NHS England Midlands Region Community pharmacy local enhanced service

Community Pharmacy Extended Care Service (Tier 1) 2023/2024

Equalities and health inequalities statement

“Promoting equality and addressing health inequalities are at the heart of NHS England values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it

- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities.”

Equity of Access, Equality and Non-Discrimination

The parties must not discriminate between or against service users, carers or legal guardians on the grounds of age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, sexual orientation, or any other non-medical characteristics, except as permitted by Law (Equality Act 2010).

The Contractor must provide appropriate assistance and make reasonable adjustments for service users, carers and legal guardians who do not speak, read or write English or who have communication difficulties (including hearing, oral or learning impairments).

Contents

Appendices

1.0 Agreement between the parties

Commissioner (NHSE)	NHS Commissioning Board ("NHS England") Midlands Region
Pharmacy Contractor	*Insert Pharmacy Contractor name's (as set out in the relevant pharmaceutical list), ODS code and address*
Local Enhanced Service (LES)	Community Pharmacy Extended Care Service (Tier 1) 2023/2024
Commencement Date	31st March 2023
End Date	*31st March 2024* unless terminated earlier in accordance with paragraph 1.2 or otherwise in accordance with this LES Agreement
Review Date	Prior to 31st March 2024

1.1 Enhanced service terms

The following services are commissioned as Enhanced Services by NHS England in accordance with *The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 PART, PART 4, Section 14(1)(n)(as amended).*

The Pharmacy Contractor shall provide the services in accordance with the terms of this LES Agreement and in full compliance with the Terms of Service or LPS contract terms that apply to the Pharmacy Contractor.

The Pharmacy Contractor must not use provision of this LES Agreement as an opportunity to attempt to influence or seek to persuade a Patient to change their choice of pharmacy, or to seek to change any prescription nominations the Patient may already have in

place with other Pharmacy Contractors under the Community Pharmacy Contractual Framework.

The Pharmacy Contractor must not use provision of this LES Agreement as an opportunity to attempt to influence or seek to persuade a Patient to participate in, or obtain, a Patient-funded service provided by the Pharmacy Contractor.

The Pharmacy Contractor shall provide the LES fully in accordance with the terms of this LES Agreement.

In consideration of the Pharmacy Contractor's provision of the LES in accordance with the terms of this LES Agreement, the Commissioner (NHSE) will pay the Service Payment to the Pharmacy Contractor in accordance with the terms of this LES Agreement.

This LES Agreement is specific to the Pharmacy Contractor and the Pharmacy Contractor may not sub-contract, assign, novate or otherwise seek to transfer any of its rights or obligations under this LES Agreement to any other party without the prior written permission of the Commissioner (NHSE).

Except where it is expressly stated to the contrary, this LES Agreement does not give rise to any rights enforceable by any person who is not a party to it.

In order to participate in the service, each contractor must complete the signed agreement below and return to NHSE Midlands as indicated. Once received, the pharmacy will be accredited, and delivery of the service can commence.

For branches of group pharmacies, this agreement should be completed by an authorised person(s) at Head Office.

1.2 Termination

The Pharmacy Contractor may terminate this LES Agreement by serving not less than 1 months' written notice on the Commissioner (NHSE). The Commissioner (NHSE) may, at their absolute discretion, agree a shorter notice period. Where, due to an emergency the

Pharmacy Contractor is not able to provide this notice period, they should contact the Commissioner (NHSE) to agree an amended timeframe with them.

The Commissioner (NHSE) may terminate this LES Agreement by serving not less than 1 months' written notice on the Pharmacy Contractor.

This LES Agreement shall terminate automatically on termination of the Pharmacy Contractor's LPS contract, or removal of either the Pharmacy Contractor from the Pharmaceutical List.

Repeated failure to provide the service in accordance with the LES agreement during normal opening hours, could result in contractual sanctions or termination of this LES agreement.

1.3 Dispute Resolution

In the event that a Contractor disputes the decision by NHS England Midlands to terminate the agreement on the grounds that the terms of the agreement have not been met and/or remedied within an appropriate time-frame, the Contractor shall make this known in writing without delay.

Upon receipt, local dispute resolution procedures will be followed in accordance with *The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013*.

1.4 Governing Law and Jurisdiction

This Agreement will be considered as a contract made in England and will be subject to the laws of England. Subject to the provisions of Section 1.3 (Dispute Resolution), the parties agree that the courts of England have exclusive jurisdiction to hear and settle any action, suit, proceedings or dispute in connection with this Contract (whether contractual or non-contractual in nature).

1.5 Signatures of parties to the agreement

IF YOU INTEND TO SIGN UP TO BOTH ELEMENTS OF THE TIER 1 SERVICE, PLEASE SIGN BOTH PARTS BELOW.

Pharmacy Name	
Pharmacy Branch ODS Code	

Simple UTI in Females

Signed for and on behalf of the Pharmacy Contractor	
Signature	
Name	
Job Title	
Date	

Acute Bacterial Conjunctivitis

Signed for and on behalf of the Pharmacy Contractor	
Signature	
Name	
Job Title	
Date	

Signed for and on behalf of the Commissioner	
Signature	
Name	**Caroline Goulding**
Job Title	**Interim Deputy Director Primary Care and Public Health Commissioning (East Midlands)**
Date	**31/03/2023**

Once signed please submit to: england.eastmidspharmacy@nhs.net

2.0 Service description

The Community Pharmacy Extended Care Service, Tier 1, aims to provide eligible patients who are registered with a General Practitioner (GP) contracted to NHS England Midlands with access to support for the treatment of the following:

- **Treatment of Simple UTI in Females (from 16 years up to 65 years of age)**
- **Treatment of Acute Bacterial Conjunctivitis (for children aged 3 months to 2 years)**

The service will be provided through Community Pharmacies contracted to NHS England Midlands who have signed this local enhanced service agreement to provide this service.

2.1 Aims of the scheme

The overall aim of the scheme is to ensure that patients can access self-care advice for the treatment of a range of conditions, and, where appropriate, can be supplied with antibiotics or other prescription only medicines to treat their condition. This provides an alternative location from which patients can seek advice and treatment, rather than seeking treatment via a prescription from their General Practitioner (GP) or Out of Hours (OHH) provider, walk in centre or accident and emergency.

- Educate patients to seek advice and treatment from the most appropriate healthcare setting
- Improve patient's access to advice and appropriate treatment for these ailments via Community Pharmacy
- Reduce GP workload for these ailments allowing greater focus on more complex and urgent medical conditions
- Educate patients with aim of reducing requests for inappropriate supplies of antibiotics
- Promote the role of the pharmacist and self-care
- Improve working relationships between doctors and pharmacists

The service is offered as a quicker alternative for patients to access healthcare. Patient may choose to refuse this service and continue to access treatments in the same way as they have done previously.

2.2 Patient eligibility

This scheme is available to patients who are registered with a GP practice contracted to NHS England Midlands. Patients can access the scheme at a pharmacy participating in the service.

In addition, the scheme is also available to patients who are temporary residents in the NHS England Midlands who are registered with a GP practice contracted to NHS England Midlands. This is to ensure, regardless of where the patient permanently resides, that they access the right care in the most appropriate setting whilst temporarily in the Midlands region.

The pharmacy will need to confirm on their payment system that these patients have been seen as a temporary resident.

Important note, this service is not intended to be delivered to patients who live outside the area and are only visiting for the day or reside just over the Midlands borders. Provision of services to out of area patients as temporary residents should be by exception.

Patients will be asked by the pharmacy to confirm their registration with the GP Practice before any supply is made.

Pharmacists are encouraged to use Summary Care Records (SCRs) to check the patient's GP practice if there is uncertainty or where they need to check the practice. Only where there is doubt, and with the consent of the patient, the pharmacist may check the registration with the GP practice (see point 2.6.1 below "checking GP Registration).

It is expected that the number of telephone calls to the GP practice to confirm patient registration will be minimal.

Patients not registered with a GP practice as described above, should be advised appropriately and if antibiotic treatment or other Prescription Only Medicine (POM) is thought to be required, they should be signposted to an appropriate provider (this maybe their own GP, or if a temporary resident in the area advice given on how to access NHS services locally).

2.3 Prescription Exemptions

Patients accessing the scheme who are entitled to free prescriptions will receive medication free of charge. All current NHS exemptions (including those with valid pre-payment certificates) are applicable, and the patient must be asked to provide evidence of their exemption. This declaration should be completed by the patient (Appendix 2) and the information recorded on PharmOutcomes.

Patients who are not exempt from prescription charges will pay a prescription charge for each item supplied under the protocols or PGDs in this service.

2.4 Scheme Requirements

The service can only be provided from community pharmacies contracted to NHS England Midlands region that have been commissioned to deliver the service and that have appropriately trained staff (available at all times) to provide the service.

The Pharmacy must be compliant with and be able to demonstrate compliance with all Essential Services within the Community Pharmacy Contractual Framework (CPCF).

Pharmacies commissioned to provide this service must ensure that all pharmacists employed to work within the pharmacy, have the appropriate training to provide the service during all hours that the pharmacy is open. This includes all locums.

Only in exceptional circumstances should a patient be signposted to another provider if the pharmacy has been unable to provide the service to the patient, and the local practice(s) should also be notified.

The Pharmacy must have a Standard Operating Procedure (SOP) or follow its company SOP to cover the service which must be available to staff at all times.

Patients can access the scheme at any participating pharmacy.

Only in exceptional circumstances should a patient be signposted to another provider if the pharmacy has been unable to provide the service to the patient, and the local practice(s) should also be notified if this is likely to be an ongoing issue.

Pharmacies commissioned to provide this service are requested to register with FuturesNHS where all documentation pertaining to the service will be maintained. Pharmacies will be provided a link once sign up is complete.

A list of pharmacies providing the service is available on the Futures NHS Platform website and shared with all GP Practices across the Midlands region.

2.5 Community Pharmacist training requirements

2.5.1 Urinary Tract Infections (UTI) training requirements

The pharmacist will need to log in to the Centre for Pharmacy Postgraduate Education (CPPE) website and access the Declaration of Competence (DoC) section to download the DoC Self-Assessment Framework for Minor Ailments. (The UTI service is a Level 2 Minor Ailments Service involving supply of POM medication under a PGD).

The DoC framework document allows the pharmacist to assess their readiness against the mandatory core competencies (consultation

skills and safeguarding) as well as suggesting other training they may find useful regarding minor ailments and PGDs.

The pharmacist then needs to download their personalised Minor Ailments DoC (interactive PDF document).

Section 1 of the DoC will automatically contain details of all CPPE training and assessments they have undertaken, and which are relevant to this service.

In section 2 the pharmacist will need to add details of the mandatory training they have completed. The requirements are;

- That they have worked through the NICE Clinical Knowledge Summaries (CKS) on simple UTI.
- They must have satisfactorily completed the Health Education England (HEE) e-learning for healthcare Antimicrobial Stewardship for Community Pharmacy e-learning and e-assessment and are registered as an antibiotic guardian.
- They must ensure that they have the correct clinical knowledge to provide the service and are familiar with NICE guidance on treating simple UTIs.
- The requirements of the LES agreement are understood and the PGD associated with the service is signed.

The pharmacist should then print their DoC and add the heading "NHSE Community Pharmacy Extended Care Service Tier1". It must then be signed and dated to complete the process. The pharmacist must confirm on the CPPE website that they have completed and signed the DoC.

The accuracy of the DoC is the pharmacist's professional responsibility.

All pharmacists working at participating pharmacies and providing the scheme should ensure that they continue, through continuing education and CPD, to keep up to date with guidance issued around of the treatment of simple UTIs.

In order to record the consultations on PharmOutcomes the pharmacist must complete a pharmacist enrolment form within the UTI module. They must give the CPPE system permission to allow PharmOutcomes to access their CPPE record in order to confirm completion of the DoC for this service. If this was not done while on the CPPE website a link within the PharmOutcomes pharmacist enrolment module will take the pharmacist to the relevant part of the CPPE website.

It is expected that the main pharmacist and one relief pharmacist have undertaken the relevant training as described and have access to a

copy of the service specification, prior to working in a pharmacy commissioned to deliver this service.

In order to record the consultations on PharmOutcomes the pharmacist must complete a pharmacist enrolment form within the Community Pharmacy Extended Care Service module. They must give the CPPE system permission to allow PharmOutcomes to access their CPPE record in order to confirm completion of the DoC for this service. If this was not done this while on the CPPE website a link within the PharmOutcomes pharmacist enrolment module will take the pharmacist to the relevant part of the CPPE website

2.5.2 Acute Bacterial Conjunctivitis training requirements

The pharmacist will need to log in to the CPPE website and access the DoC section to download the DoC Self-Assessment Framework for Minor Ailments. (The acute bacterial conjunctivitis service is a Level 2 Minor Ailments Service involving supply of POM medication under a PGD).

The DoC framework document allows the pharmacist to assess their readiness against the mandatory core competencies (consultation skills and safeguarding) as well as suggesting other training they may find useful in regard to minor ailments and PGDs.

The pharmacist then needs to download their personalised Minor Ailments DoC (interactive PDF document).

Section 1 of the DoC will automatically contain details of all CPPE training and assessments they have undertaken, and which are relevant to this service.

In section 2 the pharmacist will need to add details of the mandatory training they have completed. The requirements are;

- That they have worked through the CKS summaries on acute bacterial conjunctivitis.
- They must have satisfactorily completed the Health Education England (HEE) e-learning for healthcare Antimicrobial Stewardship for Community Pharmacy e-learning and e-assessment and are registered as an antibiotic guardian.
- They must ensure that they have the correct clinical knowledge to provide the service and are familiar with NICE guidance on treating acute bacterial conjunctivitis.
- The requirements of the LES agreement are understood and the PGDs associated with the service is signed.

The pharmacist should then print their DoC and add the heading “NHSE Community Pharmacy Extended Care Service Tier 1”. It must then be signed and dated to complete the process. The pharmacist

must confirm on the CPPE website that they have completed and signed the DoC.

The accuracy of the DoC is the pharmacist's professional responsibility.

All pharmacists working at participating pharmacies and providing the scheme should ensure that they continue, through continuing education and CPD, to keep up to date with guidance issued around of the treatment of acute bacterial conjunctivitis.

In order to record the consultations on PharmOutcomes the pharmacist must complete a pharmacist enrolment form within the acute bacterial conjunctivitis module. They must give the CPPE system permission to allow PharmOutcomes to access their CPPE record in order to confirm completion of the DoC for this service. If this was not done while on the CPPE website a link within the PharmOutcomes pharmacist enrolment module will take the pharmacist to the relevant part of the CPPE website.

2.6 Duties of Community Pharmacies

2.6.1 Checking GP registration

Before proceeding to supply treatment under the scheme, the patient MUST be asked to confirm that they are registered with a GP practice within NHS England Midlands region or, if they are being treated as a temporary resident in the area, that they are registered with a GP practice in England.

This may be done by:

- checking the patient's PMR, if the patient is already collecting prescriptions from that pharmacy;
- asking the patient to show the repeat prescription slip;
- knowing the patient to be registered with the GP practice;
- medical card
- checking the patient's SCR

Confirmation of the patient's registration at an eligible GP practice is only required if the above documentation is not available or if it is felt that a patient may be attempting to fraudulently use the scheme. Staff may telephone the patient's GP practice for confirmation of registration with the consent of the patient.

The pharmacy should not expect the GP practice to offer any other patient information as they should already be in receipt of this from the patient.

2.6.2 Consent, Consultation and Follow-Up

2.6.2.1 Consent

The pharmacist must complete one consultation and Follow-Up record for every patient.

The consultation and follow-up should be recorded on PharmOutcomes, preferably live during the consultation or, if no live connection available the paper Proforma (Appendix 3) can be used.

It should be noted that due to the large number of PGDs involved in this service the Proforma has been designed to be used in conjunction with the relevant PGD to check the full list of inclusion and exclusion criteria (any other format would make the Proforma too long and impractical to use).

The service should be delivered with a live connection to PharmOutcomes.

If not recorded live, the details of the consultation should be entered onto PharmOutcomes as soon as possible after the consultation has taken place and in all cases before the end of the next working day.

Patient consent should be captured electronically on Pharmoutcomes at the time of the consultation. A paper copy of the form can be used in exceptional circumstances, for example where the computer system is not available.

The consent process also clarifies that they are consenting not only to the service but also that the pharmacist will contact them in 7 days for a short follow-up conversation. In the case of deferred treatment, the follow up will be 7 days after actual supply. The patient's preferred contact details should be recorded on the Patient Consent form (copy of which is at Appendix 1).

The PharmOutcomes system will send a secure email to the patients' GP to inform them if there has been a supply made under a PGD so that the information can be added to the patients' medical record. Where a secure email address is not available for a practice the PharmOutcomes system will inform the pharmacy that they have to inform the practice using a different, secure method.

2.6.2.2 Children under 16 years of age

Patients under the age of 16 must be accompanied by a parent/guardian when they visit a participating pharmacy. Parent/ guardian MUST always bring the child with them to the pharmacy in order for a full assessment to be carried out by pharmacist. The parent/guardian can consent to the patient receiving the service.

2.6.3 Consultation

All consultations must be carried out by an appropriately trained pharmacist.

The patient should attend the pharmacy in person in order receive a consultation and if appropriate a supply of medication.

The pharmacist should be familiar with the PGDs and protocol involved in this service (listed in Appendix 4).

The pharmacist must carry out a professional consultation with reference to the appropriate PGDs which should involve:

- Patient assessment
- Identify any concurrent medication or medical conditions, which may affect the treatment of the patient. This should involve access to the patient's SCR, where appropriate and with patient consent.
- Provision of advice. As part of the advice they must explain that many conditions resolve without antibiotic treatment, this will help reinforce the message on the need to reduce antibiotic usage.
- If appropriate, the patient may be supplied with an OTC product. In line with NHS Guidance on OTC products, patients would be expected to purchase the OTC product. Patients exempt from prescription charges should NOT be referred to a GP to request a prescription as this would not be in line with NHS or CCG guidance.
- Supply of appropriate antibiotic medication, only if clinically appropriate, from the agreed formulary appropriate to the patient's condition
- The pharmacist may advise deferred antibiotic treatment; in this case they would complete the consultation and the data would be recorded on PharmOutcomes
- Inform the patient's GP of the supply within two working days from when the supply takes place. This will be done automatically via PharmOutcomes where the system has a valid NHS mail address for the practice.
- Where a pharmacy sees a message on PharmOutcomes to say that the notification cannot be sent electronically they must print out the notification and the information must be sent to the practice within two working days of the supply taking place (with due regard to information governance).
- If the GP practice is not able to receive PharmOutcomes notifications the pharmacist is advised to contact the practice to confirm the NHS mail address they wish to use and then inform their local NHS England Midlands region Pharmacy contracting team who will facilitate the update to PharmOutcomes.

- The patient should be asked to pay the prescription levy charge or declare the exemption applicable and sign the back of the patient exemption form (Appendix 2) in the same way as they sign a prescription.

- The person signing the form should have the declaration explained to them before they sign, especially if it is the first time they have accessed the service, and it should be highlighted that the information will be shared with their GP and NHS England Midlands region.

- Where the patient is under 16 or is not competent to sign the form, then the patient's representative should sign the form, in the same way as they do for a prescription.

- The consultation and supply should be recorded on the pharmacy PMR system.
- The pharmacist should record if the patient was referred into the service by another health care system such as NHS111 or the patient's GP practice

2.6.4 Follow-Up

2.6.4.1 Deferred Antibiotic treatment

The pharmacist may advise deferred antibiotic treatment; in this case they would complete the consultation and the data would be recorded on PharmOutcomes.

If the patient agrees to defer treatment the pharmacist should determine that they could be treated under the service PGDs if they do return. If they are excluded from a PGD supply, they should be advised to see their GP if they need treatment after waiting the agreed timescale agreed in the deferment conversation.

If the patient could be treated via the service PGDs and returns after waiting the appropriate amount of time the pharmacist can then dispense the medication without having to repeat the consultation and the supply would be recorded on PharmOutcomes in the Tier 1 Deferred Treatment Module which then forms part of the PharmOutcomes patient record.

In the consultation module, where a patient agrees to defer treatment, that option should be selected and the PharmOutcomes module will then allow the original consultation to be saved and any deferred supply must be added to the Tier 3 Deferred Treatment Module to record the supply. The pharmacy may refer to the original consultation to re-check inclusion and exclusion criteria, but the actual supply must be entered in the Tier 3 Deferred Treatment Module. This ensures that the number of patients returning for deferred

treatment can be monitored and ensures that the pharmacy is paid for the drug supplied after the patient agreed to defer supply.

2.6.4.2 7 day Follow Up

The patient must be made aware that in order to access the service they must agree to having a follow up conversation with the pharmacist 7 days after the initial consultation or deferred supply.

The follow up will only consist of a small number of questions and will usually take place over the telephone (although if the patient prefers it could be face- to face in the pharmacy). In the case of deferred treatment, the follow up will be 7 days after actual supply.

The follow up should be recorded onto PharmOutcomes as soon as possible after the conversation has taken place and in all cases before the end of the next working day.

It is completion of a 7-day follow up which generates the invoice for that patient. It is understood that some patients may not be contactable, but because the pharmacist should have explained to the patient that this is a requirement of the service and also have confirmed the appropriate contact telephone number and best time to call, this should be the exception. Pharmacists are required to try to contact the patient 3 times, at least one of these should be an evening and one of them a weekend day. If after 3 attempts they have been unable to contact the patient, they are able to record this as “Lost to follow up” within the PharmOutcomes 7-day follow-up module and this will then generate payment of the consultation fee.

2.7 Urgent referral to GP or other healthcare professional

In a situation where a patient presents with a symptom(s) that requires referral to their GP or other healthcare professional (urgent or otherwise), the pharmacist must complete the ‘Referral from Community Pharmacy’ (Appendix 5) with the patient’s details, reasons for the referral including assessment of urgency, and details of the pharmacist referring. An electronic referral message should be sent to the patients GP practice via the agreed referral pathway or alternatively the ‘Referral from Community Pharmacy’ template can be completed manually and given to the patient.

This information will also need to be recorded within PharmOutcomes.

The patient must confirm that they understand the urgency with which they need to seek healthcare support.

The patient must be made aware that the referral does not guarantee an instant GP appointment.

If the patient has been referred to the pharmacy service via a Care Navigation or CPCS Pathway and is symptomatic, but is excluded under the PGD, the pharmacist must make all reasonable attempts to contact the patients GP practice to arrange for an appointment.

If the patients GP practice is closed and/or the symptoms are sufficiently severe to warrant a referral to a doctor, the patient must be advised to contact 111 or attend A&E immediately if required.

A referral form should still be completed in these cases, unless symptoms appear life-threatening, in which case the pharmacist must dial 999 and provide the attending Paramedics with any relevant information.

2.8 Record Keeping and Labelling Requirements

A record of every consultation with or without PGD supply, any deferred treatment supplies and all follow-ups must be made on PharmOutcomes.

Only consultations and any supplies recorded on PharmOutcomes will comply with record keeping requirements and follow-ups recorded on PharmOutcomes will be used to measure activity and will result in payments being made for the service).

The log-on details for PharmOutcomes is pharmacy specific, if pharmacists move between pharmacies, they cannot use the same PharmOutcomes log-on.

Within the PharmOutcomes Community Pharmacy Extended Care module there is a pharmacist enrolment module which must be completed by the supplying pharmacist the first time that they access this module.

Once completed, this pharmacist enrolment will be recognised at all pharmacies offering the Community Pharmacy Extended Care service in the Midlands Region.

If, after completing the patient examination, the pharmacist considers that no treatment is required they should give the patient appropriate advice and record on PharmOutcomes that they have done so.

If the pharmacist considers that the most appropriate treatment for the patient is advice and supply of an OTC medication, they should record the consultation on PharmOutcomes and select the correct consultation outcome from the drop-down list in the module.

If the pharmacist considers that the most appropriate treatment for the patient is advice and supply of an antibiotic, they should record the

consultation on PharmOutcomes and select the correct condition from the drop-down list in the module. This will then provide questions relating to the PGDs for that condition and this part of the module must be completed.

If the pharmacist considers that the most appropriate treatment for the patient is advice with a deferred antibiotic supply, they should record the consultation on PharmOutcomes and select the correct condition from the drop-down list in the module. This will then trigger questions relating to the PGDs for that condition and this part of the module must be filled in at this time.

The final part of the PGD questions, which relate to the actual supply of the antibiotic, would not be completed until the patient returns after the appropriate waiting period to collect their antibiotic.

The PharmOutcomes module will allow the consultation to be saved and it should be noted that the patient has agreed to defer treatment. Details of the deferred supply may be added later using the Tier 1 Deferred Treatment Module. It is important that the correct process is followed if/when the patient returns for the antibiotic in order that the deferred supply is recorded, and the correct invoice produced. If a pharmacy goes back into the original consultation record and adds the later supply of deferred meds, the system may not pick this up for invoicing purposes.

For some patients it may be appropriate to give them advice and recommend an OTC product as well as to supply an antibiotic (either on first consultation or a deferred supply).

The consultation and antibiotic supply must be completed in the Extended Care Module and the OTC sale would take place in the normal manner.

A record of any medication supplied as part of the Extended Care Service should be documented in the Patients Medication Record (PMR) on the pharmacy IT system.

All supplies must be labelled in line with the labelling requirements for a *dispensed medicine* as stated within The Human Medicine Regulations 2012.

In addition to the above, the label must also state the words “Supplied under a PGD” to help with audit purposes.

All records electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements. Recommendations for the retention of pharmacy records for minor clinical interventions are 2 years. This includes the patient consent record.

3.0 Incident reporting & complaints

All incidents should be recorded as part of the pharmacy's clinical governance procedures.

Pharmacies will also be expected to follow their normal or company process for complaints in accordance with NHS policy, where issues arise so that improvements can be made following significant events or errors.

Pharmacies should also note that by signing up to participate in this scheme they are entering into an agreement to offer a service with NHS England Midlands. Pharmacies will therefore be subject to the right of inspection by NHS England Midlands and/or Healthwatch England representatives in line with NHS guidance.

4.0 Duties of NHS England Midlands region

NHS England Midlands will be responsible for production, approval and updating the LES agreement and PGDs for this service.

NHS England will be responsible for ensuring timely payments are made to Community Pharmacies for any consultations and supplies under this service and will be responsible for dealing with payment-based queries for this aspect of the service.

NHS England will undertake regular audits of the scheme, including review of consultation data and budget analysis. Post payment verification checks may also be made.

5.0 Payments

5.1 Submission of claims

Pharmacies must enter consultations and any supplies via PGD onto the relevant PharmOutcomes modules.

PharmOutcomes will automatically generate claims for the relevant service payments. Invoices are generated as follows:

Medication cost (drug tariff price + VAT at the prevailing rate) when supply saved during first consultation or if supplied as a deferred treatment when the deferred treatment record is completed.

Consultation fee is invoiced when the 7-day follow up is recorded.

Payments will be made monthly, as a Local Payment via the NHS Business Services Authority and will therefore appear on the monthly FP34c statement. All payments will be made at the end of the month following under Local Scheme 6 for PGD services.

5.2 Service payments

The pharmacy will be paid according to the following schedule.

Activity payments will be made when patients have been seen and the consultation plus the 7-day follow-up entered onto the system – regardless of whether any medication was supplied.

Activity will be invoiced by the system when the 7-day follow-up module has been completed for a patient seen under the service.

Fee per consultation £20.00 (where medication is supplied)

Medication costs at Drug Tariff prices plus VAT at the prevailing rate.

Fee for full consultation where either no antibiotic is supplied, or rapid referral occurs £17.00

Clinical waste – one off payment of £40 per contracted pharmacy per annum to be claimed via PharmOutcomes.

Invoices for activity will be generated by PharmOutcomes and supplied to NHSE Midlands who will add any payments due to the local payment scheme. Any payments due will appear on the FP34 statement as Local Payment 6 within the 'Details of local amounts authorised' section.

Medication costs are reimbursed at Drug Tariff prices plus VAT at the prevailing rate and will be paid by NHS England Midlands and they will be seen on the monthly statement as part of local scheme payment. Please note, any patient levy's due will be deducted from the invoice total.

5.3 Consumables and clinical waste

Consumables such as sample bottles and/or dipsticks that may be used within this service are to be provided by the contractor, and the costs of these consumables are included within the overall consultation fee.

Clinical waste consumables and collections are the responsibility of the provider to arrange. Remuneration for this is outlined in 5.2 Service Payments.

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6.0 Contractual period

This agreement is for the period 31 March 2023 until 31st March 2024.

The service will be automatically renewed at the end of the contractual period, unless terminated in accordance with Clause 1.2 or the service is decommissioned.

7.0 Confidentiality

Both parties shall adhere to the requirements of the Data Protection Act 2018 and the Freedom of Information Act 2000.

8.0 Indemnity

The pharmacy shall maintain adequate insurance for public liability and professional indemnity against any claims which may arise out of the terms and conditions of this agreement.

Any litigation resulting from an accident or negligence on behalf of the pharmacy is the responsibility of the pharmacy who will meet the costs and any claims for compensation, at no cost to NHS England Midlands region.

9.0 Service Evaluation

Towards the end of the financial year the service will be evaluated to consider its usefulness with a view to extend the service.

Appendix 1.

PATIENT CONSENT FORM

Pharmacy Stamp

Consent to participate in the: Community Pharmacy Extended Care Service for UTI/Acute Bacterial Conjunctivitis (delete as appropriate) .

I agree to take part in a short follow up conversation with the pharmacist which can be in person at the pharmacy or by telephone – this will be approximately 7 days after this consultation.

I agree that the pharmacist may access my SCR to help in the delivery of this service

Patient name and address	Bag label
Patient's telephone No for follow up	

I agree that the information obtained during the service can be shared with:

- my doctor (GP) to help them provide care to me
- NHS England (the national NHS body that manages pharmacy and other health services) to allow them to make sure the service is being provided properly by the pharmacy
- NHS England, the NHS Business Services Authority (NHSBSA) and the Secretary of State for Health to make sure the pharmacy is being correctly paid by the NHS for the service they give me

Signature	
Date	

Appendix 2

Declaration of exemption

To be completed by the patient if they are exempt from prescription fees

…… **Date Of Birth**……

Patient does not pay because:

A	☐	**is 60 years of age or over or is under 16 years of age**
B	☐	**is 16, 17 or 18 and in full-time education**
D	☐	**has a valid maternity exemption certificate**
E	☐	**has a valid medical exemption certificate**
F	☐	**has a valid prescription prepayment certificate**
G	☐	**has a prescription exemption certificate issued by Ministry of Defence**
L	☐	**has a HC2 (full help) certificate**
H	☐	**entitled to Income Support or Income-related Employment and Support Allowance**
K	☐	**entitled to income based jobseeker's allowance**
M	☐	**has a Tax Credit Exemption Certificate**
S	☐	**has a Pension Credit Guarantee (including partners)**
U	☐	**entitled to Universal Credit and meets the criteria**

* Name Date of birth NI number

I am the ☐ patient ☐ patient's representative

To be completed by the Patient/patients representative

I received ……(insert number) medicine(s) from this pharmacy

Signed: …… Date: ……

Was evidence of exemption seen? ☐ Yes ☐ No

Appendix 3

(DRAFT) Proforma for use in case of IT Failure

Nitrofurantoin PGD to treat uncomplicated UTI (females from 16yrs up to 65yrs)

Date		Patient Name and DOB	
GP Practice		Address including Postcode	

Please note: The service is only available to females who are registered with a GP in the NHSE&I Midlands Region.

Was this patient referred to you for this service?

No		*Yes, referred by NHS111*		*Yes, referred by their GP practice*		*Other please note:*	

Inclusion Criteria

Women aged 16yrs and over with 3 of the listed symptoms:

Dysuria		Urinary frequency / urgency		Lower abdominal pain	
Blood in urine (haematuria)		Polyuria			

Patients may also have suprapubic pain, cloudy or foul smelling urine.
Vaginal discharge reduces the likelihood of the woman having a bacterial UTI.

Use of Dipsticks – this is not a diagnostic indicator alone. Use dipstick only if necessary.

Women aged 16yrs and over with 2 or less of the inclusion criteria symptoms:

If a female presents with one or two inclusion criteria symptoms they can only be treated if there is a strong possibility of UTI when tested with a dipstick. - **A nitrite and/or leucocytes dipstick must be positive.**

Dipstick Results (where used)

Positive nitrite (+/- leucocyte, +/- protein) = Probable UTI		Negative nitrite (+ leucocyte) = Possible UTI	
Negative nitrite and leucocyte (+ protein) = Unlikely UTI		All dipstick tests negative = UTI very unlikely	

General Advice on UTIs to be given to all females taking part in the service.

To support the worldwide drive to reduce antibiotic usage please inform clients that about half of women will be free from symptoms within 3 days even with no treatment *(If client decides to delay treatment, you will still be paid for completing the consultation)*			
Drink plenty of fluid – 3L per day.			
Avoid caffeine containing & alcoholic drinks		Try to empty bladder when urinating	
May be precipitated by fragranced products		Importance of personal hygiene	
Paracetamol / ibuprofen for pain/discomfort		Cranberry juice & alkalizing prods – no evidence	
To prevent the recurrence of UTI the following measures can help - Maintain an adequate fluid intake. Ensure the bladder is fully emptied. Empty bladder after sexual intercourse			

Exclusion Criteria (service for females age 16yrs + only)

Male		Elderly patients with confusion suggestive of UTI	
Patients aged 65 years and over		Known hypersensitivity to Nitrofurantoin	
Patients with back or loin pain and pyrexia, consider Pyelonephritis- refer to immediately (other possible symptoms include chills, nausea, vomiting, headache, rigors)		Concomitant use of medication that has a clinically significant interaction with Nitrofurantoin. For a comprehensive list of interactions, please refer to SPC or BNF	
Recurrent UTI treated with antibiotics within previous 4 weeks		More than two episodes of UTI treated under this PGD within previous 12 months	
Catheterised patients		Haematuria only	
Blood dyscrasias (G6PD deficiency specifically)		Pregnancy or Breastfeeding	
Renal Impairment (eGFR <45ml/min)		Pulmonary disease	
Peripheral neuropathy		History of kidney stones / renal colic	
Refused consent		Acute porphyria	

Referral Information

If patient is excluded refer to GP for advice and treatment and also advise on support for self-care if appropriate.
A copy of this form may be used as a referral form if the pharmacist wishes. If the patient has been referred to the pharmacy service via a Care Navigation Pathway and is symptomatic, but is excluded under the PGD, the pharmacist must make all reasonable attempts to contact the patients GP practice to arrange for an appointment.

Medication Supply under PGD

In order for medication to be supplied the patient must give consent for information to be shared with their GP. The PharmOutcomes system will automatically inform the patients GP practice. If the practice cannot receive notifications the PharmOutcomes system will advise you to send info by another suitable method (consider GDPR)

Nitrofurantoin MR 100mg capsules twice daily for 3 days OR Nitrofurantoin 50mg tablets four times a day for 3 days. Should be taken with food. Label must state "Supplied under PGD"

Preparation supplied:	100mg S/R capsules (x 6) – FIRST LINE	
	50mg tablets (x12) – SECOND LINE	

Nitrofurantoin suspension may NOT be supplied under this service

The following advice MUST be given on every supply. (More comprehensive list of cautions + side effects in SPC)

Patient information leaflet given and discussed as necessary	
Nitrofurantoin may cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected until such symptoms stop.	
Discolouration of the urine to yellow or brown is common.	
Take all preparations with food to minimise GI effects and complete the course.	
Take the MR capsules regularly at 12 hourly intervals. Take the tablets regularly at approx. 6 hourly intervals	
Possible side effects GI disturbances (nausea, vomiting) Pruritis. Skin rashes. Abdominal pain + diarrhoea	
Severe adverse reactions are rare, but there have been reports of the following effects; Acute pulmonary reactions; Neurological effects including peripheral neuropathy; Severe allergic skin reactions including erythema multiforme; Haematological effects which are generally reversible on cessation of treatment.	
Report adverse reactions to pharmacy	
Advise clients to see GP if condition not improved after 3 days or if UTI becomes a recurring problem	
To prevent the recurrence of UTI the following measures can help - Maintain an adequate fluid intake. Ensure the bladder is fully emptied. Empty bladder after sexual intercourse	

Final Checklist. Complete all sections.

Consultation Outcome:

Patient excluded from PGD supply. Referred to GP		Consultation completed and patient has decided to defer antibiotic treatment		Supply made under PGD	

Where a supply was made, the following must also be completed:

PMR entry completed		Nitrofurantoin labelled "Supplied under PGD"		Patient consent collected?	
Levy collected?		Exemption form signed?			

Please note: Exemption forms should be retained in the pharmacy in case requested by NHS England.

For consultations carried out without a live PharmOutcomes connection the patient must sign the declaration. Otherwise consent is recorded electronically.

7 Day follow up questions:

How are you feeling today compared to 7 days ago?	**Much better**	**Better**	**Same**	**Worse**	**Much worse**
Did you follow the advice given by the pharmacist					
Have you taken the medication advised by the pharmacist?					
Have you taken the antibiotics provided by the pharmacist?					
If you needed to come back to collect deferred antibiotics, how long did you wait?					
Have you contacted your GP or any other Health Care Professional since seeing me 7 days ago? If yes, who did you contact?					
If the answer to the above question is yes, please briefly explain why					

Please ensure that the record is entered into the PharmOutcomes service module as soon as possible and within one working day of the consultation and one working day of follow up conversation www.pharmoutcomes.org

Client's Signature:	**Date:**

Pharmacists Name:	**GPhC number:**	**Signature:**	**Date:**

Appendix 4

URINE DIPSTICK ANALYSIS WITH MULTISTIX GP

(*refer to manufacturer's instructions if using an alternative dipstick)

You are reminded that dipsticks should only be used as an aid to diagnosis in symptomatic, non-catheterised females. Only dipstick if necessary. See latest NICE guidelines.

1. Collect fresh urine specimen in a clean, dry container. Mix well immediately before testing. All samples should be midstream:

- The patient washes hands and opens the collection cup without touching the inside of the cup
- Clean the urethral area with an antiseptic
- Patient should be advised not to touch the cup to the urethra or any skin when collecting the sample
- If the container/sample becomes contaminated with faeces, pubic hair or other substances, then a new collection cup/sample needs to be used.
- The patient must then urinate for 5 seconds, move the collection cup into the urine stream, fill the collection cup, remove the cup and continue urinating, making sure that that no skin aside from the urethra touches the urine.
- Place the lid on the collection cup.

2. Remove one strip from the bottle of strips and replace the cap. Completely immerse reagent areas of the strip in the urine and remove immediately to avoid dissolving out of reagents.

3. While removing, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas and/or contaminating the hands with urine.

4. Compare reagent areas to corresponding colour chart on the bottle label at the time specified. Hold strip close to colour blocks and match carefully. Avoid laying the strip directly on the colour chart, as this will result in the urine soiling the chart.

PROPER READ TIME IS CRITICAL FOR OPTIMAL RESULTS.

The following are specific readings and timings required for diagnosis of UTI.

- Read protein, blood, and nitrite at 60 seconds;
- Read leukocytes at 2 minutes.

Colour changes that occur after 2 minutes are of no diagnostic value.

Reporting Results

Results are reported in the amounts expressed on the charts on the bottle label.

Expected Values

<u>Nitrite</u>

This test relies on the breakdown of urinary nitrates to nitrites, which are not found in normal urine. Many Gram-negative and some Gram-positive bacteria are capable of producing this reaction and a positive test suggests their presence in significant numbers. A negative test does not rule out a UTI.

Blood

The significance of the trace reaction may vary among patients and clinical judgement is required for assessment in an individual case. Development of green spots or green colour on the reagent area within 60 seconds indicates the need for further investigation.

False positive readings are most often due to contamination with menstrual blood; they are also seen with dehydration which concentrates the number of RBCs produced, and exercise.

False negative readings: captopril, vitamin C, proteinuria, elevated SG, pH less than 5.1 and bacteriuria.

Protein

Normally no protein is detectable in urine, although a minute amount is excreted by the normal kidney. A colour matching any block greater than trace indicates significant proteinuria. For urine with a high specific gravity, the test area may most closely match the trace colour block even though only normal concentrations of protein are present. Clinical judgement is needed to evaluate the significance of trace results.

Leukocytes

Normal urine specimens generally yield negative results. Positive results (small or greater) are clinically significant. Trace results observed individually may be of questionable clinical significance. Trace results observed repeatedly may be clinically significant. Positive and repeated trace results indicate the need for further testing of the patient and/or urine specimen.

Interpreting urine dipstick results:	
Positive nitrite (+/- leucocyte +/- protein)	= **probable UTI**
Negative nitrite and positive leucocyte	= **possible UTI**
Negative nitrite and leucocyte, +ve blood or protein	= **consider other diagnosis**
All dipstick tests negative	= **UTI very unlikely**

Appendix 5

(DRAFT) Proforma for use in case of IT Failure

Chloramphenicol PGD for acute bacterial conjunctivitis (age 3months to 2 years)

Date		Patient Name and DOB	
GP Practice		Address including Postcode	

Please note: The service is only available to patients who are registered with a GP in the NHSE&I Midlands Region.

Was this patient referred to you for this service?

No		*Yes, referred by NHS111*		*Yes, referred by their GP practice*		*Other please note:*	

Inclusion Criteria

Children aged 3months up to 2 years where there are features indicative of a bacterial infection

- Acute inflammation of conjunctiva, characterised by irritation, itching, a sensation of grittiness in the eye, watering or sticky discharge and/or blurred vision due to discharge that clears with blinking.
- *Acute bacterial conjunctivitis is generally a self-limiting condition that does not routinely require treatment with antibiotics with 65% resolving within 5 days without treatment.*

First Line treatment:

SELF CARE which includes:
Reassurance / advice on self-limiting nature of the condition.
Bathing / Cleaning eyelids with cotton wool soaked in sterile saline or boiled and cooled water to remove crusting

Second Line treatment:

Chloramphenicol is considered second line and should ONLY be used for moderate to severe infections only where the patient considers the symptoms to be distressing or signs are judged to be severe from clinical experience

Exclusion Criteria patient with moderate to severe infection (age 3 months up to 2yrs only)

Children under 3 months of age		Children over 2 years of age	
Mild infections		Users of other prescribed eye drops / ointment	
Dry eye syndrome		Glaucoma	
Atypical symptoms of conjunctivitis		Suspected foreign body in the eye	
Eye injury		Photophobia	
Where vision has been affected		Severe pain within the eye / swelling around the eye / restricted eye movement	
Unusual looking pupils or cloudy cornea		Eye surgery / laser treatment in previous 6 months	
Recent trip abroad		Patient feels generally unwell	
Previous conjunctivitis in recent past		Hypersensitivity to chloramphenicol or any other ingredients in the eye drops	
Headache		Pupils fixed and mid-dilated or distorted from previous attacks	
Family history of blood dyscrasias		Patients who experienced myelosuppression due to previous exposure to chloramphenicol	
Copious discharge that re-accumulates after being wiped away		Patient taking bone marrow suppressant drugs	
Enlarged lymph nodes in front of the ears (associated with Chlamydia / adenoviral type)		Eye inflammation associated with a rash on the scalp or face	
Refused consent		Already had 2 courses under PGD in previous 6 months	

Management of Excluded Patients

Where the infection is considered mild, provide the self-care advice from the table on the next page.
If patient is aged under 3 months refer to a primary care clinician. If patient is aged 2yrs+ where chloramphenicol is appropriate patient / parent should be advised to purchase OTC – do not refer to GP for chloramphenicol script.
If excluded other than by age you may consider referring to a primary care clinician. Record the reason for exclusion and any action taken on PharmOutcomes.

Medication Supply under PGD

In order for medication to be supplied the patient's parent/guardian must give consent for information to be shared with their GP. The PharmOutcomes system will automatically inform the patients GP practice. If the practice cannot receive notifications the PharmOutcomes system will advise you to send info by another suitable method (consider GDPR)

Medication Supply under PGD (cont)

Chloramphenicol Eye Drops: instil 2 hourly to affected eye(s) for 48 hours then reduce to one drop every 4 hours during waking hours. Chloramphenicol eye ointment: apply four times daily for 48 hours then use twice daily.

Treatment to be continued for 48 hours after symptoms have resolved up to a maximum of 7 days.

Label must state "Supplied under PGD"

Preparation supplied:	Chloramphenicol 0.5% Eye Drops – (1 x 10ml)	
	Chloramphenicol 1% Eye Ointment – (1 x 4g)	

The following advice MUST be given on every supply. (More comprehensive list of cautions + side effects in SPC)

Self Care Advice	
Risk of serious complication from untreated infective conjunctivitis is low	
Bathe / clean eyelids with cotton wool soaked in sterile saline or boiled and cooled water to remove crusting	
Wash hands thoroughly and avoid sharing towels/ facecloths as eye infection is highly contagious	
Apply a cool compress to soothe the eye	
Remove contact lenses, if worn, until all symptoms and signs of infection have completely resolved and any treatment has been completed for 24 hours	
Patients should be advised to contact their optometrist to get their contact lens checked.	
Treatment Related Advice	
Patient information leaflet given and discussed as necessary	
Advise on correct administration of eye drops or ointment	
Course of treatment is for 48 hours after symptom resolution up to a maximum of 7 days	
Patients may experience a transient burning or stinging sensation with treatment	
Hypersensitivity reactions possible though rare	
Store eye drops in the refrigerator	
Blurred vision can occur, do not drive or operate machinery unless vision is clear	

Final Checklist. Complete all sections.

Consultation Outcome:

Patient excluded from PGD supply. Mild symptoms, self care appropriate		Patient excluded from PGD supply. Symptoms severe enough to require onward referral to primary care clinician		Consultation completed and patient has decided to defer antibiotic treatment		Supply made under PGD	

Where a supply was made, the following must also be completed:

PMR entry completed		Chloramphenicol labelled "Supplied under PGD"		Patient consent collected?	
Levy collected?		Exemption form signed?			

Please note: Exemption forms should be retained in the pharmacy in case requested by NHS England.

For consultations carried out without a live PharmOutcomes connection the patient must sign the declaration. Otherwise consent is recorded electronically.

7 Day follow up questions:

How are you feeling today compared to 7 days ago?	**Much better**	**Better**	**Same**	**Worse**	**Much worse**
Did you follow the advice given by the pharmacist					
Have you taken the medication advised by the pharmacist?					
Have you taken the antibiotics provided by the pharmacist?					
If you needed to come back to collect deferred antibiotics, how long did you wait?					
Have you contacted your GP or any other Health Care Professional since seeing me 7 days ago? If yes, who did you contact?					
If the answer to the above question is yes, please briefly explain why					

Signature of patient's parent / guardian:	**Date:**

Pharmacists Name:	**GPhC number:**	**Signature:**	**Date:**

Appendix 6

Referral from Community Pharmacy

Patient's name:……

Patient's D.O.B:……..

Patient's address:……..

……

The patient named above has accessed the Community Pharmacy Extended Care Service for UTI/Acute Bacterial Conjunctivitis (DELETE AS APPROPRIATE) and following assessment by the pharmacist on duty a referral has been recommended based on the following information:

Pharmacist's comments:……

……

……

Indication of urgency (please tick):

- **Accident and Emergency** ☐
- **Contact GP practice or other HCP within 24 hours** ☐
- **Contact GP practice or other HCP within …….. days if symptoms do not resolve** ☐

Pharmacist's name (PRINT)……

Pharmacy telephone number……..

Pharmacy address……

……

Date and time……..

Pharmacist signature……

Please ensure that this form is given to your GP or other Healthcare Professional

Appendix 7

List of Conditions and PGDs / Protocols

All PGDs and protocols are available for download on the Futures NHS platform and also from within the PharmOutcomes modules.

UTI

First line treatment –

- Nitrofurantoin MR 100mg capsules twice daily for 3 days with food

Second line treatment -

- Nitrofurantoin 50mg tablets four times a day for 3 days with food.

Duration of treatment is 3 days for all formulations

Acute Bacterial Conjunctivitis

First line treatment –

- Self-care which includes:

  • reassurance/advice on self-limiting nature of the condition

  • bathing/cleaning eyelids with cotton wool soaked in sterile saline or boiled and cooled water to remove crusting – using one cotton wool pad per eye.

Second line treatment -

- Chloramphenicol 1% eye ointment; or
- Chloramphenicol 0.5% eye drops

Continue treatment for 48 hours after symptoms have resolved up to a maximum of 7days.