NHS England

Community pharmacy advanced service specification

Seasonal influenza vaccination 1 September 2024 - 31 March 2025

Version 2.0

Publication reference: PRN00996_iii

Version updates: (changes are marked in yellow)	Updated section
Version 2.0	The following sections have been updated to the previous version of this document: Update to 3.8 and 7.5.3 to include Statement of Amendment to the flu letter. Annex B: update to reflect the change in cohorts and new vaccine requirements. Replaced wording in footer 13. Key for vaccination abbreviations updated. Added additional wording at the end of Annex B.

Contents

The terms within this advanced service specification may be subject to renegotiation during the seasonal influenza season where significant changes to supply or distribution of vaccines occurs, or where Patient cohorts are changed.

1. Service description and background

1.1. For most healthy people, seasonal influenza is an unpleasant disease, but one that usually resolves without treatment. However, older people, pregnant women and those with underlying diseases are at particular risk of severe illness if they contract it.

1.2. Seasonal influenza is a key factor in NHS resilience. It impacts on those who become ill, the NHS services that provide direct care as a result, and on the wider health and social care system. The annual immunisation programme helps to reduce unplanned hospital admissions and pressures on A&E. To improve access to NHS seasonal influenza vaccination for eligible patients, NHS England has commissioned an advanced service for community pharmacies to provide seasonal influenza vaccinations since 2015.

1.3. During the seasonal influenza vaccination campaign period, pharmacy staff will identify people eligible (either directly, or through people proposing themselves) for seasonal influenza vaccination and encourage them to be vaccinated. This advanced service covers patients aged 18 years and older who are eligible to receive the seasonal influenza vaccination as set out in the Annual Flu Letter[1] and Annex A of this document.

2. Aims and intended service outcomes

2.1. The aims of this advanced service are:

2.1.1. To sustain and maximise uptake of seasonal influenza vaccine in at risk groups[1] by continuing to build the capacity of community pharmacies as an alternative to general practice attendance;

2.1.2. to protect those who are most at risk of serious illness or death should they develop seasonal influenza, by offering protection

[1] The at-risk groups and UKHSA target vaccination levels are set out in the annual Flu Plan www.gov.uk/government/publications/national-flu-immunisation-programme-plan

against the most prevalent strains of the seasonal influenza virus through administration of seasonal influenza vaccination to eligible Patients; and

2.1.3. to provide more opportunities and improve convenience for eligible patients to access seasonal influenza vaccinations.

3. Service specification

3.1. The patient cohorts eligible for seasonal influenza vaccination from the service commencement date (as set out at paragraphs 3.4 and 3.5) under this advanced service, unless contraindicated, are those patients included in the Annual Flu Letter ("Patients") and listed in Annex A. The commissioner will announce and authorise the vaccination of Patients. This may include the priority order or staggered dates for vaccination of Patients. Pharmacy contractors must ensure that Patients are vaccinated in accordance with the announcement and authorisation by the commissioner. Groups eligible for seasonal influenza vaccination are based on the advice of the Joint Committee on Vaccination and Immunisation (JCVI) who review the latest evidence on seasonal influenza vaccines and recommend the type of vaccine to be offered to Patients.

3.2. The pharmacy contractor is required to offer Patients the opportunity of receiving a seasonal influenza vaccination at an acceptable location (in accordance with the Pharmaceutical Services (Advanced and Enhanced Service) (England) Directions. Patients do not require an NHS number or general practice registration and should not be denied vaccination on this basis. The vaccine is to be administered by an appropriately trained vaccinator, authorised under the NHS England Patient Group Direction (PGD) or the National Protocol.

3.3. Subject always to paragraphs 3.4 and 3.5, the service specification will come into force on 1 September 2024 and shall continue until 31 March 2025.

3.4. Pharmacy contractors must not commence the administration of vaccinations under this advanced service prior to the service commencement date.

3.5. The service commencement date will be announced and authorised by the commissioner.

3.6. The priority order for the administration of vaccinations to Patients will also be announced and authorised by the commissioner

3.7. Pharmacy contractors should aim to schedule their seasonal influenza vaccination service to maximise the administration of the vaccinations (following the service commencement date) to Patients by 30 November 2024.

3.8. The pharmacy contractor shall only administer the seasonal influenza vaccination using one of the seasonal influenza vaccines as listed in the Annual Flu Letter.[2] and the Statement of Amendment to the Annual Flu Letter.[3] See Annex B.

3.9. Pharmacy contractors must ensure that vaccinations offered under this advanced service are provided in line with Immunisation against infectious disease (The Green Book)[4] which outlines all relevant details on the background, dosage, timings and administration of the vaccine, and disposal of clinical waste. Pharmacy contractors must ensure that vaccination is offered in line with any JCVI guidance on the co-administration of vaccinations or the required interval between any vaccinations, including where they have been administered by another provider.

3.10. The pharmacy contractor must have a standard operating procedure (SOP) in place for this advanced service, which includes procedures to ensure cold chain integrity. All vaccines are to be stored in accordance with the manufacturer's instructions and all refrigerators in which vaccines are stored are required to have a maximum/minimum thermometer. Readings are to be taken and recorded from the thermometer on all working days and appropriate action taken when readings are outside the recommended temperature. Where vaccinations are undertaken off the pharmacy

[2] https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025

[3] https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025

[4] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book

premises, the pharmacy contractor must ensure that appropriate measures are taken to ensure the integrity of the cold chain.

3.11. Each Patient being administered a vaccine should be given a copy of the manufacturer's patient information leaflet about the vaccine or be directed to a web-based version of the leaflet.

3.12. Prior to vaccination, consent must be sought from each Patient to the administration of the vaccine. Patient consent should be recorded in the pharmacy's clinical record.

3.13. The Patient must be informed that information relating to their vaccination will be shared with their registered general practice, for the appropriate recording of the vaccination in their medical record and may be pseudonymised and shared with the commissioner for the purposes of service delivery, evaluation and research.

3.14. Where a Patient presents with an adverse drug reaction following the initial vaccination and the pharmacist believes this is of clinical significance, such that the Patient's registered general practice should be informed, this information should be shared with the registered general practice as soon as possible and a 'Yellow Card'[5] report submitted.

3.15. The pharmacy contractor is required to report any Patient safety incidents in line with the Clinical Governance Approved Particulars[6] for pharmacies.

3.16. The pharmacy contractor is required to make arrangements for the removal and safe disposal of any clinical waste and personal protective equipment related to the provision of this advanced service (including where the vaccination is undertaken off the pharmacy premises).

4. Training and premises requirements

4.1. To provide the advanced service, there must be a consultation room at the pharmacy, which meets the applicable requirements of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Vaccinations must take place in a consultation room wherever the

[5] https://yellowcard.mhra.gov.uk/

[6] https://www.gov.uk/government/publications/clinical-governance-approved-particulars

Patient expresses this preference. Vaccinations can also be offered in any area where suitable facilities are available, infection control standards can be maintained, and Patient confidentiality and dignity is able to be respected.

4.2. Vaccinations under this advanced service will usually be carried out on the pharmacy premises, but they can also be undertaken in other suitable locations, such as in the Patient's home, a long-stay care home, a long-stay residential facility or community venues (e.g. community centres). Vaccinations should be administered under the supervision of a pharmacist trained in vaccination (including a clear understanding of this advanced service). A record should be maintained of who that person is at each premises at any given time.

4.3. The responsible pharmacist at the registered pharmacy premises is professionally responsible for the safe delivery of this advanced service. If the responsible pharmacist is unable to provide sufficient supervision, for example due to workload or where vaccinations are undertaken off the pharmacy premises, an on-site pharmacist supervising delivery of the advanced service must be linked and work closely with the responsible pharmacist and superintendent pharmacist through an appropriate governance framework.

4.4. Where vaccinations are undertaken off the pharmacy premises, the pharmacy contractor must ensure there is an on-site pharmacist supervising delivery of the advanced service (or delivering the vaccination service themselves) and that vaccinators:

4.4.1. are delivering vaccines in accordance with the Community Pharmacy Inactivated influenza vaccine Patient Group Direction or the National protocol for inactivated influenza vaccine, as appropriate;

4.4.2. have professional indemnity that covers off-site vaccinations

4.4.3. continue to adhere to all professional standards relating to vaccinations;

4.4.4. follow appropriate cold-chain storage measures;

4.4.5. ensure that the setting used to administer the vaccinations is appropriate (including ensuring Patient confidentiality as appropriate); and

4.4.6. appropriately dispose of any clinical waste or personal protective equipment used during the vaccination process.

4.5. The pharmacy contractor must ensure that vaccinators:

4.5.1. have undertaken appropriate training in line with the National Minimum Standards[7] and Core Curriculum for Immunisation Training. Annual updates should be undertaken to ensure knowledge and practice remain current. Periodic face to face refresher training for vaccinators should be considered to ensure consistency of practice, peer support and to discuss any clinical issues that are arising in practice;

4.5.2. are competent to deliver the service. Competence can be demonstrated by using, for example, the vaccination services Declaration of Competence (DoC)[8] for registered pharmacists or the UKHSA competency assessment tool[9]. The pharmacy contractor must keep evidence of competency relating to any staff that they employ/engage to deliver the service;

4.5.3. are appropriately trained and made aware of the risks associated with the handling and disposal of clinical waste and that correct procedures are used to minimise those risks. A needle stick injury procedure must be in place; and

4.5.4. have a valid DBS certificate if vaccinations are to be undertaken in the Patient's own home (including a care home).

5. Service availability

5.1. The pharmacy contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No Patient shall

[7] National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners, revised February 2018
[8] The Declaration of Competence is available on the CPPE website: https://www.cppe.ac.uk/doc
[9] Flu vaccinator competency assessment tool

be excluded or experience particular 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.

5.2. If the pharmacy temporarily or permanently ceases to provide the service, they must update their NHS website profile as soon as possible to reflect that the service is not available from the pharmacy.

6. Data collection and reporting requirements

6.1. The pharmacy contractor must maintain appropriate electronic records to ensure effective ongoing service delivery, in line with the terms of this section. Records must be managed in line with 'Records Management Code of Practice for Health and Social Care'.[10]

6.2. Pharmacy contractors must use an NHS assured point of care system to record the administration of vaccinations.

6.3. The pharmacy contractor must ensure that any staff recording the administration of the vaccination have received relevant training to be able to update records appropriately and accurately. There must be robust user and access management processes to ensure high levels of security, including frequent updates to system access levels to add users who join the pharmacy team or remove accounts where staff leave or do not have shifts scheduled at the pharmacy.

6.4. One point of care system must be used to record vaccinations in any calendar month except where it is necessary to make amendments to previously recorded vaccination events or where this has been agreed with the commissioner during the transition to a new point of care system.

6.5. Pharmacy contractors must adhere to defined standards of record keeping ensuring that the vaccination event is recorded on the same day that it is administered unless exceptional circumstances apply. Where the point of care system is unavailable due to exceptional circumstances beyond the control of the pharmacy contractor, then the record of vaccination events

[10] https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care

must be added to the point of care system as soon as possible after the point of care system becomes available again.

6.6. Where a record of the vaccination needs amending or has not been created on the point of care system, the pharmacy contractor shall be responsible for undertaking the amendment or creation as soon as reasonably possible following notification from the Patient or another healthcare professional that the record is not complete or correct.

6.7. Data recorded via the point of care system regarding the Patient's vaccination will be shared with the Patient's registered general practice (where this is known) automatically. Where a problem occurs with this notification system, the pharmacy contractor must ensure a copy of the vaccination notification is sent or emailed (via secure email) to the Patient's registered general practice as soon as reasonably possible.

6.8. Some of the data recorded in point of care systems will be shared with the NHS Business Services Authority's (NHSBSA) Manage Your Service (MYS) platform as part of normal payment arrangements (see section 7 below). An application programming interface (API) is in place to facilitate transfer of this data into the MYS platform to improve payment claim accuracy. Details of the API and the data transferred from point of care systems to MYS are listed at Annex C.

6.9. The pharmacy contractor must promptly comply with any reasonable request for information from the commissioner relating to this advanced service.

6.10. Data recorded in point of care systems that has been pseudonymised may be shared with the commissioner for service monitoring, evaluation and research purposes.

7. Payment arrangements

7.1. Claims for payments for this advanced service must be made via the NHSBSA's MYS platform. 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 and

the pharmacy contractor will not receive any payment for the administration of those vaccinations.

7.2. A fee payment will be made in line with the Drug Tariff determination[11] per administered dose of the seasonal influenza vaccine.

7.3. The pharmacy contractor will also be reimbursed for the cost of the seasonal influenza vaccine administered[12]. An allowance at the applicable VAT rate will also be paid.

7.4. Pharmacy contractors must record the administration of the vaccination in accordance with paragraph 6.5, in the point of care system prior to making the claim for payment. There will be no provision for manually altering claims via the MYS platform.

7.5. The pharmacy contractor will not be reimbursed or remunerated, under this advanced service, for the administration of the seasonal influenza vaccination or the vaccine administered outside of the eligibility criteria as set out in this advanced service for vaccination. The pharmacy contractor will not be paid for vaccinations administered:

7.5.1. to patients who are not in a cohort eligible for seasonal influenza vaccination (as set out in the Annual Flu Letter and as set out at Annex A);

7.5.2. outside of the announced and authorised dates during which the pharmacy contractor may administer the vaccination to Patients; or

7.5.3. using vaccines which are not included in the list of recommended licensed vaccines in the Annual Flu letter, the Statement of Amendment to the Annual Flu Letter and the Green Book.

[11] Funding for this service will be in addition to and outside of the core CPCF funding.
[12] Any purchase margin by pharmacies relating to the seasonal flu vaccine would be included in the calculation of allowed purchase margin that forms a part of agreed NHS pharmacy funding.

Annex A: Groups included in this advanced service

This service covers those patients most at risk from influenza **aged 18 years and older**, as listed below.

The selection of these eligible groups has been informed by the target list from the annual Flu Letter and Immunisation against infectious disease: The Green Book.

Eligible groups	Further details
All people aged 65 years or over	Including those becoming age 65 years by 31 March 2025.
People aged from 18 years to less than 65 years of age with one or more serious medical condition(s) outlined below:	
Chronic (long term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD).
Chronic heart disease, such as heart failure	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease. This includes individuals with atrial fibrillation, peripheral vascular disease or a history of venous thromboembolism.
Chronic kidney disease at stage three, four or five	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease	Cirrhosis, biliary atresia, chronic hepatitis.
Chronic neurological disease, such as Parkinson's disease or motor neurone disease or learning disability	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological or neuromuscular disease (e.g. polio syndrome sufferers). Clinicians should offer immunisation, based on individual assessment, to clinically vulnerable individuals including those with cerebral palsy, severe or profound and multiple learning disabilities (PMLD), Down's syndrome, multiple sclerosis, dementia, Parkinson's disease, motor neurone disease and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.
Diabetes	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet-controlled diabetes.

	Addison's disease, secondary or tertiary adrenal insufficiency requirement steroid replacement.
Immunosuppression, a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, patients undergoing radical radiotherapy, solid organ transplant recipients, bone marrow or stem cell transplant recipients, people living with HIV infection (at all stages), multiple myeloma or genetic disorders affecting the immune system (eg IRAK-4, NEMO, complement disorder, SCID). Individuals who are receiving immunosuppressive or immunomodulating biological therapy including but not limited to, anti-TNF-alemtuzumab ofatumumab, rituximab, patients receiving protein kinase inhibitors or PARP inhibitors, individuals treated with steroid sparing agents such as cyclophosphamide and mycophenolate mofetil. Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day. Anyone with a history of haematological malignancy, including leukaemia, lymphoma, and myeloma and those with systemic lupus erythematosus and rheumatoid arthritis, and psoriasis who may require long term immunosuppressive treatments. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered seasonal influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immune-compromised patients may have a suboptimal immunological response to the vaccine.
Splenic dysfunction or asplenia	This also includes conditions such as homozygous sickle cell disease, hereditary spherocytosis, thalassemia major and coeliac syndrome that may lead to splenic dysfunction.
Morbid obesity	Adults with a Body Mass Index ≥40kg/m^2[2,13]
Pregnant women (including those women who become pregnant during the flu season)	Pregnant women aged 18 or over at any stage of pregnancy (first, second or third trimesters).

[13] Many of this patient group will already be eligible due to complications of obesity that place them in another risk category

People living in long-stay residential care homes or other long-stay care facilities	Vaccination is recommended for people aged 18 or over living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, or university halls of residence. For the pharmacy service this only applies to those aged 18 or over.
Carers	People aged 18 or over who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill.
Close contacts of immunocompromised individuals	People who are close contacts, aged 18 and over, of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable.
Frontline workers in a social care setting without employer led occupational health schemes	Frontline workers, employed by a registered residential care/nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza. Vulnerable means those patients/clients in a clinical risk group for flu or who are aged 65 years and over.
Hospice workers without employer led occupational health schemes	Frontline workers, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza.
Frontline workers without employer led occupational health schemes	Frontline workers employed through direct payments and/or personal health budgets to deliver domiciliary care to patients and service users.

Annex B: Seasonal influenza vaccines for 2024/25

Eligible groups	Vaccine
At risk adults aged 18-64 years (including pregnant women)	18-64 years: offer cell-based quadrivalent influenza vaccine (QIVc)*. Aged 60-64 years: offer cell based quadrivalent influenza vaccine (QIVc), or High-dose quadrivalent influenza vaccine (QIV-HD) *Egg-grown quadrivalent influenza vaccine (QIVe) may be offered only when every attempt to use QIVc or in the case of 60-64 years also QIV-HD, has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.
All adults aged 65 years and over	Offer adjuvanted quadrivalent influenza vaccine (aQIV)* or High-dose quadrivalent influenza vaccine (QIV-HD). *Cell-based quadrivalent influenza vaccine (QIVc) may be offered only when every attempt to use aQIV or QIV- HD has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed. It is recommended that aQIV is offered 'off label' to those who become 65 before 31 March 2025.

Key for vaccine abbreviations:

aQIV – Adjuvanted Quadrivalent Influenza Vaccine

QIV-HD – High-dose quadrivalent influenza vaccine

QIVc – Cell-based Quadrivalent Influenza Vaccine

QIVe – Influvac sub-unit Tetra Vaccine

Please see amended list of all influenza vaccines marketed in the UK for 2024/25 for manufacturer contact details.

Providers who have ordered QIVr are responsible for securing alternative supplies of recommended vaccine and will be reimbursed by NHSE in the usual way.

Annex C: API Data Transfer

Data captured via NHS assured point of care system is shared directly with the NHSBSA via an application programming interface (API).

Full details of the API can be found here: Manage your service (MYS) | NHSBSA

Dataset transmitted by the API:

- Date of administration
- ODS code
- Patient name
- Patient date of birth
- Patient NHS number
- Patient address (including postcode)
- Patient's GP ODS code, practice name and address (including postcode)
- Name of vaccine administered