¹ Pharmaceutical Journal 2006;276:583

² Choosing health through pharmacy 2005-2015 A programme for pharmaceutical public health

Clients will also be given advice on the avoidance of pregnancy and sexually transmitted infections (STIs) through safer sex and condom use, advice on the use of regular contraceptive methods and provide onward signposting to services that provide long-term contraceptive methods, offered and assistance in Chlamydia postal screening and diagnosis and management of STIs.

Resource implications

Pharmacies will be paid £15 per consultation to cover pharmacist and staff time, training and other duties as outlined in the services. EHC is reimbursed at cost price (cheapest readily available brand, as within Drug Tariff, Chemist and Druggist or wholesalers list price) plus VAT.

Chlamydia postal testing kits will be provided free of charge via Chlamydia Screening based at Broad Street and the pharmacy will be reimbursed £5 per returned screen to the lab.

Additionally if a pregnancy test is deemed necessary to exclude pregnancy, as part of the EHC supply, the pharmacy will be reimbursed at £5, to cover the cost of the test and counselling.

Purpose of the Agreement

This agreement relates to the Emergency Hormonal Contraception (EHC) Service by participating community pharmacies within Calderdale.

The agreement is for the pharmacy to supply Emergency Hormonal Contraception (EHC) in line with local protocols to appropriate clients, in line with the requirements of the patient group direction(s), by pharmacists who have completed the required competency declaration process from commissioned Pharmacies within Calderdale.

Additionally this service includes the offer and provision of Chlamydia postal testing kits and pregnancy tests as necessary.

Selection of provider

The Pharmacies for this service have been selected on the basis of:

1. Availability of a suitable consultation area (as defined for the Medicines Use Review service)
2. Achievement of appropriate specified competencies to provide.

The Services

Client presents in pharmacy

- Pharmacies will ensure they offer a user-friendly, non-judgmental, client-centred confidential service.
- 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.

EHC consultation

- The complete EHC consultation must be carried out within the pharmacy consultation room (see premises section).
- The EHC consultation must be carried out by a pharmacist who is considered competent to provide; see section below.
- The pharmacist will assess the need and suitability for a client to receive EHC, in line with the PGD(s) and 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(s) 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. Cu-IUD should be offered to all clients.
- 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 pharmacist, as part of the EHC consultation will stress the importance of STI screening:-
 - If a client is asymptomatic the pharmacist will offer the client a Chlamydia postal screening kit. The pharmacist will fill in the personal details on the kit for the client (to ensure the client receives their result, to enable commissioners to monitor use in order to inform future provision and to reduce the chances of the client disposing of the kit and not using it). The pharmacist will go through the screening process with the client and inform the client that the screening team will contact them confidentially to clarify their result.
 - The Chlamydia screening postal kits are to be provided to all clients who meet the criteria, regardless of age, with a reason documented for if and why the offer was declined as appropriate.
 - If a client is symptomatic, the pharmacist should refer the client into the Sexual Health Service. The pharmacist must make an appointment with the service for the client on the basis that they are symptomatic and priority to be seen. This will improve the chance of follow-up for the client.

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 by the West Yorkshire PGD(s) and will be paid under this agreement.

Although the RPS has issued guidance regarding advance supply of EHC this is not covered by the PGD(s) 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
- Provision of Chlamydia postal screening
- 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.

Referral

- Refer any client who is identified as unsuitable for the supply of Emergency Hormonal Contraception under the PGD(s) or service specification to a GP or SHS.
- If a referral is made the pharmacist should make every effort to contact the GP/ SHS clinic, 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.

Excluded clients

Clients excluded from the PGD(s) criteria or service specification criteria will be referred by the pharmacy to another local service that will be able to assist them, as soon as possible, e.g. GP, SHS or will be invited to purchase the Pharmacy medicine product if the exclusion from supply via the PGD(s) is only due to an administrative matter, e.g. client over 25 but not in receipt of an income-based prescription exemption (income support, income-based job seekers allowance, named on a valid working families Tax Credit NHS exemption certificate or HC2 full help with health costs certificate).

If the client is excluded from accessing EHC due to a service specification exclusion (i.e. accredited pharmacist not available, client over 25 and not in receipt of an income-based prescription exemption) the pharmacist cannot claim a consultation fee as this exclusion should be ascertained before the consultation.

If following a consultation, a client is excluded or otherwise unable to access EHC the pharmacist 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.

Supply of condoms

The pharmacist will offer each client a supply of condoms, free of charge, as part of the EHC consultation.

The number of condoms supplied will depend on the requirements of the client and should be determined as part of the discussion on safe sex and the use of regular contraception methods, including LARCs. A client can be supplied up to 12 condoms per EHC consultation.

Ideally the client should be offered a choice of condom (ordering an EHC Condom Pack will ensure the pharmacy is supplied with a range of types).

Only condoms provided by CHFT should be used as part of the EHC service.

The supply of condoms should be recorded on PharmaOutcomes

Condoms must not be supplied other than as part of an EHC consultation.

Resources to support delivery of the service

Supply of condoms

Condoms for use in providing the EHC service are ordered from The Sexual Health Centre, Broad Street Plaza, 51 Northgate, Halifax HX1 1UB

Tel: 01422 261370

Accessibility

The expectation is that the service is available throughout the pharmacies opening hours (both core and supplementary). The service is to be delivered by the pharmacy for at least 45 weeks of the year with no continuous break of more than two weeks.

When the pharmacy is unable to provide the service the pharmacy has a duty to signpost any potential clients to another provider of EHC, convenient to the client, who are able to provide the service to the client. This may be another pharmacy, SHS or GP. The client must be informed of all possible providers.

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.

The pharmacies procedure for dealing with a client who presents for EHC, when the pharmacist on duty or is unable to provide the service (i.e. they have not completed the declaration of competency process), is accessible to all pharmacy staff to ensure that any client who presents to the pharmacy is dealt with in an appropriate and timely manner in line with this service specification.

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) £4.42*

Ulipristal - Ellaone (HRA) £16.95

*It is expected that Pharmacies will provide Upostelle levonorgestrel (Consilient Health) at £4.42 EHC as described in Appendix 1.

Pharmacies will maintain adequate stocks of Chlamydia postal screening kits. These can be ordered free of charge from the screening team. See resource section for contact details.

Staff

Pharmacies providing the service must be commissioned by CHFT to provide the service.

This service can only be delivered by a registered pharmacist.

It is the duty of the pharmacy commissioned to provide the sexual health (EHC) service to ensure that all individual pharmacists delivering this service from their premises are:

- Fit to Practise
- Suitable to deliver the service
- Can demonstrate they are competent to deliver the service

Asking for copies of the Declaration of Competencies (DoC) from all pharmacists who provide the service from within your pharmacy can be a mechanism of ensuring that as a pharmacy contractor you can demonstrate that the pharmacists providing the service are competent to deliver the EHC service. The commissioner may request from a pharmacy copies of the DoC for each pharmacist who has supplied EHC under this 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 PGDs (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 Ulipristal, their place in EHC provision and the Product’s Licence/ SPC.
- Sign both the Levonorgestrel and Ulipristal PGD in each pharmacy where they work / will provide the EHC service to ensure the authorisation process for working under the PGDs 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 CMBC.

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 EHC service must be carried out within the pharmacy consultation room (as defined by for the MUR service). EHC consultations must not take place over-the-counter or in another area of the pharmacy premises.

The pharmacy will advertise that they provide the service.

Resources to support delivery of the service

Some of the resources can also be obtained online through the following website:

http://www.cpw.org/pharmacy-contracts-services/local-services/sexual-health-inc-ehc-.shtml#SH_Calderdale

For further information please see website <http://sexualhealth.cht.nhs.uk>

Storage of paperwork

Completed paperwork must be stored as outlined in the agreement. However, as this service supplies medication via PGDs to those under 18, additional requirements are needed for storage:

- The record of consultation is kept on PharmOutcomes
- If a PGD is superseded, the superseded PGD must 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)

Quality Indicators

	Quality Performance Indicator	Threshold	Method of Measurement	Report Due
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	Quality Performance Indicator	Threshold	Method of Measurement	Report Due
Performance monitoring	The pharmacy is fully promoting the services available and promotes uptake	100% compliance	CHFT Contract Assurance process (including self-assessment) Mystery shopper feedback	Frequency of assurance visit as determined by the CHFT
Performance monitoring	The pharmacy provides information and signposting to the website (http://sexualhealth.cht.nhs.uk) to promote the available services and promotes uptake.	100% compliance	CHFT Contract Assurance process (including self-assessment)	Frequency of assurance visit as determined by the CHFT
Clinical Governance- Patient Safety	The pharmacy ensures that the SOP is in line with the service specification and reviews this SOP and the referral pathways for the service on an annual basis.	100% compliance	CHFT Contract Assurance process (including self-assessment) Mystery shopper feedback	Frequency of assurance visit as determined by the CHFT
Suitably Qualified Workforce	The pharmacy can demonstrate that pharmacists and staff involved in the provision of the service have completed the DoC and have undertaken CPD and/or training relevant	100% compliance	See accreditation section CHFT Contract Assurance process (including self-assessment)	Annual renewal of service agreement
Improving Service Users & Carers Experience	The pharmacy participates in an annual CHFT organised audit of service provision	100% compliance	Return of all audit forms within timescales specified by CHFT.	CHFT full service review
Improving Service Users & Carers Experience	The pharmacy co-operates with any locally agreed CHFT led assessment of service user experience	100% compliance	Evidence of patient suggestions to enhance service and the investigation of these together with summary of outcome, e.g. taken forward/not taken as impractical	CHFT full service review

Service Evaluation

The service will be annually reviewed to ensure it is working correctly, meets the needs of patients, healthcare professionals, the NHS and to check whether any improvements could be made. Feedback will be to the LPC/ CHFT and any other stakeholder groups and the scope of the annual review may include (but is not limited to) the following areas:

- Number of consultations per pharmacy, postcode area and in Calderdale
- Trends in numbers accessing the service through each pharmacy, postcode area and in Calderdale
- Frequency of client use
- The reason for the request
- Analysis of exemption and inclusion criteria for each client
- Length of time between of unprotected sexual intercourse and EHC consultation
- The numbers of EHC supervised compared to not-supervised
- Costs of service
- Assessment of user experience (if included)
- Number of incidents reported to the CHFT regarding the service and if appropriate an analysis of the incidents
- Feedback from mystery shoppers (if carried out)
- Feedback received from stakeholders about the service (if included)
- Drug dispensed.
- Pregnancy tests performed as part of the service
- Chlamydia screens, via postal kits performed as part of service or reason for refusal.

Appendix 1

Ulipristal Information

Ulipristal allows for the provision of emergency contraception to women who are at risk of unwanted pregnancy and present within 120 hours (5 days) following unprotected sexual intercourse or contraceptive failure (therefore increasing the effectiveness and window of opportunity by 48 hours following unprotected sexual intercourse)

Ulipristal can be supplied via the PGD in the following circumstances:

- Between 0-120 hours as first drug of choice if client declines copper coil and ulipristal is not contraindicated and EC is justified. See EHC Decision tree

There may be occasions when the first –line choice of EHC is not deemed to be the most appropriate. When determining whether to supply the second-line choice pharmacists must ensure that the supply is in-line with the PGD and that the relative efficacy of treatments and risks of pregnancy are fully discussed with the patient. Please refer to the check list in EHC decision tree.

Treatment choice and supply

Following discussion with the client of the three options for emergency contraception, their merits, effectiveness and limitations, the pharmacist is to use their professional judgement as to which treatment option(s) are the most appropriate for the client.

Treatment options for emergency contraception;

- *Cu-IUD*
- *Ulipristal*
- *Levonorgestrel*

Cu-IUD must always be considered and advised as first choice, as it is the most effective form of emergency contraception and can be used up to day 19 of the menstrual cycle.

It is important to note that if Cu-IUD has been chosen by the client a supply of hormonal emergency contraception (Levonorgestrel or Ulipristal) must be offered to the client if clinically appropriate. This gives additional protection should the client be lost to follow up (e.g. not make the appointment for the Cu-IUD fitting) or is not being able to have the Cu-IUD fitted. If a client accepts a Cu-IUD, the pharmacist must make every effort to obtain the client an appointment for fitting.

Drug Interactions

Ulipristal has some notable drug interactions which must be considered when selecting treatment choice.

- Medicinal products affecting gastric pH- Proton Pump Inhibitors, antacids and H2 Receptor antagonists- reduces efficacy; concomitant use not recommended. The clinical relevance of this interaction for single dose administration of ulipristal acetate as emergency contraception is not known.
- Hormonal Contraceptives- Faculty would recommend that after taking UPA (Ella one) for EC, a woman should not start a hormonal contraceptive method for at least 5 days and be advised to use barrier methods or to abstain from sex until effective hormonal contraceptive cover has been achieved.

- The effectiveness of a progestogen-containing contraceptive method that is quick started immediately after administration of UPA might be reduced by UPA due to competition at the progesterone receptor site.
- The effect of UPA in delaying ovulation might be reduced by quick-starting a progestogen-containing contraceptive
- Women should be advised that when hormonal methods of ongoing contraception are started (after at least 5 days of Ella one) then the usual recommended contraceptive precautions should be taken (barrier or abstinence) for a number of days, depending of the method used:

Statement from the Clinical Effectiveness Unit - September 2015

- Combined hormonal contraception – Pill, patch, ring (except Qlaira) --7 days
- Progesterone only pill- 2 days
- Parenteral progesterone injection / implant -7 days
- Qlaira – 9 days
- Vaginal ring or Evra patch – 7 days
- Liver enzyme inducing medication- Ulipristal must not be used.(use double dose of Levonelle)
- Liver Enzyme Inhibitors- ketoconazole, itraconazole, clarithromycin, nefazodone: increase plasma level of ulipristal acetate. Clinical relevance of this is unknown.

Mid-cycle or cycle not known

The consultation must include an assessment of where the client is in her menstrual cycle. For clients who are mid-cycle (days 10-15 of 28 day cycle OR within 3 days before and 2 days after expected ovulation) or who are unsure of the date of their last menstrual period, Ulipristal is the preferred treatment choice as it offers a higher efficacy around the time of ovulation than Levonorgestrel.

For women on the contraceptive pill the pill-free days should be used to calculate the cycle (not days of the withdrawal bleed).

Ulipristal patient advice

- That pregnancy can still occur, despite treatment – 2% failure rate
- If menstrual periods are delayed by more than 7 days or if periods are abnormal in anyway (light, heavy or painful), the patient should seek medical advice.
- To seek medical advice if there is any lower abdominal pain.
- That if a pregnancy has occurred, following failure of Ulipristal treatment, client should contact GP/ The Sexual Health Centre for follow-up to ensure that it is not ectopic.
- Clients need to use a reliable barrier method as specified under Drug Interactions or until the next menstrual period (or abstain from sexual intercourse). Please note that ovulation may be delayed which could possibly increase pregnancy risk later in cycle. **This should be emphasised strongly.**

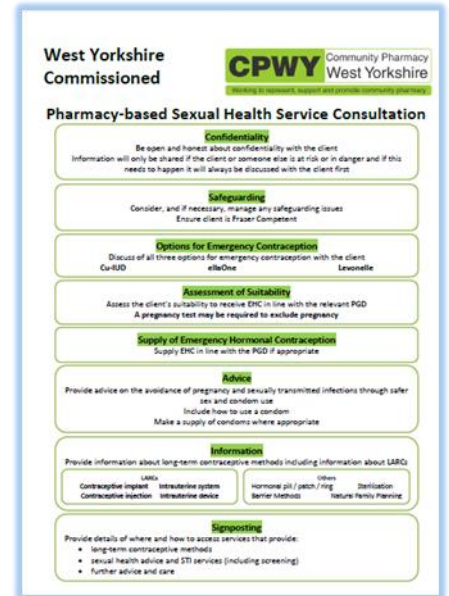
Other points to note

- Under the terms of the PGD Ulipristal can only be used once per cycle.
- Should NOT be used if suspicion of an implanted pregnancy
- Should avoid breast feeding for one week taking

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
- Offer a Chlamydia postal screen



*Key Point – The pharmacy is providing a **Sexual Health Service***

Pharmacists and their teams are being commissioned to provide a holistic sexual health service in which supply of EHC forms only a part of this service.

The Consultation record and PharmOutcomes has been updated to capture the addition of Ulipristal.

Referral

Clients presenting for emergency contraception but who are excluded from the EHC PGD criteria will be referred to another local service that will be able to assist them, as soon as possible, e.g. Sexual Health service, GP or will be invited to purchase the Pharmacy Medicine product if the exclusion from supply via the PGD is only due to an administrative matter, e.g. age range/ prescription exemption status.

When a referral is made the pharmacist should make every effort to contact the Sexual Health Centre / GP to book an appointment for the client and inform the client of the time

and location of the appointment. Taking this active approach reduces the chance that a client will be lost to follow up.

If the pharmacist on duty is not able to supply emergency contraception (e.g. they have not completed the training and declaration of competence) the pharmacy has the option of making a referral to another pharmacy. In these circumstances the pharmacy to which the client is being referred must be contacted to check that an accredited pharmacist will be available to provide the Sexual Health (EHC) Service for the client.

Taking an active approach to referrals reduces the chance that a client will be 'lost to follow up'.

This could make the difference between an unintended pregnancy or not.

If following a consultation, a client is excluded or otherwise unable to access EHC the pharmacist 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.

PGD matters

This service is underpinned by two PGDs which can be accessed from:

http://www.cpw.org/pharmacy-contracts-services/local-services/sexual-health-inc-ehc.shtml#SH_Calderdale

- Supply of Levonorgestrel Emergency Hormonal Contraception (EHC) from Community Pharmacies
- Supply of Ulipristal Acetate Tablets 30mg Emergency Hormonal Contraception (EHC) From Community Pharmacies

When working under any PGD the pharmacist must be familiar with the content and limitations of the PGD and work within these at all times.

Pharmacists must ensure that they are working within the relevant, in-date PGD. Different organisations PGDs will differ and PGDs will be amended in each version.

Clients excluded from the PGD criteria will be referred to another local service that will be able to assist them, as soon as possible, e.g. The Sexual Health service or GP or will be invited to purchase the Pharmacy medicine product if the exclusion from supply via the PGD is due to age.

Pharmacists must be familiar and competent in the use of PGDs.

NICE have produced Good practice guidance for Patient Group Directions which provides good practice recommendations for individual people and organisations involved with PGDs, with the aim of ensuring patients receive safe and appropriate care and timely access to medicines, in line with legislation. The guidance is available:

<http://www.nice.org.uk/guidance/MPG2>

A Patient Group Direction- Information Sheet is available from

<http://www.cpw.org/doc/335.pdf>.

Sexual Health (EHC) Service - General Information

General information to assist with providing the service is available at www.cpwy.org and includes:

- Confidentiality Poster- <http://www.cpwy.org/doc/417.pdf>
- Aide Memoire- <http://www.cpwy.org/doc/580.pdf>
- Barnado's Questions- <http://www.cpwy.org/doc/280.pdf>
- Fraser Guidelines- <http://www.cpwy.org/doc/281.pdf>
- Talking 1 to 1 with a Young Person- <http://www.cpwy.org/doc/282.pdf>
- How to use a condom- <http://www.kypf.org.uk/contraception/condom/how-to-use-a-condom/>
- Sexual Health (EHC) Service - General Information- Provides information under each of the headings of the consultation aide memoire and includes some suggested questions and links- <http://www.cpwy.org/doc/540.pdf>
- Overview from a GP talking about EHC services in pharmacy:
<http://www.youtube.com/watch?v=oudvg5wQDL4>

Support and advice

If you are not sure of any aspect regarding the sexual health service or supply of EHC, the pharmacist can seek advice from The Sexual Health Centre.

The Sexual Health Centre, Broad Street Plaza, 51 Northgate, Halifax HX1 1UB

Tel: 01422 261370

Other matters

The supply of ellaOne will be made free of charge to the client at NHS expense.

The pharmacist supervises the client taking the ellaOne tablet.

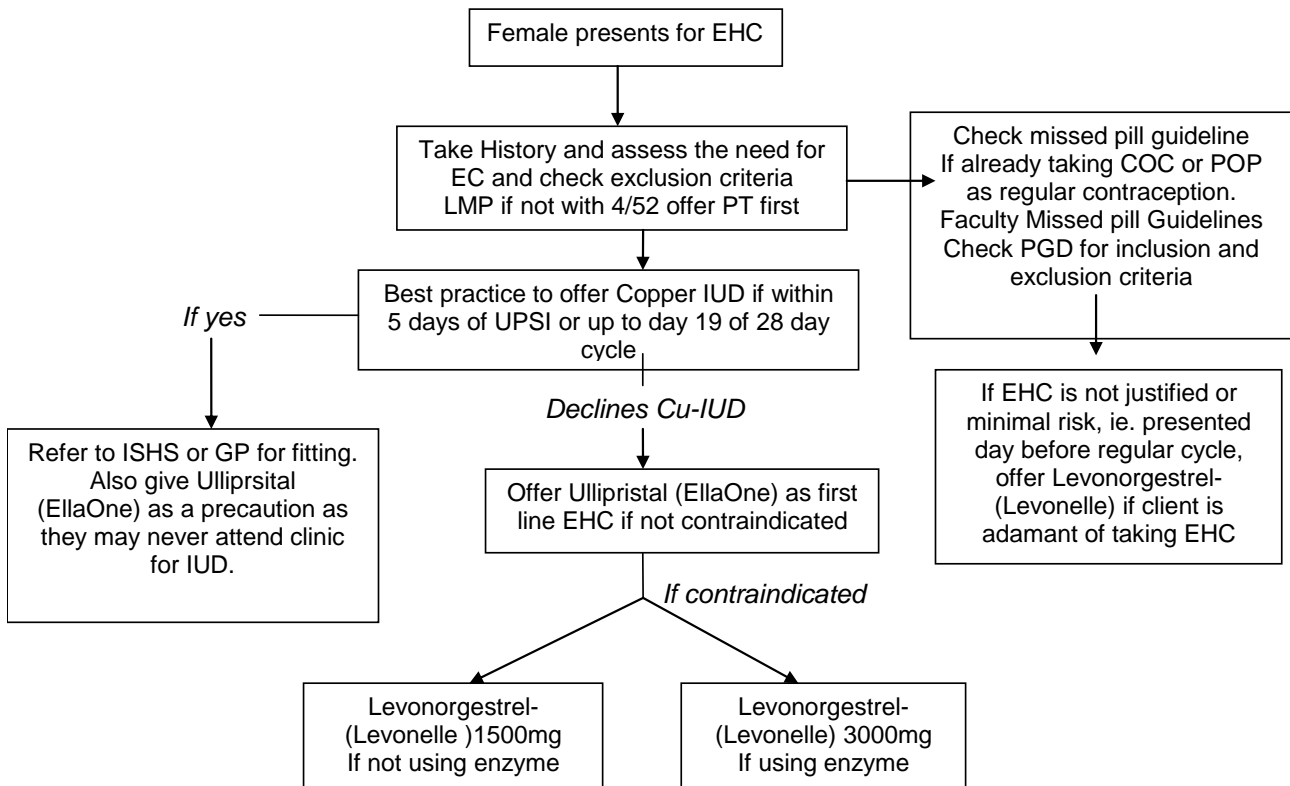
Reimbursement

A fee of £15 will be paid per sexual health consultation, irrespective of whether or not medication is supplied, plus the cost of reimbursement of Levonorgestrel 1500mcg tablet (Consilient Health Levonorgestrel 1500mcg (Upostelle), £4.42) or Ulipristal Acetate (ellaOne, £16.95).

Claims process

The process for submitting claims remains the same. Each consultation should be added onto PharmOutcomes in a timely manner, and within the same month of the activity taking place.

Emergency Contraception- Decision tree



Check concomitant medication and breast feeding

1. If UPA – Advise not to breast feed for one week after the treatment and to express and discard breast milk in order to stimulate lactation. Offer LNG if not acceptable.
2. If using enzyme inducing medication including St John's Wort – use double dose LNG instead of UPA 30mg (off licence)
3. If given UPA but taking oral contraception (COC or POP) – need to abstain from sex for 5 days after ellaOne and also to stop using COC and POP for 5 days followed by start of regular contraception and use of condom . see checklist

Checklist for quick starting of regular contraception after 5 days of taking Ella one

- Client should be advised to abstain from sex for 5 days after Ella one and to stop ongoing contraception for 5 days as well if they are already on COC or POP and then do quick start of effective contraception and to use barrier methods or abstinence for additional days -
 - Combined hormonal contraception –Pill, patch, ring -7 days
 - Qlaira – 9 days
 - Progesterone only pill- 2 days
 - Parenteral progesterone injection -7 days
 - Nexplanon – 7 days
 - Qlaira – 9 days
 - Vaginal ring or Evra patch – 7 days

Abbreviations:
 ISHS = Integrated Sexual Health Service
 EHC = Emergency hormonal contraception
 UPA – Ullipristal acetate 30mg/ellaOne
 LNG = Levonorgestrel
 LMP = last menstrual period
 UPSI = unprotected sexual intercourse
 Cu-IUD = copper intrauterine device
 POP = Progestogen-only pill
 COC = Combined oral contraceptive pill

Pregnancy test in 3 weeks and if positive contact ISHS or GP to discuss options

Recommend sexual health screen especially if new sexual contact

SCHEDULE 2 – FINANCE & PAYMENT

1. PAYMENT

Remuneration will be made to the pharmacy according to the following:

Service delivery costs will be paid at £15 per consultation to include:

- Pharmacist time to provide the consultation
- Associated staff time to support the pharmacist in providing the service
- Training costs
- Printing consultation forms
- Completing claims (by inputting data onto PharmOutcomes) and audit.

Treatments are reimbursed at cost price (based on the cheapest readily available brand), as in Drug Tariff, Chemist and Druggist or wholesalers list price) plus VAT at the appropriate rate (currently 5%) as stated in the Formulary.

Returned Chlamydia screens to the lab will be paid at £5 per screen. This will be paid once the data is triangulated with the lab data, by the commissioner.

Payment will be made retrospectively on a monthly basis. Payment will be made upon submission of service activity data to PharmOutcomes before the end of each month to ensure payment by Community Pharmacy West Yorkshire. Community Pharmacy West Yorkshire will not be able to backdate claims without recourse to the commissioner. Backdated claims will only be considered in special circumstances.

Each pregnancy test will be paid at £5. This will only be paid if the pharmacist has deemed it necessary to exclude pregnancy as part of EHC supply under the contract and the pharmacist has recorded the supply through PharmOutcomes.

£5 per test will cover the cost of the test and time taken for counselling the client.

2. INVOICING

Each consultation should be added onto PharmOutcomes in a timely manner, and within the same month of the activity taking place.