

<b>Service Specification No.</b>	N/A
<b>Service</b>	<b>Extended Care at the Chemist Service</b>
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<b>Provider Lead</b>	Community Pharmacy Contractor
<b>Period</b>	1 <sup>st</sup> April 2023 – 31 <sup>st</sup> March 2024
<b>Date of Review</b>	Annual

## 1. Population Needs

1.1 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.

1.2 NHS Cheshire and Merseyside ICB (Sefton) currently commission the Care at the Chemist service across community pharmacies within Sefton. Care at the Chemist allows pharmacists to provide a range of treatments for minor ailments to patients within Sefton. Pharmacies are currently limited to providing over-the-counter (OTC) medicines within the product license. By implementing PGDs, community pharmacists will be able to treat a wider scope of conditions, thus reducing burden on General Practice and out of hours (OOH) services.

## 2. Outcomes

### 2.1. NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

## **2.2 Local defined outcomes**

- An increase in people able to self-manage minor ailments by accessing timely advice and cost-effective medicines available from the community pharmacy.
- A reduction in demand for appointments in other health care settings: General Practice, NHS 111, Accident and Emergency (A&E).

## **3. Scope**

### **3.1 Aims and objectives of service**

- This Service Specification defines the terms and standards required by the commissioners “NHS Cheshire and Merseyside ICB (Sefton)” for the provision of the Extended Care at the Chemist Service under which the commissioned Service Provider (The Community Pharmacy Contractor) and the accredited community pharmacist will provide an Extended Minor Ailments Service in line with the requirements of this service specification and the locally agreed PGD and treatment guidelines, to patients in Sefton
- The Service Provider must be commissioned to provide Care at the Chemist in order to provide the Extended Care at the Chemist Service.
- The Extended Care at the Chemist service aims to:
  - Support patients to recover quickly and successfully from episodes of ill health that are suitable for management in a community pharmacy setting
  - Ensure that patients have a positive experience of care in a community pharmacy setting.
  - Release capacity in other healthcare settings by providing convenient access to advice and treatment in community pharmacy.
- The service aims to divert patients with specified uncomplicated conditions from general practice and other urgent care settings (e.g., OOH, urgent care center, A&E department) into community pharmacy where the patient can be seen and treated in a single episode of care.
- The service is particularly aimed at common, self-limiting, or uncomplicated conditions where the condition can be appropriately diagnosed in a community pharmacy setting (without needing an intimate examination, laboratory tests or access to full medical records) and the medication can be readily supplied.
- The Extended Care at the Chemist Service aims to enable more patients to access NHS treatment and advice without requiring a GP, OOH or A&E appointment to provide a prescription.

### 3.2 Service description

- The service comprises patient assessment and advice, and provision of Prescription Only Medicine (POM) according to the criteria specified in the relevant PGD, followed by a communication to the patient's registered GP to advise of the treatment provided.
- The list of conditions and treatments included in the scheme is shown in the table below. From time to time, the Commissioner may add, remove or amend the conditions and/or treatments included in the scheme and will notify providers of this by means of an updated list of Conditions and Treatments.

Condition	Treatment
Uncomplicated lower urinary tract infection in non-pregnant women aged between 16 and 65 years of age	Nitrofurantoin 100mg modified release capsules Nitrofurantoin 50mg capsules/tablets

- The Commissioner will provide PGDs via PharmOutcomes. Pharmacists are expected to use their professional judgment in the application of this guidance to individual patients.
- The service will be available to patients registered with a GP practice in NHS Cheshire and Merseyside ICB (Sefton) and who meet the eligibility criteria as set out in the relevant PGD.
- Patients will be asked by the pharmacy to confirm their registration with the GP Practice before accessing the service. 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.
- Patients not registered with a GP practice as described above, should be advised appropriately and if antibiotic treatment or other 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).
- Patients may self-refer or be referred through CPCS or another route.
- The pharmacist must gain consent for details of the consultation to be shared with the patient's GP. If patient consent is not given the patient is excluded from this service and the patient should be signposted to an appropriate provider
- The pharmacist will assess the patient according to the criteria specified in the relevant PGD.
- It is acknowledged that pharmacists will not have access to the full medical record when conducting consultations and will need to assure themselves that the patient (or

patient's representative) can provide a reliable history of the presenting condition and other relevant elements of the patient's history (e.g., long term conditions, concomitant medication).

- The SCR should be used, when available, to clarify / augment the patient history.
- Pharmacists can and should decline to provide medicines under the Service where a reliable history cannot be obtained, in order to care for people in a safe environment and protect them from avoidable harm.
- If the patient is eligible for treatment under the specified PGD, the pharmacist will supply medication to the patient supported by advice on its use.
- If the patient is ineligible for inclusion in the PGD, the pharmacist will provide self-care advice and safety netting to the patient. An OTC product may be supplied if appropriate through the Care at the Chemist service or over the counter purchase.
- If the pharmacist believes a prescription medication is needed but are unable to supply under the respective PGD, a referral to another healthcare provider (e.g., GP/OOH Service/A&E) will be made following pathways as set out in the CPCS. The urgency with which a referral needs to be made is based on the presenting symptoms.
- If medication is to be supplied, it will be dispensed and labelled in accordance with the respective PGD. A record of supply must be made on the patient's PMR.
- 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 (as set out in the respective PGDs). 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.
- A record of the consultation will be made on PharmOutcomes at the time of the consultation. In case of IT failure, the relevant pro-forma in Appendix 1 should be completed at the time of the consultation and the supply should be entered onto PharmOutcomes at the soonest possible moment following its restoration.
- A notification will be sent to the patient's registered GP practice from PharmOutcomes on completion of the provision on the system. In case of IT issues, the pharmacy will print this and send via secure NHS mail to the GP surgery, or via post.
- The service provider must keep all completed electronic consultation proformas for a period of 8 years (in adults) or until 25th birthday in a child (age 26 if entry made when the young person was 17) or eight years after death in line with NHS health records retention policies.

- The pharmacist will determine whether the patient is exempt from paying prescription charges or not. If the patient is not exempt and is supplied a medication, the pharmacist will charge the patient an amount equivalent to the prescription charge and will be reimbursed for the consultation fee/NHSBSA Drug Tariff price of medicines issued less the prescription charge.
- The service provider must keep the Directory of Services (DoS) up to date for NHS 111 etc.

### **3.3 Pharmacist training and development**

- Commissioned Service Providers will be responsible for ensuring that only appropriately accredited pharmacists will deliver the Service, and that accredited pharmacists are available whenever the branch is open.
- Pharmacists who deliver this service must complete a Declaration of Competence in Minor Ailments through the Centre of Pharmacy Postgraduate Education (CPPE).
- Pharmacists are expected to reflect on their knowledge, skills, and competences before making the declarations, and to address any learning and development needs before starting to deliver the service.
- Pharmacists who deliver the Service must complete any training required as set out in the respective PGDs.
- Pharmacists providing the service need to read all the PGDs and sign the Pharmacist Self Declaration Form in each premises from which they provide the service. A signature on the Self Declaration form is a legal requirement for provision of medicines under PGDs and provides assurance that the pharmacist has personally read the PGDs and addressed any learning and development needs.
- Service Providers should retain a copy of the Pharmacist's PGD Self Declaration Form, and Declaration of Competence certificate within the pharmacy for inspection.
- Prior to completing their first Extended Care at the Chemist provision, the pharmacist must complete an enrolment on PharmOutcomes declaring that they have completed a Declaration of Competence, completed any required training, and have read and understood all PGDs within the service.
- The responsible pharmacist on each given day has overall responsibility for ensuring the service is delivered in accordance with this service specification.

### **3.4 Antimicrobial Stewardship**

- Pharmacists and their teams delivering the service must be aware of the principles of antimicrobial stewardship. Pharmacy teams need to:
  - Counsel patients when minor conditions do not require an antibiotic and will resolve without treatment

- Be able to discuss the issue of antimicrobial resistance and be aware that using antibiotics when they are not needed can increase the risk of antibiotics not working in the future for the individual and the population at large.
- Discuss supportive measures that will relieve symptoms without antibiotics (e.g., painkillers) and make over the counter supplies of these as required
- Counsel patients to take any antibiotics supplied according to the directions.
- Counsel patients to complete the course of antibiotics supplied.
- Inform patients that if a course of antibiotics is not completed (e.g., because of a side effect or because cultures suggest a change to a different medicine) then the remainder should be returned to the pharmacy for disposal.
- Advise patients that they should never use antibiotics prescribed for anyone else.

### **3.5 Signposting**

- If the pharmacy for whatever reason cannot provide the service, then the patient should be directed to the nearest pharmacy that can. The referring service provider must contact the pharmacy to ensure that an accredited pharmacist is on duty before signposting patients.

### **3.6 Equality and Diversity**

- The service provider must comply with the requirements of the Equality Act 2010 and will not treat one group of people less favorably than others because of age, disability, gender reassignment, marriage or civil partnership, race, religion or belief, sex or sexual orientation, pregnancy and maternity.

### **3.7 Payment**

- Claims for payment for this service should be made using PharmOutcomes
- The pharmacy contractor will be paid £15 per consultation plus re-imburement for any drug supplied minus the prescription charge if collected.
- Claims must be submitted no later than the 5<sup>th</sup> of the following month to which the claim relates

### **3.8 Population covered**

- This service is available to patients registered with NHS Cheshire and Merseyside ICB (Sefton) GP practices and who meet the eligibility criteria as set out in the respective PGDs.

- Patients may access the service following signposting from another provider (e.g., GP, OOH service, NHS 111), by pharmacy staff or by self-referral.

### **3.9 Any exclusion criteria and thresholds**

- Any patients registered with a GP practice outside of NHS Cheshire and Merseyside ICB (Sefton).
- Any exclusion criteria as set out in the respective PGDs

### **3.10 Interdependence with other services/providers**

- The service will involve working collaboratively with GP practices and other services and health professionals, as necessary.

## **4. Applicable Service Standards**

### **4.1 Applicable national standards (e.g., NICE)**

- All Medicines supplied under the service must be labelled to comply with the Human Medicines Regulations 2012.
- Medicines supplied under the Extended Care at the Chemist Service must be supplied with a patient information leaflet.
- Records created during the delivery of the Extended Care at the Chemist Service should be managed according to the NHS Code of Practice.

### **4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g., Royal Colleges)**

- General Pharmaceutical Council Standards for Pharmacy Professionals
- The Extended Care at Chemist Service may only be provided by Pharmacists with a current registration with the General Pharmaceutical Council from premises that hold a current contract to supply NHS Pharmaceutical Services.

### **4.3 Applicable Local Standards**

- It is expected that the service will be offered consistently throughout the opening hours of the branch including evenings, weekends, and Bank Holidays.
- It is expected that Service Providers contributes to any locally agreed NHS Cheshire and Merseyside ICB (Sefton) led assessment of the service or service user experience.
- The service provider must have a complaints procedure that complies with Local Authority Social Services and National Health Service complaints (England) Regulations 2009.

- Complaints directly linked to the quality of this service must be reported to the commissioner as set out in the NHS standard contract.
- Incidents and significant events should be reported to the commissioner using ULYSSES  
<https://ulysses.midlandsandlancashirecsu.nhs.uk/Incident.aspx?link=D0155A369162E2E15F>
- NHS Cheshire and Merseyside ICB (Sefton) will monitor the quality of the Service by utilising a range of options, including but not limited to:
  - Seeking feedback from Providers and patients
  - Cross referencing the following data:
    - Claims for payment
    - Reports from PharmOutcomes

#### **4.4 Key performance indicators**

- Number of patient consultations
- Number of patients supplied with treatment and treatment supplied
- Number of patients excluded from treatment and reason for exclusion
- Number of patients referred onto other services e.g., GP, OOH etc.

### **5. Applicable quality requirements and CQUIN goals**

#### **5.1. Applicable quality requirements**

- The service provider must have a standard operating procedure (SOP) in place for this service that specifically detail the operational delivery of the Extended Care at the Chemist service in accordance with this specification and which includes procedures to ensure health and safety and infection control procedures are maintained in line with any relevant guidelines. All staff involved in the provision of this service should ensure they are familiar with and adhere to the SOP.
- The service provider must ensure that all staff working in the pharmacy have relevant knowledge, are appropriately trained, and operate within SOPs; this includes understanding when to recommend the service to clients and using sensitive client-centered communication skills.
- The service provider should review their SOP for the service when there are any major changes in the law affecting the service or in the event of any incidents. In the absence of any of these events they will be reviewed every 2 years.
- The SOP must be available to the commissioner if requested



- Pharmacists and their staff must be fully aware of their responsibility to safeguard vulnerable adults and refer appropriately as per local safeguarding procedures. Pharmacies must also have internal procedures in place to deal with safeguarding concerns.
- The pharmacy must be able to deliver this locally commissioned service for all their contracted hours (this includes both core and supplementary hours).
- If the service is not provided in accordance with this service specification, the commissioners reserve the right to recover the appropriate payment and the pharmacy will become ineligible to provide this locally commissioned service.
- The pharmacy must give 3 months' notice if it intends to stop delivering under this locally commissioned service.
- NHS Cheshire and Merseyside ICB (Sefton) will provide at least 3 months' notice of termination of this service.
- Failure to participate in any service audits or assessments organised by NHS Cheshire and Merseyside ICB (Sefton) when required, will lead to claims for payment being rejected.
- If, for whatever reason, the pharmacy ceases to provide the essential services under the pharmacy contractual framework then the pharmacy will become ineligible to provide this locally commissioned service

## 5.2 Applicable CQUIN goals

- N/A

## 6. Location of Provider Premises

- Participating pharmacies within Sefton

## 7. Individual Service User Placement

- N/A

## Appendix 1

### Nitrofurantoin Patient Group Direction

For the supply of nitrofurantoin by a registered pharmacist for the treatment of uncomplicated urinary tract infections in non-pregnant women aged between 16 and 65 years of age.

Pro-forma to be used in case of IT failure only. Supply must be entered onto PharmOutcomes as soon as possible.

Date of supply	Time of supply	Name of practitioner
Patient name and DoB	Address including post code	GP practice

### Patient consent to share information with GP

If you give consent for data sharing, the information you provide will be passed to your GP.

Consent to share

Yes  No

Consent is required to continue with this service

### Inclusion criteria

Non-pregnant women aged between 16-65 years of age presenting with symptoms associated with an uncomplicated lower urinary tract infection

Does the patient have a minimum of 2 of the 3 key symptoms/signs?

- Dysuria (Burning pain when passing urine)
- New Nocturia (Passing urine more often than usual at night)
- Urine cloudy to the naked eye

Inclusion criteria met.

Yes  No

If inclusion criteria not met do not continue with this service

## Exclusion criteria

- Male
- Hypersensitivity or serious ADR from nitrofurantoin or to any other components of the preparation
- Under 16 years of age
- Over 65 years of age
- Pregnancy (known or suspected)
- Breastfeeding
- Risk of treatment failure (Received antibiotic treatment for UTI within 1 month, 2 or more UTI episodes in the last 6 months or 3 or more episodes in last 12 months, taking antibiotic prophylaxis for recurrent UTI)
- Previous failed antibiotic treatment for same episode
- Indwelling catheter or intermittent self-catheterisation
- Suspected SEPSIS (Use the "Sepsis screening and action tool")
- New signs/symptoms of pyelonephritis (Kidney pain or tender back under ribs, new or different myalgia, flu like illness, nausea or vomiting, shaking chills (rigors) or temperature over 37.9 °C)
- Genitourinary causes of urinary symptoms (changes to vaginal discharge, check sexual history to exclude STIs, urethritis (urethral inflammation post sexual intercourse, irritants, STIs), genitourinary symptoms of menopause/atrophic vaginitis/vaginal atrophy)
- Frank Haematuria
- Confused or dehydrated
- Diabetes
- Known renal impairment
- Known hepatic impairment
- History of renal stones/renal colic, known abnormality of the urinary tract (e.g., Vesicoureteric reflux, reflux nephropathy, neurogenic bladder, urinary obstruction, stent, recent instrumentation)
- Known haematological abnormalities (Anaemia, blood dyscrasias, known porphyria, vitamin B (particularly folate) deficiency)
- G6PD deficiency
- Electrolyte imbalance
- Known or susceptibility to peripheral neuropathy, or known neurological disorder
- Known pulmonary disease

- Concomitant use of medication that has clinically significant interactions with nitrofurantoin (For a comprehensive list of interactions refer to SPC and BNF)
- Immunosuppressed
- Persistent symptoms
- Decline to provide consent or non-capacity to consent
- None of the above

**Action to be taken if patient excluded**

- Share self-care and safety netting advise using TARGET Treating your infection- UTI leaflet
- Suspected pyelonephritis/SEPSIS- urgent referral for medical review
- Referral to medical practitioner

The urgency with which a referral needs to be made is based on the presenting symptoms

A referral to another healthcare provider (e.g., GP, OOH services, A&E) will be made following local pathways as set out in the CPCS.

**Patient consent**

Does patient consent to treatment

- Yes  No

If patient declines treatment record any advice given, details of any referrals made and actions to be taken by patient.

**Medicine supply information**

- Macrobid 100mg modified release capsule (first line)
- Nitrofurantoin 50mg tablets
- Nitrofurantoin 50mg capsules

Quantity supplied	Batch number	Expiry date
Levy collected	Nitrofurantoin labelled/PMR entry completed	Exemption form signed

**Written/verbal information to be given to patient**

- Provide the patient with the manufacturer's Patient Information Leaflet

- Advise patient how to take the medicine
- Advise patient to take at regular intervals
- Advise the patient to complete the 3-day course even if the original infection appears better
- Nitrofurantoin may be taken with food if it causes stomach upset
- Advise patient of possible side effects and their management and who to contact for further advice (Refer to BNF and SPC for details)
- Advise patient of potential interactions (Refer to BNF and SPC for details)
- The activity of nitrofurantoin is reduced when the pH of the urine is increased. It may be prudent to avoid alkalinising agents e.g., potassium citrate in people taking nitrofurantoin
- Encourage patient to maintain a good fluid intake
- Nitrofurantoin may color the urine yellow or brown. This is quite normal and not a reason to stop taking the medicine
- Advise patient that if they experience any unacceptable side effects, they should see their GP for further advice
- Advise patient If the condition becomes recurrent to contact their GP for further investigation
- Antibiotics and oral contraceptives - see information below. Advice should be provided around the usual precautions if nausea and vomiting should arise from taking the antibiotics
- Provide patient with a copy of the TARGET UTI leaflet -  
<https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&chapterid=441>
- Provide self-care advice- see TARGET UTI leaflet for further information
- Provide advice on ways to reduce recurrence of further episodes - see TARGET UTI leaflet for further information
- Provide advice on when patient should seek further advice/help (safety netting advice)- see TARGET UTI leaflet for further information
- Advise patient to stop taking nitrofurantoin immediately and seek medical advice if patient develops pulmonary, hepatic, haematological or neurological reactions (e.g., breathing difficulties, abdominal pain, discomfort, bruising and bleeding).

#### Antibiotics and oral contraceptives

The US Center for Disease Control and Prevention, the World Health Organization, and the Faculty of Sexual & Reproductive Healthcare's Clinical Effectiveness Unit (FSRH CEU) have concluded that common non-enzyme-inducing antibiotics do not impair the effectiveness of hormonal contraception, including combined oral contraceptives, patches, or rings and that extra precautions are not required when antibiotics are prescribed (other than enzyme inducing antibiotics). See

<https://www.fsrh.org/standards-and-guidance/fsrh-guidelines-and-statements/drug-interactions/>

### Follow up advise to be given to patients

- Advise patient to seek urgent medical review if symptoms worsen rapidly or significantly at any time or fail to improve within 48h of starting antibiotics
- Advise patient that if a rash or other signs of hypersensitivity occur, to stop taking the medicine and seek immediate medical advice/attention
- Advise patient to seek medical attention immediately if patient becomes systemically unwell

### Referral for medical advice

A referral to another health care provider (e.g., GP, OOH services, A&E) should be made using existing local pathways as set out in the CPCS. The urgency with which a referral needs to be made is based on the presenting symptoms.

Referral made to  GP  OOH  A+E  Other

**Please note: Exemption forms should be retained in the pharmacy in case requested by the NHS Cheshire and Merseyside ICB (Sefton) For consultations carried out without a live PharmOutcomes connection the patient must sign the declaration. Otherwise, consent is**

Patient signature	Date
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Pharmacist name	GPhC number	Signature	Date
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