

# **Pharmacy standards in cystic fibrosis care in the UK**

**Third edition**

September 2022

## Contents

<b>Background</b>	<b>3</b>
<b>1. Introduction</b>	<b>3</b>
<b>2. Pharmaceutical services</b>	<b>4</b>
2.1 Support services	
<b>3. CF specialist pharmacist</b>	<b>5</b>
3.1 Clinical pharmacy technician	
3.2 People with CF/their parents or carers	
3.3 Role of the CF specialist pharmacist	
<b>4. Medicines optimisation for CF specialist pharmacy teams</b>	<b>7</b>
4.1 CF specialist pharmacist/person with CF interactions	
<b>5. References</b>	<b>10</b>

# Background

This document has been produced by the United Kingdom Cystic Fibrosis Pharmacy Group (UKCFPG) Steering Committee. It updates the 'Pharmacy Standards in Cystic Fibrosis Care' 2011, building on original work done by the Cystic Fibrosis Pharmacists' group in 2002. It is intended as a guide for all those involved in the pharmaceutical care of people with cystic fibrosis (CF).

## 1. Introduction

The principal objective of the pharmacy service for people with CF is to ensure that all people with CF have their medicines optimised at an individual level. Medicines optimisation is defined as 'a patient-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines'.<sup>1</sup> It is the process through which the pharmacy team co-operate with an individual and other healthcare professionals in designing, implementing, and monitoring a therapeutic plan to produce the best possible health outcomes. It is essential that the person with CF is at the centre of, and is included in any decision-making.

The appointment of cystic fibrosis specialist pharmacists has reduced medication errors, increased the availability of prescriptions, and strengthened the primary–secondary care relationship through the development of shared care prescribing protocols.<sup>2</sup>

Some people with CF will have (or have already received) organ transplantation as treatment for cystic fibrosis, most commonly lung (or heart-lung) transplantation, but also liver transplantation. Such people continue to have cystic fibrosis, and their pharmaceutical needs are typically much more complex after organ transplantation due to the additional immunosuppressant medications that are needed. These medicines cause and are subject to many interactions with other medicines commonly used in cystic fibrosis, and they require expert prescribing and monitoring to avoid adverse effects. CF specialist pharmacists need to co-ordinate with the transplant service to make sure that medicines prescribed post-transplant are well managed and that all required medicines are readily available to people with CF.

## 2. Pharmaceutical services

All people with CF should have support from their local primary care pharmacy team but due to the range and complexity of their pharmaceutical needs, a CF specialist pharmacist should support each person with CF. The specialist pharmacist is an essential part of the CF multidisciplinary (MDT) team hosted at the CF centre. Each CF centre is commissioned to provide an appropriate level of CF specialist pharmacist to support everyone under the care of that centre.

### 2.1 Support services

Effective provision of a pharmacy service relies on the knowledge and skills of a CF specialist pharmacist and availability and quality of various support services.

#### Clinical pharmacy technician

- To support individualised medicines reconciliation on admission to hospital and at other times as required.
- To support inpatient one-stop dispensing schemes, the use of people with CF's own medicines, self-administration schemes and individualised counselling around medicines use.
- To support the management of medications supplied via homecare.
- To support the management of home intravenous (IV) antibiotic therapy.
- To support the remote monitoring of medicines and adherence with therapy.
- To support service development and improvement work.

#### Outpatient, inpatient and discharge dispensing services

- To provide timely supply and counselling of medication.

#### Aseptic dispensing service

- To provide aseptically manufactured products while in hospital, for example, IV antibiotic desensitisation regimes, total parental nutrition. This may be provided in-house or outsourced.

#### Access to a medicines information service

- To provide expert information about the treatment of children and/or adults with CF as appropriate.

#### Access to an on-call pharmacy service

- For the supply of urgent medication, information, and advice. This service should be available 24 hours a day, seven days a week.

#### Procurement and distribution

- To provide an efficient medicine supply service.

#### Homecare service

- To offer the long-term supply of medication in the most cost-effective and convenient way taking into account the needs of the individual, in line with national homecare standards.<sup>3,4</sup> Also, to offer home IV antibiotics to people with CF where appropriate.

## 3. CF specialist pharmacist

Each CF centre should employ one or more CF specialist pharmacists with training and experience in CF care, with a minimum staffing ratio as described in the current 'Standards for the Clinical Care of Children and Adults with Cystic Fibrosis in the UK'<sup>5</sup> and in England the 'NHS England Service Specifications'.<sup>6,7</sup> This level of staffing is required to oversee the routine pharmaceutical care practice as described below.

Since the 'Standards of Care' and 'Service Specification' documents were first published, the care of people with CF has been revolutionised by the introduction of oral disease-modifying therapies for large numbers of people with CF. The resource required to manage these medicines should be considered additional to that described in the current Standards of Care and should be included in the pharmacy resource provided in each CF centre.

Continuity and succession planning should be in place to ensure the appropriate service level is maintained if the CF specialist clinical pharmacist is unavailable.

### 3.1 Clinical pharmacy technician

Clinical pharmacy technicians operate across the clinical pharmacy service in all NHS hospitals in the UK. Appropriately using the skills of clinical pharmacy technicians supports the CF specialist pharmacist to fully utilise their skills to improve patient care.

#### Clinical pharmacy technicians can support people with CF by:

- Ensuring complete medicines reconciliation is undertaken on admission to or discharge from hospital and at outpatient or annual review.
- Acting as the main point of contact for primary care pharmacists (based in community pharmacies, GP practices or primary care networks (PCNs)).
- Acting as a go-between on CF-related pharmaceutical matters between CF centres and lung transplant centres where appropriate.
- Acting as a point of contact for people with CF for medicines-related issues.
- Counselling people with CF on new or altered medicines.
- Managing the administration around repeat prescribing, including homecare services.
- Supporting the governance and medicines safety agenda in CF.
- Supporting audit and research in the CF MDT.
- Collecting data and delivering patient interventions to support medicines adherence and remote monitoring.

In some hospitals, clinical pharmacy technicians have also been used to provide the manufacture of sterile products at ward level (for example, drawing up IV medicines) and to administer medicines to patients (usually oral medicines rounds).

### 3.2 People with CF/ their parents or carers

#### People with CF and (where appropriate) their parents or carers should:

- See a CF specialist pharmacist soon after diagnosis (whether diagnosed through newborn screening or as a result of a later diagnosis).
- Have face-to-face (or 'virtual') access to a CF specialist pharmacist at each outpatient appointment if required and should be seen by the full MDT, including the CF specialist pharmacist, at least biannually.
- Be reviewed at an appropriate frequency by a CF specialist pharmacist while an inpatient, during normal working hours with access to on-call and weekend clinical pharmacy support via non-specialist pharmacists, as detailed above. The CF specialist pharmacist should be able to provide daily review (at least Monday to Friday) for any person with CF who is acutely unwell.
- Have a full medication review by a CF specialist pharmacist at annual review including individualised assessment of adherence with medicines. From this review relevant information should be disseminated to the individual, the MDT, GP, transplant centre and where appropriate the community pharmacist with appropriate consent in place.
- Be able to contact the CF specialist pharmacist or an appropriate member of the pharmacy team in case of issues with access to their usual medicines in primary care, or regarding medicines homecare services.

- Have timely access to advice from a CF specialist pharmacist when required.

### **3.3 Role of the CF specialist pharmacist**

#### **CF specialist pharmacists should:**

- Attend inpatient CF ward rounds.
  - Attend CF MDT meetings.
  - Be available during outpatient clinics to support people with CF.
  - Prescribe medicines routinely for people with CF within their scope of practice, where appropriately qualified and validated.
  - Provide support and advice for community pharmacists who provide a service for people cared for at the CF centre.
  - Liaise with commissioning colleagues within the relevant commissioning organisations to set budgets for medicines used in CF, implement commissioning policies, and deliver financial efficiency programmes.
  - Support and educate pharmacy, nursing, and medical colleagues at centres within a shared care network.
  - Liaise with paediatric/adult centres during transition of care.
  - Establish and maintain close links with the transplant pharmacist at their linked lung transplant centres including liaison during the referral process for transplantation for individuals with CF.
  - Liaise with the relevant transplant centre after transplantation to ensure clear lines of responsibility for medication delivery and review, and to co-ordinate advice and guidance around medication changes that may interact with immunosuppressant therapy.
  - Be an active member of United Kingdom Cystic Fibrosis Pharmacy Group (UKCFPG) and/or the European Cystic Fibrosis Pharmacists Group (ECFPG) as part of the European Cystic Fibrosis Society (ECFS).
  - Maintain CF-specific Continuing Professional Development (CPD) through appropriate study and attendance at relevant study days, national and international conferences.
- Consider the need for further development to support people with CF in taking their medicines appropriately (coaching, motivational interviewing, adherence support techniques).
  - Carry out, contribute to, and publish research relevant to the pharmaceutical care of people with CF.

# 4. Medicines optimisation for CF specialist pharmacy teams

- Where a person with CF is referred to, these standards apply equally to a parent or caregiver where appropriate.
- While the principles of excellent pharmaceutical care in CF remain consistent across different nations the commissioning arrangements vary.

## 4.1 CF specialist pharmacist/person with CF interactions

- A CF specialist pharmacist should be available to all people with CF cared for by the CF centre.
  - Where network care is provided, the CF specialist pharmacist may not be able to review all people with CF at peripheral centres, but they should have the ability to input into the care of those people with CF.
  - The pharmacy team should put the best care of the person with CF at the heart of everything that they do and should actively advocate for them.
  - Shared decision-making around the use of medicines should be embedded within the practice of the pharmacy team.
- Support the CF MDT in understanding the commissioning and reimbursement of high-cost medicines used in CF within the context of the responsible commissioner.
  - Assist in the completion of any required prior-approval forms and, where no mechanism exists to routinely fund a particular treatment, Individual Funding Requests<sup>8</sup> (or local equivalent as per the responsible commissioner's policy).
  - Liaise with the responsible commissioner to resolve inequality of access to medicines and to set budgets for high-cost medicines (those commissioned outside of a tariff-system), based on predicted usage.
  - Ensure there is effective communication with other members of the CF MDT, primary care, other specialties, and transplant centres.
  - Carry out horizon scanning and critical evaluation of recent studies on new and existing therapies.
  - Compare practice to that of other centres nationally and internationally to ensure that evidence-based treatments are being offered equitably.
  - Contribute to the tender process for homecare services such as home intravenous antibiotics, providing medicines information and advice relating to medicines used in CF, and represent the interests of the CF service at local homecare review or governance meetings.

### CF specialist pharmacist prescribing

- CF specialist pharmacists should undergo training as independent prescribers to best support CF MDT working.
  - Once qualified, CF specialist pharmacists should actively prescribe as part of the CF MDT.
  - CF specialist pharmacist prescribers should prescribe within their scope of practice.
  - Prescribing should be supported by shared decision-making.
  - Prescribing should be supported through informed consent as appropriate.
- Contribute to the education and training of other healthcare professionals, including primary care, other members of the MDT and other professions in secondary and tertiary care.
  - Lead training for others within the pharmacy department in relation to CF.
  - Advise on the legal and ethical framework for the use of medicines, including additional requirements when prescribing unlicensed/off-label medicines and to ensure that prescribers are aware when they are prescribing unlicensed/off-label medicines, and that people with CF are kept informed about the medicines they are prescribed.

### Managing formularies, clinical guidelines, and treatment protocols

CF specialist pharmacists should:

- Assist in the completion of formulary applications to ensure medicines are introduced into clinical practice via local joint hospital and primary care formulary processes, including the development of shared care protocols where appropriate.
- Advise on the administration of medicines, including the safe administration of IV drugs, administration via enteral feeding tubes and the selection of formulations most appropriate to a person with CF.

- Source medicines, including unlicensed medicines of a suitable quality when required.
- Resolve medication supply problems and liaise with primary care to ensure ongoing supply is available to all patients or to suggest alternative medication where necessary.
- Lead and contribute to CF research and development.
- Work collaboratively with other members of the MDT to optimise the use of medicines in individual patients (for example, with physiotherapists to optimise nebulised therapy or dietitians to optimise pancreatic enzyme replacement therapy).
- Be aware of, and advise on minimising the environmental impacts of medication use in people with CF. This should include considerations of overprescribing or stockpiling of medicines, and the comparative environmental impact of different medicines (for example metered dose vs dry powder inhalers).

#### Medicines reconciliation should:

- Be undertaken within 24 hours of admission to hospital and at least annually (as part of annual review) as a minimum.
- Include a review of alternative and over-the-counter medicine usage.
- Include a review of medicines supplied via homecare and other specialties within secondary care.
- Include a review of someone's adherence with their medication regimen.
- Ensure that an accurate history is recorded, including all previous allergic reactions and adverse effects.
- Ensure that all relevant information is effectively disseminated to primary care (with appropriate consent), including use of electronic summary care records where available.

#### Prescription monitoring and medication review service

##### CF specialist pharmacists should:

- Ensure medication and formulations are appropriate for the person with CF at that point in time.
- Prescribe – to support the CF service (where appropriately qualified).
- Promote adherence with local and national formularies.

- Investigate and report medication errors and put systems in place to minimise the risk of harm associated with medicines.
- Ensure prescriptions are complete, unambiguous, and legal including those sent to homecare providers.
- Identify and manage drug/drug and drug/patient interactions and optimise the effectiveness of treatments while minimising the risks of adverse effects.
- Support people to make informed decisions about their own treatments.
- Provide support and advice on the treatment of people with CF being cared for outside of the specialist CF unit (for example on surgical, admissions or maternity wards).

#### Identifying patient and medication risk factors

##### CF specialist pharmacists should:

- Ensure individual characteristics including age, expectation of care, pregnancy, breastfeeding, and organ dysfunction are taken into account whenever a drug is prescribed, or whenever a person's characteristic alters.
- Use someone's response to previous and current medication in addition to the evidence base to guide their future treatment.
- Advise on the risks and benefits of non-drug and complementary therapies.
- Ensure appropriate informed consent is given before commencing any medicines in line with national recommendations.

#### Preventing, detecting, and reporting adverse drug events

##### CF specialist pharmacists should:

- Document and report all reactions to newer medicines and serious reactions to established medicines to the MHRA via the [yellow card system](#).
- Actively monitor for and document toxicity caused by medication including allergies/hypersensitivity, contraindications, and other adverse drug reactions.
- Advise on the appropriate use, storage, and disposal of medicines to minimise adverse events and risk to others and the environment.
- Manage the use of medicines during pregnancy and ensure all exposure to medication during pregnancy is recorded and documented via [UK Teratology Information Service](#).



## Individualising drug and dosage requirements

CF specialist pharmacists should:

- Maximise therapeutic potential and minimise adverse effects of medicines by tailoring the treatment regimen to the individual.
- Manage therapeutic drug monitoring of relevant medicines (for example aminoglycosides, antifungals and immunosuppressants) depending on an individual's pharmacokinetic variables.
- Monitor and review the outcome of a person's need for medication.
- Consider the ongoing need for prescribed medicines at each review, and/or carry out deprescribing of medicines where appropriate.
- Work with people to promote and support adherence to their prescribed treatments.
- Optimise use of medicines, taking account of and respecting the person's wishes and lifestyle.
- Advise on the most appropriate treatments for people with CF approaching the end of life.

## Antimicrobial stewardship

CF specialist pharmacists should:

- Participate in the production of CF centre antimicrobial guidelines.
- Work closely with prescribers to ensure that the most appropriate antimicrobials are selected, taking into account individual and organism factors.
- Liaise with local antimicrobial stewardship teams to monitor and review local usage within the CF MDT.

## Educating and counselling patients and carers

CF specialist pharmacists should:

- Provide appropriate education and counselling to each person with CF that enables the safe and effective use of their medicines.
- Provide information, as a minimum, in verbal and written formats comprehensible to the intended audience.
- Improve adherence with medicines by identifying intentional and unintentional non-adherence, and support and empower people with CF to improve their adherence.
- Agree an informed plan with each person to achieve a concordant approach to treatment and adherence.

- Support people with CF in accessing prescription exemption certification and pre-payment options where appropriate.
- Consider the burden of any prescribed treatments and the impact on the person with CF.

## Providing medication closer to home

- Services should be established that allow people with CF to receive chronic medication via an agreed model, including where appropriate, homecare services.
- Homecare services and outsourced outpatient dispensary models should be used wherever possible to minimise the impact of VAT on the cost of medicines supplied to people with CF.
- Any external provision of pharmacy services to people with CF should be overseen by the CF specialist pharmacist and audited against set standards.
- Homecare services should be audited against the [Royal Pharmaceutical Society's Professional Standards for Homecare Services](#).

## Evaluating medicines use and financial management

CF specialist pharmacists should:

- Provide financial reporting to the CF MDT, more widely within the provider organisation and to commissioners through appropriate mechanisms.
- Contribute to budget planning for high-cost and in-tariff medicines.
- Contribute to business cases involving medicines use in CF.
- Audit treatment guidelines and new therapies.
- Audit pharmacy and homecare service.

## Research and service improvement

CF specialist pharmacists should:

- Lead on clinical pharmacy service improvement within the CF MDT and pharmacy team.
- Deliver practice-based research.
- Contribute to wider MDT research agendas.

## 5. References

- 1 NICE. Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes (NG5). 2015.
- 2 Redfern J, Webb K. Benefits of a dedicated cystic fibrosis pharmacist. *Journal of the Royal Society of Medicine*, 2004; 97: 2–7.
- 3 Royal Pharmaceutical Society. Professional Standards for Homecare Services in England. 2013.
- 4 Hackett M. Department of Health. Homecare Medicines: Towards a vision for the future. 2011.
- 5 Cystic Fibrosis Trust. Standards for the Clinical Care of Children and Adults with Cystic Fibrosis in the UK. 2011.
- 6 NHS England. Service Specification: Cystic Fibrosis – Adults. 2018.
- 7 NHS England. Service Specification: Cystic Fibrosis – Children. 2018.
- 8 NHS England. Standard Operating Procedures: Individual Funding Requests. 2018.

# Cystic Fibrosis Trust

Cystic Fibrosis Trust is the charity uniting people to stop cystic fibrosis. Our community will improve care, speak out, support each other and fund vital research as we race towards effective treatments for all.

**We won't stop until everyone can live without the limits of cystic fibrosis.**

## **Cystic Fibrosis Trust**

One Aldgate  
2nd Floor  
London EC3N 1RE

**020 3795 1555**

**[cysticfibrosis.org.uk](https://cysticfibrosis.org.uk)**

We welcome your feedback on our resources. You can also ask for this resource in large print or as a text file.

Email **[infoteam@cysticfibrosis.org.uk](mailto:infoteam@cysticfibrosis.org.uk)**