

Service specification:

NHS lateral flow device tests supply service for patients potentially eligible for COVID-19 treatments

Advanced service

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Contents

1. Service background	4
2. Service objectives	4
3. Requirements for service provision	4
4. Service description	5
5. Testing and test outcomes	7
6. Data and information management	7
7. Payment arrangements	8
8. Withdrawal from the service	8
9. Monitoring and post-payment verification	8
9.1 Monitoring	8
9.2 Post-payment verification	9

1. Service background

The NHS offers COVID-19 treatment to people with COVID-19 who are at risk of becoming seriously ill. Prior to the introduction of this service, rapid lateral flow device (LFD) tests were available to order by these patients on GOV.UK or by calling NHS 119. These kits were then delivered directly to the patient's home.

Since 6 November 2023, LFD tests are no longer available via GOV.UK or via NHS 119. LFD tests still need to be available and easily accessible to people who are potentially eligible for COVID-19 treatments through routine NHS access routes. It is estimated that in the short-term, the number of potentially eligible patients is around 5.3m.

Although access to LFD tests may be supplemented by other pathways (e.g., through anticipatory or specialist care), community pharmacy is well placed within the local community to provide local and rapid access for patients.

Access to COVID-19 community-based treatment will continue to be based on a confirmed COVID-19 infection, achieved with a diagnostic LFD test, in line with some of the recommended treatment's product licences. Given the short efficacy window for treatment and practical implications of point-of-care testing, tests need to be available for eligible patients to access in advance of developing symptoms.

2. Service objectives

The objective of this service is to offer eligible, at-risk patients access to LFD tests to enable testing at home for COVID-19, following symptoms of infection. A positive LFD test result will be used to inform a clinical assessment by the patient's clinician to determine whether the patient is suitable for, and will benefit from, NICE-recommended COVID-19 treatments.

3. Requirements for service provision

Prior to provision of the service, the pharmacy contractor must:

- a) be satisfactorily complying with their obligations under Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations (Terms of Service of NHS pharmacists) in respect of the provision of Essential services and an acceptable system of clinical governance.
- b) notify NHS England that they intend to provide the service by completion of a registration declaration on the NHS Business Services Authority's (NHSBSA) Manage Your Service (MYS) platform.

The pharmacy contractor must have a standard operating procedure (SOP) for the service. This should be reviewed regularly and following any significant incident or change to the service. The pharmacy contractor must ensure that all pharmacy staff involved in the provision of the service are familiar with and adhere to the SOP.

The contractor is required to report any patient safety incidents in line with the clinical governance approved particulars for pharmacies.¹

The pharmacy contractor must ensure that they update NHS Profile Manager to show that the pharmacy provides the service, and this is consequently visible on the pharmacy's NHS website profile and in the Directory of Services (DoS).

The pharmacy contractor must seek to ensure that the service is available throughout the pharmacy's full opening hours (i.e., core and supplementary).

LFD Tests should be ordered by pharmacies via their usual wholesalers. If the community pharmacy has no LFD tests in stock at the time of a patient request, the pharmacy must liaise with a neighbouring pharmacy which has stock, to support the patient/patient representative in obtaining LFD tests.

The pharmacy contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible person shall be excluded, nor experience difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

4. Service description

This is a walk-in service where patients/patients' representatives can collect one box of five LFD tests from a participating community pharmacy, on confirmation that the patient is part of the cohort which is potentially eligible for COVID-19 treatments.

The full list of eligible patients who are at risk of getting seriously ill from COVID-19, and therefore are potentially eligible for COVID-19 treatments, can be found in NICE guidelines: [Supporting information on risk factors for progression to severe COVID-19](#).

¹ [Clinical governance approved particulars for pharmacies – GOV.UK \(www.gov.uk\)](#)

Contractors should make sure they are referring to the latest version of the eligibility risk factors to confirm a patient's eligibility, in the absence of a patient's NHS letter confirming the patient's eligibility for free LFD tests.

Patients who become newly eligible for access to free LFD tests should be made aware of eligibility by their doctor or specialist at the point they are diagnosed with a qualifying condition or commence a qualifying treatment regimen.

The pharmacy contractor must confirm the patient's eligibility for a supply of LFD tests. This could be by:

- seeing the patient's NHS letter which confirms eligibility;
- having a discussion with the patient or their representative about the patient's medical history, confirming they have a qualifying condition;
 - the pharmacist or pharmacy technician may wish to review the [National Care Records Service \(NCRS\)](#) and then use their clinical judgement;
- referring to the pharmacy's clinical records for the service; where the pharmacy has previously seen, and made a record of having seen, a copy of the patient's NHS letter confirming eligibility.

Following the publication of updated final guidance by NICE on 13/03/2024, a number of additional patient groups are now eligible for COVID-19 treatments. In line with these recommendations, NHS England is expanding access to LFD testing from 1 April 2024 for:

- people aged 85 years and over
- people with end-stage heart failure who have a long-term ventricular assistance device
- people on the organ transplant waiting list
- people aged 70 years and over, or who have a BMI of 35 kg/m² or more, diabetes or heart failure, and:
 - are resident in a care home, or
 - are already hospitalised

The pharmacy contractor should satisfy themselves that the patient is eligible to receive LFD tests – i.e. has at least one risk factor for progression to severe COVID-19, as set out in the [NICE guidelines](#); that it is providing tests to potentially eligible patients at appropriate intervals; and that requests do not exceed what is deemed reasonably required for an eligible patient.

(For example, the pharmacy is not supplying tests beyond the requirements of the eligible patient; not supplying multiple boxes of tests in a single visit; not supplying multiple boxes of tests over a short period.)

Eligible patients should only receive one box of five LFD tests per consultation.

Community pharmacies will order LFD tests through their usual suppliers.

5. Testing and test outcomes

Patients will have been advised to take an LFD test as soon as possible if they have any symptoms of COVID-19, even if their symptoms are mild. Patients are advised to only use a test if they have symptoms.

If a patient tests positive, they have been advised to call their general practice, NHS 111 or hospital specialist as soon as possible.

If a patient tests negative, but still has symptoms of COVID-19, they have been advised to take a total of three rapid LFD tests over three consecutive days. If any of the tests are positive, they should stop testing and contact their general practice, NHS111 or hospital specialist as soon as possible. Full information can be found here : [NHS England » Letter to patients: Important information about treatments for Covid](#)

6. Data and information management

The pharmacy contractor must advise the patient or the patient's representative of the following information-sharing that will take place:

- The sharing of information about the service with NHS England, as part of service monitoring and evaluation.
- The sharing of information about the service with NHSBSA and NHS England, for the purpose of contract management and as part of post-payment verification.

The pharmacy contractor must maintain appropriate records of the supply of an LFD test kit and the following information must also be recorded on NHSBSA's Manage Your Service (MYS) portal:

- Patient's NHS number (if available)
- Patient's full name
- Patient's date of birth
- Patient's address

- Confirmation of eligibility, i.e. patient letter seen/clinical history assessment against eligibility criteria
- Confirmation one box of five LFD tests supplied
- Date of supply
- The batch/lot number of LFD tests supplied.

If the lateral flow test kit is being requested on behalf of someone else, the following additional information must be recorded in the pharmacy contractor's records and recorded on the MYS portal:

- Patient representative full name
- Patient representative address.

7. Payment arrangements

Pharmacy contractors providing this service will be paid according to arrangements set out within the Drug Tariff Part VIC. This will include a fee for each supply to an eligible patient or patient representative and arrangements to cover the cost of the tests provided.

Contractors will need to submit their claims for payment within the MYS portal, as part of the normal month end claims process.

Claims for payment should be submitted within one month of, and no later than three months from the claim period for the chargeable activity provided. Claims which relate to work completed more than three months after the claim period in question, will not be paid.

8. Withdrawal from the service

If the pharmacy contractor wishes to stop providing the service, they must notify the commissioner that they are no longer going to provide the service via the MYS platform, giving at least 30 days' notice prior to cessation of the service. Contractors may be asked for a reason why they wish to stop providing the service.

9. Monitoring and post-payment verification

9.1 Monitoring

Pharmacies may be required to provide additional reports for service evaluation and monitoring purposes. These criteria and evaluation periods will be agreed nationally with Community Pharmacy England and communicated to contractors when any submission is required.

In the event of problems with service provision by a pharmacy contractor, the commissioner will assess the ongoing ability of the pharmacy to provide the service.

9.2 Post-payment verification

NHS England has a duty to be assured that, where contractors make claims for payment for activity in services, they meet all the specified requirements of the service. NHS England will work with the NHSBSA Provider Assurance team to undertake pre- and post-payment verification checks on claims made. Contractors may be asked to verify purchases of LFD Tests, e.g. by providing copies of invoices.

It is the contractor's responsibility to provide evidence of claims when requested by NHSBSA for post-payment verification. In cases where evidence is not available or does not demonstrate that the service activity was delivered – and so these claims cannot be verified – they may be referred to the Pharmaceutical Services Regulations Committee (PSRC) to decide whether an overpayment has been made.

In such cases, where the PSRC decides an overpayment has been made and will need to be recovered, contractors will be contacted by NHSBSA and notified of the overpayment recovery process.

Any overpayment recovery would not prejudice any action that the NHS may also seek to take under the performance-related sanctions and market exit powers within The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

Accurate record keeping is an essential part of the service provision. The necessary records specified in the service specification required for reimbursement must be kept for a period of three years to demonstrate service delivery in accordance with the service specification, and to assist with post-payment activities. These records must be provided by a contractor when requested by the NHSBSA Provider Assurance team.