

Service Specification No.	TBC
Service	Supply of vancomycin and fidaxomicin for the urgent treatment of <i>Clostridioides difficile</i> by community pharmacy providers within NHS Surrey Heartlands ICB
Commissioner Lead	NHS Surrey Heartlands ICB
Provider Lead	Named community pharmacy premises
Period	1 st Nov 2022 – 31 st March 2025
Date of Review	1 st April 2025

1. Population Needs

1.1 National/local context and evidence base

1.1.1 Introduction

This locally commissioned service (LCS) specification outlines the specialised service to be provided by a limited number of community pharmacies in Surrey Heartlands. The specification of this service is designed to cover the supply of two antimicrobials, vancomycin and fidaxomicin, only when urgent treatment is required for *Clostridioides difficile* (C.diff) AND supply cannot be made in a timely manner through routine dispensing routes.

1.1.2 Background

In July 2021, NICE published new guidance on treatment of C.diff that included recommendations for prescribing vancomycin and fidaxomicin in primary care.

[Overview | Clostridioides difficile infection: antimicrobial prescribing | Guidance | NICE](#)

Before NICE guidance was published, prescribing of these drugs was extremely low and stock was not routinely held by community pharmacists. Whilst the prescribing by primary care, in line with the NICE guidance, was deemed appropriate by the Area Prescribing Committee in November 2021, it was noted that access in a timely manner could be compromised by community pharmacy next day delivery schedules – particularly at weekends or Bank Holidays when no wholesaler deliveries are made.

Acute trust consultants confirmed that a short delay up to one day would not be clinically significant for community treated patients but quicker access to first line choice antimicrobial would be appreciated to avoid delay in treatment of acutely unwell patients. For the occasions when the ordering and/or delivery schedule of a pharmacy will mean significant delay to access of vancomycin or fidaxomicin this locally commissioned service has been developed.

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

- To improve access to these medicines when they are required by ensuring timely supply.
- To support patients and carers by providing up-to-date advice and guidance on self-care.
- To gather intelligence about any issues related to access because of local routine supply processes.

3. Scope

3.1 Aims and objectives of service

3.1.1 Aim:

To reduce the risk of complications from and spread of C.diff, and to optimise antibiotic use and reduce antibiotic resistance by providing access to treatment in a timely manner when routine routes of supply will cause clinically unacceptable delay.

3.1.2 Objectives:

- To ensure that people with C.diff and who have been prescribed vancomycin or fidaxomicin are
 - Able to access the drugs within primary care, promptly, from a choice of locations within Surrey Heartlands geography (at least one per place will be commissioned)
 - Provided with advice on self-care of C.diff infection
- To learn from use of the service if there are any issues with local routine routes of supply

3.2 Drugs covered

Each provider will be required to stock (as a minimum) the following items:

Drug	Preparation	Volume	Consumables
Fidaxomicin	200mg tablets	1 original pack (20 tablets)	
Fidaxomicin	40mg/ml granules for solution	1 original pack (7.7g for 110ml solution)	Oral syringes and adaptor for paediatric doses*
Vancomycin	125mg capsules	4 original packs (40 capsules)	
Vancomycin	250mg capsules	8 original packs (80 capsules)	

* An appropriate commercially available oral syringe and adaptor suitable for dispensing of liquid medicines should be selected by the healthcare professional in order to allow the patient or caregiver to measure the correct dose. The adaptor should be suitable for use in combination with the selected oral syringe and fits the bottle neck size, for example a press-in bottles adaptor (27 mm) or universal bottle adapter (SPC accessed 13/9/22)

3.3 Population covered (inclusion and exclusion) criteria

XX community pharmacies will provide the service based on location and opening hours. An expression of interest form is available at appendix 1 to apply for service provision. Appointed sites are listed in appendix 2.

3.3.1 Inclusion:

- Adults and children as per NICE guidance, BNF and SpC
- Patients can only be accepted into the service on presentation of a valid FP10 prescription (or via EPS – Electronic Prescription service) for vancomycin or fidaxomicin. An emergency supply can also be made at the request of a prescriber with a prescription to follow.

3.4 Service description/care pathway

The service requires the pharmacy to:

- 1) Fill any prescription presented for fidaxomicin or vancomycin presented for urgent treatment when referred by a pharmacy that cannot supply without significant delay.
- 2) Advise patients or carers about:
 - drinking enough fluids to avoid dehydration
 - preventing the spread of infection
 - seeking medical help if symptoms worsen rapidly or significantly at any time.
- 3) Complete and return a quarterly data collection form to monitor service use and identify issues with routine supply routes in Surrey Heartlands (appendix 3).

To provide the service, the pharmacy must be able to meet the following requirements:

- a. The pharmacy holds the specified medicines, required to deliver this service, in stock and will dispense (and re-order) these in response to an NHS prescription presented.
- b. The pharmacy must keep each a minimum stock level of the drugs described in section 3.2.

Full packs as described in section 3.2 must be kept in stock, if a pack is split to fulfil a prescription, then a new full pack should be re-ordered.

- c. If the pharmacy is not able to dispense the prescription when presented, then they need to find another community pharmacy that is able to fill the prescription. This should be done by telephoning another community pharmacy to ensure they have the medication in stock, it should not be assumed that because a community pharmacy is on the service list they can supply on every occasion.
- d. In the event of supply issues or long-term availability problems, the pharmacy will inform the Medicines Optimisation Team at Surrey Heartlands ICB and Surrey LPC by email or phone enabling the issue to be cascaded to relevant parties:
 - o Surrey LPC: Julia Powell at lpc@communitypharmacys.co.uk
 - o NHS Surrey Heartlands: Debbie Bunn at Deborah.bunn@nhs.net or sarah.watkin1@nhs.net
- e. The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the delivery of the service.
- f. The pharmacy will have and maintain a Standard Operating Procedure to meet all these service requirements and reflect changes in practice or guidelines.
- g. The pharmacy must demonstrate it has sufficient indemnity cover to support the provision of this service.
- h. The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols. This includes all locum pharmacists.
- i. The ICB will promote awareness of the service with prescribers and other healthcare professionals including the Acute Trusts.
- j. The ICB will regularly review the service and drug choice to ensure that it reflects the availability of new medicines and changes in practice or guidelines.
- k. When drugs held in stock expire - stock should be replenished as soon as possible and a claim can be made by the pharmacy to the ICB via Claim form (appendix 4) to cover the cost and replacement of these drugs.
- l. The ICB will disseminate information on the service to other health care professionals in order that they can signpost patients to the service.

The ICB and Local Pharmacy Committees will disseminate information on the service to other pharmacy contractors in order that they can signpost patients to the service

3.5 Interdependence with other services/providers

- Details of the pharmacies will be circulated to all GP surgeries, Acute Trusts, Out of Hours GP providers and to other Community Pharmacies.
- During working hours, it is anticipated that in the first instance, prescriptions should be presented at any local community pharmacy, and this urgent service used mainly in those situations where the medication cannot be obtained in a timely manner (up to one day after prescription presentation).

3.6 Monitoring and Audit

- The provider should audit the standards of the service on an annual basis to ensure compliance with the LCS requirements and identify areas for improvement, which the provider would need to address.

- The provider is required to submit an annual (1st April – 31st March) audit return form (appendix 5) to the ICB's Medicines Optimisation Team (MOT) on an annual basis (by the 30th April of each year).
- The level of service provided will be monitored by such means as required by Surrey Heartlands ICB.
- The provider should obtain feedback on the service from the patients who use it. This feedback should be reviewed by the provider and where appropriate, changes should be made in order to improve the quality of the service. If feedback obtained is related to changes in this LCS, this should be given to the ICB (section 9).

4. Training and Competence

The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service. The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols. This includes all locum pharmacists

7. Applicable Service Standards

7.1 Applicable standards

Applicable standards include but are not limited to:

- NICE guidance [Overview | Clostridioides difficile infection: antimicrobial prescribing | Guidance | NICE](#)
- Community pharmacy contractual framework [Community Pharmacy Contractual Framework: 2019 to 2024 - GOV.UK \(www.gov.uk\)](#)

7.2 Further information

- Surrey PAD [Prescribing Advisory Database \(res-systems.net\)](#)
- British National Formulary (BNF) [BNF \(British National Formulary\) | NICE](#)
- Summaries of Product Characteristics (SPC) [Home - electronic medicines compendium \(emc\)](#)

8. Pricing and Costs

8.1 Pricing

Surrey Heartlands ICB agree to pay the following:

- Annual retainer of £435 for pharmacies participating in the scheme.
- Upfront payment for stock levels required to initiate the service at Drug Tariff price plus VAT.
- Reimburse the cost of medicines on the list which have expired. The reimbursement will be claimed by invoicing the ICB at the cost in the Drug Tariff (plus VAT) at the time of the claim. Payments will be made within 30 days of the invoice. A template is available at appendix 4.
- Should, following a review, items be removed from the list then the usual 'out of date' claims process should be followed for the next 6 months. The removed items should not be re-ordered and any remaining undispensed stock (after 6 months) should be claimed as 'out of date/no longer in use'. Such changes will be communicated to the providers and timescales outlined.

8.2 Claims

- Each community pharmacy contracted to provide this service will receive payment from the ICB following receipt of the invoice claim form for expired stock (appendix 4) via NHS Shared Business Services.

The Provider must submit an invoice to SBS via an e-Invoicing platform in accordance with SC 36.49 with the invoice claim form as an attachment to the electronic invoice. E-Invoicing guidance can be found here:

<https://www.sbs.nhs.uk/supplier-einvoicing>

The invoice claim form

- Must be completed FULLY,
- Must be scanned legibly,
- Must have all sections of the form completed by **typing** and **NOT handwritten** (other than the signature).

Providers transitioning to e-Invoicing may continue to submit invoice claim forms on paper but only with the written permission of the Commissioner.

Invoice claim forms that are submitted on paper:

- Must be completed FULLY,
- Must be legible as they will be scanned by SBS,
- Must not be printed on dark paper or in purple ink as this will spoil the scanning process,
- Must have all sections of the form completed by **typing** and **NOT handwritten** (other than the signature),
- Must NOT have staples as this may create problems when the form is scanned by SBS and
- Must be sent **NHS Surrey Heartlands ICB, QXU Payables M895, Phoenix House, Topcliffe Lane, Wakefield, WF3 1WE.**

Personal identifiable data must not be included with any invoice or any on documentation relating to claims for payment sent to the Commissioner

9. Termination

The provider may terminate this agreement by giving NHS Surrey Heartlands ICB 3 months' notice in writing of its intention to do so. Such notice, once given, may only be withdrawn with the agreement of NHS Surrey Heartlands ICB who shall not be required to agree.

NHS Surrey Heartlands ICB may terminate this agreement:

- By giving 3 months' notice of termination in writing. Such notice, once given, may only be withdrawn with the agreement of the provider who shall not be required to agree.
- By giving any period of notice it considers appropriate, including none, if it considers this to be necessary in the interests of patient safety.
- If it is brought to the ICB's attention that a provider has breached the requirements as set out in this service specification, then the provider may be asked to withdraw from providing the service.

10. Location of Provider Premises

The Surrey PAD (<https://surreyccg.res-systems.net/PAD/>) contains the list of providers who are commissioned to provide this service. Search vancomycin or fidaxomicin

11. References

1. National Institute for Health and Care Excellence [NG199]: Clostridioides difficile infection: antimicrobial prescribing. NICE July 2021. Available from: [Overview | Clostridioides difficile infection: antimicrobial prescribing | Guidance | NICE](#)
2. Surrey Heartlands Area Prescribing Committee. Vancomycin and fidaxomicin in Clostridioides difficile. Surrey Prescribing Advisory Database November 2021. Available from: [Profile : Vancomycin - Clostridioides difficile \(res-systems.net\)](#) and [Profile : Fidaxomicin - Clostridioides difficile \(res-systems.net\)](#)
3. Electronic Medicines Complete. Summary of Product Characteristics for vancomycin products [Search Results - \(emc\) \(medicines.org.uk\)](#)
4. Electronic Medicines Complete. Summary of Product Characteristics for fidaxomicin products [Search Results - \(emc\) \(medicines.org.uk\)](#)
5. British National Formulary. Vancomycin [Vancomycin | Drugs | BNF | NICE](#)
6. British National Formulary. Fidaxomicin [Fidaxomicin | Drugs | BNF | NICE](#)

Appendix 1:

Expression of interest to provide a C. difficile stock supply service within NHS Surrey Heartlands ICB

ALL SECTIONS ON THIS APPLICATION FORM MUST BE COMPLETED

Pharmacy stamp (including name and address): Opening hours:

	Mon:
	Tue:
	Wed:
	Thu:
	Fri:
	Sat:
	Sun:

Pharmacy premises questions	Circle either Yes or No
The pharmacy premises has a consultation room available?	Yes / No
This consultation room can provide sufficient level of privacy and safety and meets any national contractual requirements?	Yes / No

I wish to provide this service and on appointment, I will ensure that the requirements as set out in the service specification are adhered to when providing this locally commissioned service.

Lead contact name (BLOCK CAPITALS):.....

Lead contact position:.....

Lead contact signature:.....

Lead contact email address:.....

Lead contact telephone number:.....

Date:.....

Please return this completed form to:

- Julia Powell, at lpc@communitypharmacys.co.uk
- On receipt of the completed application form, the Medicines Optimisation Team will review all expressions of interest received and appoint up to six pharmacies with at least one in each of North Surrey, Guildford and Waverley, Surrey Downs and East Surrey. Longer opening hours will be given preference if there are multiple applications from any one Place.
- You will be contacted to confirm the decision made in relation to you expression of interest.

Appendix 2:

**Current Community Pharmacy Providers of the C. difficile stock supply service within NHS
Surrey Heartlands ICB**

Date: xx/xx/xxx

Place	Pharmacy name & address	Telephone number	Opening hours

Appendix 3:

Data collection form for C. difficile stock supply service within NHS Surrey Heartlands ICB

ALL SECTIONS ON THIS APPLICATION FORM MUST BE COMPLETED

Pharmacy stamp (including name and address):

	Time period covered:
	Total number of patients:

This form is required quarterly from each provider and should be completed for each patient seen to fulfil the service requirements of:

- 1) Advising patients or carers about:
 - drinking enough fluids to avoid dehydration
 - preventing the spread of infection
 - seeking medical help if symptoms worsen rapidly or significantly at any time.
- 2) Completing and returning a quarterly data collection form to monitor service use and identify issues with routine supply routes in Surrey Heartlands.

Lead contact name (BLOCK CAPITALS):.....

Lead contact position:.....

Lead contact signature:.....

Lead contact email address:.....

Lead contact telephone number:.....

Date:.....

Please return this completed form to:

- Charlotte Kihlstrom, Administrator Medicines Optimisation Team: charlotte.kihstrom1@nhs.net

Individual Patient Data collection form for C. difficile stock supply service within NHS Surrey Heartlands ICB (form Of....)

Patient →	1	2	3	4	5
Question ↓					
1. Drug and quantity prescribed					
2. Was all quantity supplied on presentation of the prescription and no requirement for an owing [Y/N]					
If No: 2a. Reason for non-supply or partial supply					
2b. Action taken e.g. signpost to alternative supplier					
3. Day & Date prescription issued					
4. Was prescription issued within normal GP working hours [Y/N]					
5. Date and time medication supplied					
6. Were other pharmacies tried before presenting to you [Y/N]					
If Yes: 6a Reason (if known) for referral to you from another community pharmacy					
6b Name / address of previous sites tried					
7. Infection prevention control advice given [Y/N]					

C. difficile stock supply invoice claim form

Requirements of this form

- **NO patient identifiable** data should be included. This includes any patient names, NHS numbers and addresses.
- All sections of the form should be **typed** and **NOT handwritten** (other than the signature).

Please note that payment will not be made unless this form has been completed FULLY in the line with the requirements above

Pharmacy stamp (including name and address): **Contact details:**

	Name:
	Position:
	Email:
	Tel:

Billing address	Invoice date:
XXCKIHLSTROM NHS Surrey Heartlands ICB, QXU Payables M895, Phoenix House, Topcliffe Lane, Wakefield, WF3 1WE	*Invoice number:

QUANTITY	DESCRIPTION (delete rows as necessary)	UNIT PRICE (£)	AMOUNT (£)
1	Annual retainer	435	
	<i>Insert year covered</i>		
	<u>Initial drug stock</u> <i>Use current drug tariff price +VAT</i>		
10P	Fidaxomicin 250mg tablets x20 tabs		
10P	Fidaxomicin 40mg/ml granules x7.7g		
40P	Vancomycin 125mg capsules x40 caps		
80P	Vancomycin 250mg capsules x80 caps		
	<u>Expired stock</u> <i>Use current drug tariff price +VAT</i>		
	<i>Insert drug name, presentation and quantity</i>		
TOTAL DUE			

*Invoices received without an invoice number will be returned. NHS Shared Business Services is able to process invoice numbers of up to 39 alphanumeric characters.

Appendix 5:

Annual audit return form 1st April – 31st March

Please return this FULLY completed form by the 30th April of each year to:

Charlotte Kihlstrom (Administrator, Medicines Optimisation Team): charlotte.kihlstrom1@nhs.net

Pharmacy stamp (including name and address):

- Please confirm that your standard operating procedures for this service have been updated within the last 12 months:

- Please confirm that that you have obtained feedback on the service from the patients who use in order to improve the quality of the service provided?
.....

- If any of the patient feedback obtained was related to changes in this LCS, please include this below:
.....

- Please confirm that pharmacists (including locum pharmacists) and staff involved in the provision of the service are aware of and operate within local protocols relevant to this service:
.....

Lead contact name (BLOCK CAPITALS):.....

Lead contact position (BLOCK CAPITALS):.....

Lead contact signature:.....

Lead contact email address:.....

Lead contact telephone number:.....

Date:.....