



Community Pharmacy Extended Care Service (Tier1)

(Midlands Region)

Service 1 – Treatment of Simple UTI in females

Service 2 – Treatment of Acute Bacterial Conjunctivitis

NHS England and NHS Improvement



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General Service Conditions for NHS England & Improvement Midlands

Community Pharmacy Extended Care Service (Tier1) 2020

The following services are commissioned by NHS England & Improvement Midlands in accordance with The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 PART 4, Section 14 (n).

These services can only be provided from those pharmacies that have signed the SLA and returned the signature page to NHS England & Improvement Midlands.

1.0 Introduction

Patient Group Directions (PGDs) provide a legal framework that allows some registered health professionals such as Pharmacists to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber. Supplying and/or administering medicines under PGDs is reserved for those situations where this offers an advantage for patient care, without compromising patient safety.

The Community Pharmacy Extended Care Service includes a suite of PGDs which will allow pharmacists to treat patients presenting with certain conditions that otherwise would have to be seen by prescribers in General Practice.

This Service Level Agreement contains the fixed standard conditions which apply to all the PGD services listed within the separate schedules. Within each schedule there are separate service conditions which relate to the delivery of that particular PGD service.

1.1 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 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.

2.0 Scheme requirements

The service may be provided at an authorised Community Pharmacy contracted to NHS England & Improvement Midlands subject to the following;

- The Pharmacy must be compliant with, and be able to demonstrate compliance with all Essential Services within the Community Pharmacy Contractual Framework (CPCF).
- The Pharmacy must have an approved consultation area which meets the requirements set out in the CPCF for Advanced Services. All face to face consultations must take place in a confidential environment, and any telephone or video consultations must be undertaken such that the conversation cannot be overheard.
- The Pharmacy must have a Standard Operating Procedure (SOP) in place for the service.
- The Pharmacy contractor must participate in all parts of the service as detailed in this specification, along with any subsequent amendments as agreed jointly with NHS England & Improvement Midlands and the corresponding Local Pharmaceutical Committees (LPC's). This agreement will be in writing, signed by the Pharmacy Manager or Authorised Person on behalf of the contractor, and will be considered an Enhanced Service.

2.1 Patient eligibility

This scheme is available to patients who are registered with a GP practice contracted to NHS England & Improvement Midlands. Patients can access this scheme at any participating pharmacy. In order to be eligible for this service, patients must consent to data sharing with their GP practice in the event that medication is supplied or a referral is made. Anonymised data will also be shared with NHS England & Improvement to allow service provision to be monitored for quality and payment.

3.0 Contractual Period

This agreement is for the period 1st October 2020 to 31st March 2022, but may be subject to an earlier review if deemed necessary.

4.0 Termination of the scheme

Any pharmacy that has signed this Service Level Agreement and is participating in the scheme may terminate the agreement by giving written notice of their intention at least 28 days before cessation. No reason needs to be given for termination of the agreement.

NHS England & Improvement Midlands may terminate the scheme by giving written notice to all participating pharmacies and relevant LPCs. A minimum of 28 days written notice will be provided.

If for whatever reason, the pharmacy does not fulfil its obligation to provide all Essential Services under the Pharmacy Contractual Framework, the pharmacy will become ineligible to provide this Enhanced Service and the Service Level Agreement would be terminated with immediate effect.

NHS England & Improvement Midlands has a responsibility to ensure that all participating pharmacies deliver the scheme in accordance with the Service Level Agreement. If it is found that a Contractor fails to meet any of the obligations of this agreement, they will be notified in writing of

the nature of the breach. Where the breach is not remedied within appropriate time-frames or NHS England & Improvement Midlands deems it is not capable of remedy, NHS England & Improvement Midlands will be entitled to terminate this agreement with immediate effect.

5.0 Duties of NHS England & Improvement Midlands

NHS England & Improvement Midlands will be responsible for developing, authorising, and updating the PGDs within the scheme to ensure they are appropriate, legal and that relevant governance arrangements are in place. NHS England & Improvement Midlands will also be responsible for the appropriate advertising, promotion and on-going support for the scheme, including distribution of any support material. These will be made available to all pharmacies participating in the scheme and to other relevant stakeholders who may refer patients into the scheme.

NHS England & Improvement Midlands will be responsible for ensuring timely payments are made to Community Pharmacies which are participating in the scheme, and will be responsible for dealing with operational and payment based queries.

NHS England & Improvement Midlands will, alongside relevant CCG partners and LPCs, undertake monthly audits of the scheme, including review of consultation data and budget analysis. Post payment verification checks may also be made.

6.0 Complaints and incident reporting

Pharmacies will be expected to follow standard operating procedures for complaints that are in accordance with NHS policy.

Any significant incidents or issues that arise during provision of the scheme should be recorded as part of the pharmacy's clinical governance procedures, and notified to the Primary Care Team of NHS England & Improvement Midlands.

7.0 Dispute resolution

In the event that a Contractor disputes the decision by NHS England & Improvement 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 Pharmaceutical Regulations 2013.

8.0 Patient Confidentiality, Data Protection, Freedom of Information and Transparency

The Parties acknowledge their respective obligations arising under the Freedom of Information Act 2000, Data Protection Act 1998, the Human Rights Act 1998, and under the common law duty of confidentiality, and must assist each other as necessary to enable each other to comply with these obligations. The Contractor must complete and publish an annual information governance assessment and must demonstrate satisfactory compliance as defined in the NHS Information Governance Toolkit (or any successor framework). Any changes to legislation that arise out of the

General Data Protection Regulations (GDPR) will become applicable to this contract upon the date of enforcement.

9.0 Indemnity

The Contractor 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 Contractor is the responsibility of the Contractor who will meet the costs and any claims for compensation, at no cost to NHS England & Improvement Midlands.

10.0 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).

11.0 Governing Law and Jurisdiction

This Contract will be considered as a Contract made in England and will be subject to the laws of England. Subject to the provisions of Section 7 (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)

12.0 Completion of Signed Agreement

In order to participate in the scheme, each contractor must complete the signed agreement, and return to NHS England & Improvement Midlands as indicated. The contractor can choose which of the PGD services they wish to provide by indicating this on the form. Once received, the pharmacy will be accredited for the Extended Care Service Tier 1 module on PharmOutcomes, and delivery of the service can commence.

FOR BRANCHES OF MULTIPLE PHARMACY GROUPS, THIS AGREEMENT SHOULD BE COMPLETED BY AN AUTHORISED PERSON(S) AT HEAD OFFICE AND A COPY SENT TO EACH PARTICIPATING BRANCH FOR THEIR INFORMATION.

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Community Pharmacy Extended Care Service (Tier 1)

For

**Treatment of Simple Urinary Tract Infections
(UTI) in Females (from 16 years up to 65 years of age)**

(Midlands Region)

Community Pharmacy Extended Care Service (Tier 1)

Treatment of Simple UTI in Females (from 16 years up to 65 years of age)

1.0 Introduction

The service aims to provide any eligible patient who is registered with a GP practice contracted to NHS England & Improvement Midlands, with access to medication for the treatment of simple urinary tract infection (UTI) via Community Pharmacy. The service will be provided through Community Pharmacies contracted to NHS England & Improvement Midlands who have signed up to provide this service.

2.0 Patient eligibility

This scheme is available to females from 16 years up to 65 years of age who are registered with a GP practice contracted to NHS England & Improvement Midlands. Patients can access the scheme at any participating pharmacy in the Midlands Region.

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 eligibility needs to be verified. Only where there is doubt, and with the consent of the patient, the pharmacist may check the registration with the GP practice (see section 4.1 below "checking GP Registration").

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).

It is anticipated that patients who will make use of the service will access it via the pharmacy where they generally get their prescriptions dispensed. In addition to this, the pharmacist should check the patient's SCR and it is therefore expected that the number of telephone calls to the GP practice to confirm patient registration will be minimal.

2.1 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/patient's representative must be asked to provide evidence of their exemption. This declaration should be completed by the patient/patient's representative (Appendix 1) 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 PGDs in this service.

3.0 Service requirements

3.1 *Who can provide the service?*

This service can only be provided from community pharmacies contracted to NHS England & Improvement Midlands, that have been commissioned to do so, and that have appropriately trained staff available at all times to provide the service.

Pharmacists working at participating pharmacies can provide this Enhanced Service if they have completed the mandatory training requirements. They must document their service readiness using a Declaration of Competence (DoC) completed specifically for this service.

It is expected that locums and relief pharmacists undertake the relevant training as described below and have access to a copy of this service specification, prior to working in a pharmacy which has been commissioned to provide the service.

3.2 *Pharmacist 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 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 CKS summaries on simple UTIs.
- They must have satisfactorily completed the PHE 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 SLA are understood and the PGD associated with the service is signed.

The pharmacist should then print their DoC and add the heading “NHSE&I 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 enrollment 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 enrollment module will take the pharmacist to the relevant part of the CPPE website.

3.3 Additional requirements

COVID 19 related requirements –

Whilst COVID 19 is circulating within the community and in line with guidance that has been issued to General Practice, it remains important to reduce avoidable footfall in community pharmacies to protect patients and staff from the risks of infection. As a result, telephone consultations will be permissible for this service such that patients can receive advice and care without attending in person, unless in the professional opinion of the Pharmacist, a face to face consultation is required.

Video consultations will also be permissible for this service if contractors are able to meet the relevant criteria and standards set out by NHS England & Improvement for Community Pharmacy video consultations.

For those patients that present at the pharmacy, the Pharmacist will need to use their professional judgement and reference organisational risk assessments in order to determine whether to provide a face to face consultation. If this is necessary and/or appropriate, refer to section 4.4 which provides guidance and links to national documents regarding infection control measures and use of Personal Protective Equipment (PPE).

The Pharmacy must have an accredited consultation area which has been approved for Advanced Services for the consultations to take place. The Pharmacy Contractor will provide a professional consultation service for eligible patients who present with symptoms indicative of a simple UTI, and all consultations must take place in a confidential environment. Any consultations that are undertaken remotely (eg via telephone or video) must be done so in a confidential manner.

The Pharmacy must have an SOP in place to cover the service.

Patients can access the scheme at any participating pharmacy, and there is a requirement for the service to be available during all hours that the pharmacy is open.

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.

A list of pharmacies providing the service will be made available on the relevant LPC websites and shared with all other participating pharmacies and GP practices. Therefore, if for any reason the

pharmacy wishes to withdraw from the service NHS England & Improvement Midlands will need to be informed immediately.

4.0 Duties of Community Pharmacists

4.1 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 contracted to NHS England & Improvement Midlands.

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. They should offer the patient's details i.e. name, date of birth, and postcode or address, and merely ask the practice to confirm 'yes' or 'no' whether the patient is registered with them. The pharmacy should not expect the GP practice to offer any other patient information as the pharmacy should already be in receipt of this from the patient.

4.2 Consultation

The pharmacist must carry out a professional consultation with reference to the appropriate PGD and in accordance with the Standard Operating Procedure for the service.

- The pharmacist will conduct the consultation. This may be face-to-face, over the telephone or via an approved video link if appropriate. The pharmacist must, using the relevant PharmOutcomes module, collect information on the patient's condition and make appropriate records during the consultation. The pharmacist will assess the patient's condition using a structured approach to respond to symptoms.
- Where the pharmacist undertakes a telephone or approved video consultation, but is unable to collect all of the information they require from the patient **or** they feel that it is clinically appropriate to see the patient before making a decision on their condition, the pharmacist shall conduct a face-to-face consultation.
- The pharmacist will ensure that any relevant 'Red Flags' are recognised and responded to as part of the consultation process.
- If at this stage, it is identified that the patient needs to be referred to access higher acuity services, the procedure set out in section 5.0 should be followed.

- The pharmacist will 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.
- Eligible patients that present with three or more indicative symptoms of lower UTI will not ordinarily need to provide a urine sample unless deemed required to aid diagnosis.
- Urine dipstick tests are NOT diagnostic when used alone, but for a female, who does not have a catheter, and who presents with less than three indicative symptoms of lower UTI then the dipstick may be used to check for the presence of leucocytes and nitrites to aid diagnosis for these women (appendix 3).
- Recording should be done at the time of the consultation using the online PharmOutcomes platform. In exceptional circumstances, where no live connection is available, a paper Proforma may be used (Appendix 2). Where a paper based proforma is completed during the consultation, the information must be uploaded onto PharmOutcomes as specified below (section 4.3).
- Supply of medication if appropriate, and labelled as specified within the PGD.
- As well as the provision of verbal advice, patients should, if required, be provided with printed information relevant to their condition, or where this consultation takes place over the telephone or via approved video link, the pharmacist should signpost to relevant online resources if required. This should include self-care messages, expected symptoms, the probable duration of symptoms, and when and where to go for further advice or treatment if needed. Printed or online information can be sourced from www.nhs.uk.
- Inform patient's GP of the supply within two working days from when the consultation takes place (see section 4.3).

An NHS prescription charge per item should be collected on supply of any medication supplied via the PGD, unless the patient is exempt from prescription charges, in accordance with the National Health Service (Charges for Drugs and Appliances) Regulations 2015. Any NHS prescription charges collected from patients will be deducted from the sum payable to the pharmacy.

The consultation and supply should be recorded in the patients' record on the pharmacy PMR system.

Please note that a consultation fee is paid whether a medicine has been supplied or not. The pharmacist can claim the lower consultation fee if no medicine is required as any advice given is done so in accordance with the PGD, and as such is not designated as an Essential Service. Correct fees will be applied by PharmOutcomes automatically, based on the information recorded.

All consultations must be carried out by a pharmacist.

It is of paramount importance that all providers of this scheme note that normal rules of patient confidentiality apply.

At the end of every consultation, the pharmacist should give a closing statement to the patient:

“If your symptoms do not improve or become worse, then either come back to see me or seek advice from your GP. You can call NHS 111 or 999 if the matter is urgent and a pharmacist or GP is not available.”

4.3 Consultation form

All information relating to the consultation should be recorded at the time of the consultation by inputting the information directly onto PharmOutcomes. **The paper based proforma (Appendix 2) should only be used where there is an IT failure within the pharmacy.**

If the paper based proforma has to be used, then the information must be transferred onto PharmOutcomes at the earliest opportunity and by the end of the next working day at the latest.

Patient consent will need to be given for data sharing. If consent is refused, the service cannot be provided and the patient advised accordingly. The PharmOutcomes system will send a secure email to the patient's GP to inform of the supply so that the information can be added to the patients' medical record. If an email failure notification is received, a copy of the consultation record should be printed from PharmOutcomes and sent to the patient's general practitioner for information within two working days.

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 the LPC who can facilitate the update of the PharmOutcomes system.

4.4 Face to face consultations

If the patient presents at the pharmacy, or following a telephone or approved video consultation the Pharmacist deems it necessary to see the patient face to face, then consideration must be given to how the consultation can be undertaken in order to protect the patient and pharmacy staff from the risk of infection.

A risk assessment and any actions required to mitigate against infection, in particular COVID-19, must be carried out prior to delivering the service. Reference to PHE and NHSE&I guidelines should be followed, and these can be accessed via the following link -

<https://www.england.nhs.uk/coronavirus/primary-care/infection-control/>

Consideration should be given, but is not limited to the following;

- Check that the patient does not have symptoms indicative of COVID-19 infection prior to undertaking a face to face consultation.
- Maintain social distancing within the pharmacy and consultation room where possible.
- Utilise protective screens where possible
- Use PPE in accordance with current guidelines for face to face consultations, and consider advice/provision of face coverings for the patient.
- Ensure availability of hand sanitiser and/or hand washing facilities
- Adopt robust infection control measures within the consultation room such as cleaning surfaces, chairs and any equipment before and after each consultation
- Remove and dispose of any used PPE safely and in accordance with relevant guidance.

4.5 *Deferred antibiotic process*

The pharmacist may advise deferred antibiotic treatment; in this case they would complete the consultation and the data would be recorded in PharmOutcomes. If the patient returns after waiting for 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 relevant module so that the supply is linked to the correct consultation.

The PharmOutcomes module will allow the consultation to be saved and then the deferred supply should be added to the deferred treatment module if the patient returns and requires antibiotics.

5.0 **Escalation and referral process**

In those situations where a patient presents with a symptom(s) that requires escalation or referral to a GP or other healthcare professional (urgent or otherwise), the pharmacist has three options as set out below. The pharmacist should use their clinical judgement to decide the urgency, route and need for referral:

Option A - Refer the patient for an urgent in-hours appointment (Monday to Friday 08:00-18:30). After agreeing this course of action with the patient, the pharmacist should telephone the patient's general practice to secure them an appointment. When referring patients to a GP, pharmacists should not set any patient expectations of any specific treatment or outcome. Direct numbers for practices will be available by searching the DoS, using the DoS search tool which is used in the area. The pharmacist may wish to print a copy of the consultation record for the patient to take with them to the consultation at their general practice.

Option B - Call the NHS 111 service when the patient's own general practice is not available. After agreeing this course of action with the patient, the pharmacist should call NHS 111 using the healthcare professionals' line for fast access to a clinician, if this is required. The clinical service will provide advice which may result in onward referral of the patient or support to resolve the issue so that the episode of care can be completed.

Option C - Refer the patient to A&E or call 999. If the patient presents with severe symptoms indicating the need for an immediate medical consultation, the pharmacist should tell the patient to attend A&E immediately or call an ambulance. The pharmacist must record such referrals within PharmOutcomes.

In all circumstances, if the patient presents with symptoms outside the scope of the service, the patient should be managed in line with the pharmacist's best clinical judgement.

6.0 **Record Keeping and Labelling Requirements**

A record of every consultation must be made on PharmOutcomes. (NB only consultations recorded on PharmOutcomes will comply with record keeping requirements and result in a payment 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 UTI module there is a pharmacist enrollment module which must be completed by the supplying pharmacist the first time that they access this module. Once completed, this pharmacist enrollment will be recognised at all pharmacies offering the UTI service.

In addition, a record of any medication supplied through this scheme 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 Schedule 5 of The Medicines (Marketing Authorisations Etc) Regulations 1994, No 3144 as amended.

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

http://www.pjonline.com//news/recommendations_for_the_retention_of_pharmacy_records

7.0 Service Funding and Payment Procedures

Pharmacies must enter consultations onto PharmOutcomes which automatically generates a claim for payment.

Payments will be made on a monthly basis, and this will be done 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 that to which the payment relates.

7.1 Service payments

The pharmacy will be paid according to the following schedule.

Fee per consultation £15.00 (where medication is supplied)

Medication costs at Drug Tariff prices plus 20% VAT

Fee for full consultation where either no antibiotic is supplied or rapid referral occurs £12.00

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.

NHS England & Improvement Midlands will make provision for each pharmacy to be provided with a clinical waste bin if required, and will arrange for periodic collections when bins are full. Details of the arrangements will be provided separately by NHS England and Improvement Midlands.

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Appendix 1

Declaration of exemption

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

Patient Name..... Date Of Birth.....

The patient does not pay because:

- | | | |
|---|--|--|
| A | | is 60 years of age or over <u>or</u> 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 <u>or</u> 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 <u>and</u> meets the criteria |

The information I have given is correct and complete and I confirm proper entitlement to exemption

I am the patient

I am the 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

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Appendix 2 – 2020 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.

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 <i>(If client decides to delay treatment, you will still be paid for completing the consultation)</i>	
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	
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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 & Improvement.

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

Client's Signature:	Date:
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Pharmacists Name:	GPhC number:	Signature:	Date:
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Appendix 3

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

Nitrite

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.

<u>Interpreting urine dipstick results:</u>	
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



Community Pharmacy Extended Care Service (Tier 1)

For

Treatment of Acute Bacterial Conjunctivitis

(for children aged 3 months to 2 years)

(Midlands Region)

Community Pharmacy Extended Care Service (Tier 1)

Treatment of Acute Bacterial Conjunctivitis (for children aged 3 months to 2 years)

1.0 Introduction

The service aims to provide any eligible patient who is registered with a GP practice contracted to NHS England & Improvement Midlands, with access to medication for the treatment of acute bacterial conjunctivitis via Community Pharmacy. The service will be provided through Community Pharmacies contracted to NHS England & Improvement Midlands who have signed up to provide this service.

2.0 Patient eligibility

This scheme is available for children aged from 3 months to 2 years only who are registered with a GP practice contracted to NHS England & Improvement Midlands. Patients can access the scheme at any participating pharmacy in the Midlands Region.

Parents/guardians will be asked by the pharmacy to confirm the child's 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 eligibility needs to be verified. Only where there is doubt, and with the consent of the parent/guardian, the pharmacist may check the registration with the GP practice (see section 4.1 below "checking GP Registration").

Where the child is not registered with a GP practice as described above, the parent/guardian 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).

It is anticipated that patients who will make use of the service will access it via the pharmacy where they generally get their prescriptions dispensed. In addition to this, the pharmacist should check the patient's SCR and it is therefore expected that the number of telephone calls to the GP practice to confirm patient registration will be minimal.

2.1 Prescription exemptions

As this service is only available for children aged between 3 months and 2 years of age any medication required will be supplied free of charge as per the standard NHS exemption.

3.0 Service requirements

3.1 Who can provide the service?

This service can only be provided from community pharmacies contracted to NHS England & Improvement Midlands that have been commissioned to do so, and that have appropriately trained staff available at all times to provide the service.

Pharmacists working at participating pharmacies can provide this Enhanced Service if they have completed the mandatory training requirements. They must document their service readiness using a Declaration of Competence (DoC) completed specifically for this service.

It is expected that locums and relief pharmacists undertake the relevant training as described below and have access to a copy of this service specification, prior to working in a pharmacy which has been commissioned to provide the service.

3.2 Pharmacist 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 PHE 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 SLA are understood and the PGDs associated with the service is signed.

The pharmacist should then print their DoC and add the heading “NHSE&I 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 acute bacterial conjunctivitis.

In order to record the consultations on PharmOutcomes the pharmacist must complete a pharmacist enrollment 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 enrollment module will take the pharmacist to the relevant part of the CPPE website.

3.3 Additional requirements

COVID 19 related requirements –

Whilst COVID 19 is circulating within the community and in line with guidance that has been issued to General Practice, it remains important to reduce avoidable footfall in community pharmacies to protect patients and staff from the risks of infection. As a result, telephone consultations will be permissible for this service such that patients can receive advice and care without attending in person, unless in the professional opinion of the Pharmacist, a face to face consultation is required.

Video consultations will also be permissible for this service if contractors are able to meet the relevant criteria and standards set out by NHS England & Improvement for Community Pharmacy video consultations.

For those patients that present at the pharmacy, the Pharmacist will need to use their professional judgement and reference organisational risk assessments in order to determine whether to provide a face to face consultation. If this is necessary and/or appropriate, refer to section 4.4 which provides guidance and links to national documents regarding infection control measures and use of Personal Protective Equipment (PPE).

The Pharmacy must have an accredited consultation area which has been approved for Advanced Services for the consultations to take place. The Pharmacy Contractor will provide a professional consultation service for eligible patients who present with symptoms indicative of acute bacterial conjunctivitis, and all consultations must take place in a confidential environment. Any consultations that are undertaken remotely (eg via telephone or video) must be done so in a confidential manner.

The Pharmacy must have an SOP in place to cover the service.

Patients can access the scheme at any participating pharmacy, and there is a requirement for the service to be available during all hours that the pharmacy is open.

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.

A list of pharmacies providing the service will be made available on the relevant LPC websites and shared with all of the participating pharmacies and GP practices. Therefore, if for any reason the pharmacy wishes to withdraw from the service NHS England & Improvement Midlands will need to be informed immediately.

4.0 Duties of Community Pharmacists

4.1 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 contracted to NHS England & Improvement Midlands.

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. They should offer the patient's details i.e. name, date of birth, and postcode or address, and merely ask the practice to confirm 'yes' or 'no' whether the patient is registered with them. The pharmacy should not expect the GP practice to offer any other patient information as the pharmacy should already be in receipt of this from the patient.

4.2 Consultation

The pharmacist must carry out a professional consultation with reference to the appropriate PGD and in accordance with the Standard Operating Procedure for the service.

- The pharmacist will conduct the consultation. This may be face-to-face, over the telephone or via an approved video link if appropriate. The pharmacist must, using the relevant PharmOutcomes module, collect information on the patient's condition and make appropriate records during the consultation. The pharmacist will assess the patient's condition using a structured approach to respond to symptoms.
- Where the pharmacist undertakes a telephone or approved video consultation, but is unable to collect all of the information they require from the patient **or** they feel that it is clinically appropriate to see the patient before making a decision on their condition, the pharmacist shall conduct a face-to-face consultation.
- The pharmacist will ensure that any relevant 'Red Flags' are recognised and responded to as part of the consultation process.
- If at this stage, it is identified that the patient needs to be referred to access higher acuity services, the procedure set out in section 5.0 should be followed.
- The pharmacist will 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.

- Recording should be done at the time of the consultation using the online PharmOutcomes platform. In exceptional circumstances, where no live connection is available, a paper Proforma may be used (Appendix 2). Where paper based proforma is completed during the consultation, the information must be uploaded onto PharmOutcomes as specified below (section 4.3).
- Supply of medication if appropriate, and labelled as specified within the PGD
- As well as the provision of verbal advice, patients should, if required, be provided with printed information relevant to their condition, or where this consultation takes place over the telephone or via approved video link, the pharmacist should signpost to relevant online resources, if required. This should include self-care messages, expected symptoms, the probable duration of symptoms, and when and where to go for further advice or treatment if needed. Printed or online information can be sourced from www.nhs.uk.

Inform patient's GP of the supply within two working days from when the consultation takes place (see section 4.3).

An NHS prescription charge per item should be collected on supply of any medication supplied via the PGD, unless the patient is exempt from prescription charges, in accordance with the National Health Service (Charges for Drugs and Appliances) Regulations 2015. Any NHS prescription charges collected from patients will be deducted from the sum payable to the pharmacy.

The consultation and supply should be recorded in the patients' record on the pharmacy PMR system.

Please note that a consultation fee is paid whether a medicine has been supplied or not. The pharmacist can claim the lower consultation fee if no medicine is required as any advice given is done so in accordance with the PGD, and as such is not designated as an Essential Service. Correct fees will be applied by PharmOutcomes automatically, based on the information recorded.

All consultations must be carried out by a pharmacist.

It is of paramount importance that all providers of this scheme note that normal rules of patient confidentiality apply.

At the end of every consultation, the pharmacist should give a closing statement to the patient:

"If your symptoms do not improve or become worse, then either come back to see me or seek advice from your GP. You can call NHS 111 or 999 if the matter is urgent and a pharmacist or GP is not available."

4.3 Consultation form

All information relating to the consultation should be recorded at the time of the consultation by inputting the information directly onto PharmOutcomes. **The paper based proforma (Appendix 2) should only be used where there is an IT failure within the pharmacy.**

If the paper based proforma has to be used, then the information must be transferred onto PharmOutcomes at the earliest opportunity and by the end of the next working day at the latest.

Patient consent will need to be given for data sharing. If consent is refused, the service cannot be provided and the patient advised accordingly. The PharmOutcomes system will send a secure email to the patient's GP to inform of the supply so that the information can be added to the patients' medical record. If an email failure notification is received, a copy of the consultation record should be printed from PharmOutcomes and sent to the patient's general practitioner for information within two working days.

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 the LPC who can facilitate the update of the PharmOutcomes system.

4.4 Face to face consultations

If the patient presents at the pharmacy, or following a telephone or approved video consultation the Pharmacist deems it necessary to see the patient face to face, then consideration must be given to how the consultation can be undertaken in order to protect the patient and pharmacy staff from the risk of infection.

A risk assessment and any actions required to mitigate against infection, in particular COVID-19, must be carried out prior to delivering the service. Reference to PHE and NHSE&I guidelines should be followed, and these can be accessed via the following link -

<https://www.england.nhs.uk/coronavirus/primary-care/infection-control/>

Consideration should be given, but is not limited to the following;

- Check that the patient does not have symptoms indicative of COVID-19 infection prior to undertaking a face to face consultation.
- Maintain social distancing within the pharmacy and consultation room where possible.
- Utilise protective screens where possible
- Use PPE in accordance with current guidelines for face to face consultations, and consider advice/provision of face coverings for the patient.
- Ensure availability of hand sanitiser and/or hand washing facilities
- Adopt robust infection control measures within the consultation room such as cleaning surfaces, chairs and any equipment before and after each consultation
- Remove and dispose of any used PPE safely and in accordance with relevant guidance.

4.5 Deferred antibiotic process

The pharmacist may advise deferred antibiotic treatment; in this case they would complete the consultation and the data would be recorded in PharmOutcomes. If the patient returns after waiting for 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 relevant module so that the supply is linked to the correct consultation.

The PharmOutcomes module will allow the consultation to be saved and then the deferred supply should be added to the deferred treatment module if the patient returns and requires antibiotics.

5.0 Escalation and referral process

In those situations where a patient presents with a symptom(s) that requires escalation or referral to a GP or other healthcare professional (urgent or otherwise), the pharmacist has three options as set out below. The pharmacist should use their clinical judgement to decide the urgency, route and need for referral:

Option A - Refer the patient for an urgent in-hours appointment (Monday to Friday 08:00-18:30). After agreeing this course of action with the patient, the pharmacist should telephone the patient's general practice to secure them an appointment. When referring patients to a GP, pharmacists should not set any patient expectations of any specific treatment or outcome. Direct numbers for practices will be available by searching the DoS, using the DoS search tool which is used in the area. The pharmacist may wish to print a copy of the consultation record for the patient to take with them to the consultation at their general practice.

Option B - Call the NHS 111 service when the patient's own general practice is not available. After agreeing this course of action with the patient, the pharmacist should call NHS 111 using the healthcare professionals' line for fast access to a clinician, if this is required. The clinical service will provide advice which may result in onward referral of the patient or support to resolve the issue so that the episode of care can be completed.

Option C - Refer the patient to A&E or call 999. If the patient presents with severe symptoms indicating the need for an immediate medical consultation, the pharmacist should tell the patient to attend A&E immediately or call an ambulance. The pharmacist must record such referrals within PharmOutcomes.

In all circumstances, if the patient presents with symptoms outside the scope of the service, the patient should be managed in line with the pharmacist's best clinical judgement.

6.0 Record Keeping and Labelling Requirements

A record of every consultation must be made on PharmOutcomes. (NB only consultations recorded on PharmOutcomes will comply with record keeping requirements and result in a payment 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 acute bacterial conjunctivitis module there is a pharmacist enrollment module which must be completed by the supplying pharmacist the first time that they access this module. Once completed, this pharmacist enrollment will be recognised at all pharmacies offering this service.

In addition, a record of any medication supplied through this scheme 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 Schedule 5 of The Medicines (Marketing Authorisations Etc) Regulations 1994, No 3144 as amended.

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

(http://www.pjonline.com//news/recommendations_for_the_retention_of_pharmacy_records)

7.0 Service Funding and Payment Procedures

Pharmacies must enter consultations onto PharmOutcomes which automatically generates a claim for payment.

Payments will be made on a monthly basis, and this will be done 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 that to which the payment relates.

7.1 Service payments

The pharmacy will be paid according to the following schedule.

Fee per consultation £15.00 (where medication is supplied)

Medication costs at Drug Tariff prices plus 20% VAT

Fee for full consultation where either no antibiotic is supplied or rapid referral occurs £12.00

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Appendix 1

Declaration of exemption

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

Patient Name..... Date Of Birth.....

The patient does not pay because:

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

The information I have given is correct and complete and I confirm proper entitlement to exemption

I am the patient

I am the 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

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Appendix 2 – 2020 Proforma for use in case of IT Failure

Chloramphenicol PGD for acute bacterial conjunctivitis (age 3 months 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.

Inclusion Criteria

Children aged 3 months 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	
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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 & Improvement.

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

Signature of patient's parent / guardian:	Date:
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Pharmacists Name:	GPhC number:	Signature:	Date:
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COMMUNITY PHARMACY EXTENDED CARE SERVICE (Tier 1) 2020

SIGNED AGREEMENT

****FOR BRANCHES OF MULTIPLE PHARMACY GROUPS, THIS AGREEMENT SHOULD BE COMPLETED BY AN AUTHORISED PERSON(S) AT HEAD OFFICE**

On behalf of (Pharmacy Name and Address)

.....

Contractor Code (F Code).....

Service to be provided (please tick all that apply)

Treatment of Simple UTI in females Treatment of Acute Bacterial Conjunctivitis

I have read and understood the terms in this service specification and agree to provide the standard of service specified.

Signature.....

Print name.....

Designation.....

Date.....

*If signing on behalf of several branches, please attach the list of branches to this form to confirm their participation in the service.

On behalf of NHS England and Improvement Midlands, I commission the above pharmacy to provide the service detailed in this service specification for the Community Pharmacy Extended Care Service (Tier 1).

Signature (on behalf of NHS England & Improvement) :



Print name : Rebecca Woods

Designation: Head of Primary Care – NHSE&I Midlands (West) Date 1st December 2020

Please return a signed electronic copy of this form by email to a.pickard@nhs.net