

Classification: Official

Publication reference: PRN00628



# Community pharmacy advanced service specification

## Seasonal influenza vaccination

1 September 2023 - 31 March 2024

This document is the advanced service specification for community pharmacy for the 2023/24 seasonal influenza vaccination programme.

Version 1.0, 4 August 2023

## **Equalities and health inequalities statement**

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in ensuring that services are provided in an integrated way where this might reduce health inequalities."

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# Summary of changes for 2023/24

## Summary of key changes from the 2022/23 seasonal flu advanced service specification

- Patient cohorts amended to reflect the content of the 2023/24 Annual Flu Letter.
- Patient cohorts and seasonal influenza vaccines amended to reflect the content of the 2023/24 Annual Flu Letter.
- Update to relevant organisation names.
- Minor amendment to aims of the service with the addition of an aim to protect the most at risk from serious illness and death.
- Addition of the requirement of the Commissioner to announce and authorise the Patients eligible for seasonal influenza vaccinations, which may include the priority order or staggered dates for vaccination of Patient groups.
- Clarification that Patients do not require an NHS number or general practice registration to be eligible for the service.
- Minor amendments to the wording around the start of the advanced service.
- Minor amendments to wording relating to patient consent to share information.
- Removal of the manual requirement to share the data with the Patient's general practice.
- Minor amendment to the response required to an adverse drug reaction in that a 'Yellow Card' report should be submitted.
- Minor amendments to the wording around use of the patient group direction and national immunisation protocols.
- Amended to mandate the use of an NHS assured point of care system to record the administration of influenza vaccinations and the requirements of the use of the system (record keeping, training etc).
- Amended requirement to record the vaccination event on the day of administration or, in exceptional circumstances, as soon as possible thereafter.

- Minor amendments to the wording around timings of making a claim to the NHS BSA MYS platform.

The terms within this service specification may be subject to renegotiation during the flu 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, influenza (flu) 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 catch it.
- 1.2. Flu 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 flu vaccination for eligible patients, NHS England has commissioned an advanced service for community pharmacies to provide flu vaccinations since 2015.
- 1.3. During the seasonal flu vaccination campaign period, pharmacy staff will identify people eligible for flu vaccination and encourage them to be vaccinated. This advanced service covers eligible patients aged 18 years and older who are specified in Annex A of this document, based on information in the Annual Flu Letter<sup>1</sup>.

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<sup>1</sup> The at-risk groups and UKHSA target vaccination levels are set out in the annual Flu Plan <https://www.gov.uk/government/collections/annual-flu-programme>

## 2. Aims and intended service outcomes

2.1. The aims of this service are:

- 2.1.1. to sustain and maximise uptake of flu vaccine in at risk groups<sup>1</sup> 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 influenza, by offering protection against the most prevalent strains of the influenza virus through administration of seasonal flu vaccination to eligible patients; and
- 2.1.3. to provide more opportunities and improve convenience for eligible patients to access flu vaccinations.

## 3. Service specification

- 3.1. The patient groups eligible for seasonal flu vaccination under this service, unless contraindicated, are listed in Annex A. The commissioner will announce and authorise the vaccination of patients in these groups in the Primary Care Bulletin. This may include the priority order or staggered dates for vaccination of patient groups. Pharmacy contractors must ensure that patients are vaccinated in accordance with the announcement and authorisation by the commissioner. Groups eligible for influenza vaccination are based on the advice of the Joint Committee on Vaccination and Immunisation (JCVI) who review the latest evidence on influenza vaccines and recommend the type of vaccine to be offered to patients.
- 3.2. The pharmacy contractor is required to offer eligible patients the opportunity of receiving a flu vaccination at the pharmacy. 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. The advanced service will come into force on 1 September 2023 and shall continue until 31 March 2024.
- 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 in the Primary Care Bulletin.

The priority order for the administration of vaccinations to eligible patients will also be announced and authorised by the commissioner in the Primary Care Bulletin.

- 3.6. The seasonal flu vaccination to be administered under this service is one of the flu vaccines listed in the Annual Flu Letter<sup>2</sup>. See Annex B.
- 3.7. Pharmacy contractors must ensure that vaccinations offered under this service are provided in line with Immunisation against infectious disease (The Green Book)<sup>3</sup> which outlines all relevant details on the background, dosage, timings and administration of the vaccine, and disposal of clinical waste<sup>4</sup>. 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.
- 3.8. The pharmacy contractor must have a standard operating procedure (SOP) in place for this 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 premises, the pharmacy

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<sup>2</sup> <https://www.gov.uk/government/publications/national-flu-immunisation-programme>

<sup>3</sup> <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book>

<sup>4</sup> While the Green Book references eligible patient groups for vaccination, community pharmacy staff are to refer to Annex A of this service specification for the groups eligible for this service. The list of eligible patients for this service does not include all those patients outlined in the annual Flu Plan<sup>1</sup> or the Green Book.

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

- 3.9. 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.
- 3.10. Prior to vaccination, consent must be sought from each patient to the administration of the vaccine.
- 3.11. The patient should be informed that information relating to their vaccination will be shared with their 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. Patient consent should be recorded in the pharmacy's clinical record.
- 3.12. 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 general practice should be informed, this information should be shared with the general practice as soon as possible and a 'Yellow Card'<sup>5</sup> report submitted.
- 3.13. The pharmacy contractor is required to report any patient safety incidents in line with the Clinical Governance Approved Particulars<sup>6</sup> for pharmacies.
- 3.14. 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 service (including where the vaccination is undertaken off the pharmacy premises).

## 4. Training and premises requirements

- 4.1. To provide the service, there must be a consultation room at the pharmacy, which meets the applicable requirements of the Pharmaceutical Services

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<sup>5</sup> <https://yellowcard.mhra.gov.uk/>

<sup>6</sup> <https://www.gov.uk/government/publications/clinical-governance-approved-particulars>



Regulations. Vaccinations must take place in a consultation room wherever the 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 (eg community centres). Vaccinations should be administered under the supervision of a pharmacist trained in vaccination (including a clear understanding of this 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 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 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 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)

- 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 individuals providing the service:
  - 4.5.1. have undertaken appropriate training in line with the National Minimum Standards<sup>7</sup> 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)<sup>8</sup> for registered pharmacists or the UKHSA competency assessment tool<sup>9</sup>. 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 eligible patient shall be excluded or experience particular difficulty in accessing and effectively using

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<sup>7</sup> [National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners, revised February 2018](#)

<sup>8</sup> The Declaration of Competence is available on the CPPE website: <https://www.cppe.ac.uk/doc>

<sup>9</sup> [Flu vaccinator competency assessment tool](#)

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 should 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'.
- 6.2. Pharmacy contractors must use an NHS assured point of care system to record the administration of vaccinations. The point of care system may either be provided by the commissioner or the pharmacy contractor can make their own arrangements for an NHS assured system of their choice.
- 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 employment 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 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 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 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 general practice.
- 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 comply with any reasonable request for information from the commissioner relating to the provision of services under this advanced service.
- 6.10. Data recorded in point of care systems that has been pseudonymised may be shared with NHS England 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<sup>10</sup> per administered dose of vaccine.
- 7.3. The pharmacy contractor will also be reimbursed for the cost of the vaccine administered<sup>11</sup>. 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 vaccines administered to patients outside of the eligibility criteria set out in Annex A, or outside of the announced and authorised dates, or for administration of vaccines that are not one of the recommended licensed vaccines listed in the annual Flu Letter and the Green Book.

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<sup>10</sup> Funding for this service will be in addition to and outside of the core CPCF funding.

<sup>11</sup> 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<sup>1</sup> and Immunisation against infectious disease: The Green Book<sup>3</sup>**Error! Bookmark not defined..**

Eligible groups	Further details
All people aged 65 years or over	Including those becoming age 65 years by 31 March 2024.

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.

Eligible groups	Further details
Chronic neurological disease, such as Parkinson's disease or motor neurone disease or learning disability	<p>Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological or neuromuscular disease (e.g. polio syndrome sufferers).</p> <p>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.</p>
Diabetes	<p>Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet-controlled diabetes.</p> <p>Addison's disease, secondary or tertiary adrenal insufficiency require steroid replacement.</p>
Immunosuppression, a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)	<p>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).</p> <p>Individuals who are receiving immunosuppressive or immunomodulating biological therapy including but not limited to, anti-TNF-alemtuzumab ofatumumab, rituximab, patients receiving protein inhibitors or PARP inhibitors, individuals treated with steroid sparing agents such as cyclophosphamide and mycophenolate mofetil.</p> <p>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.</p> <p>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.</p> <p>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</p>

Eligible groups	Further details
	<p>influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician.</p> <p>Some immune-compromised patients may have a suboptimal immunological response to the vaccine.</p>
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 $\geq 40\text{kg/m}^2$ <sup>12</sup>
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).
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.

<sup>12</sup> Many of this patient group will already be eligible due to complications of obesity that place them in another risk category



Eligible groups	Further details
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 2023/24

Eligible groups	Vaccine
At risk adults aged 18-64 years (including pregnant women)	<p>Offer cell-based quadrivalent influenza vaccine (QIVc) or recombinant quadrivalent influenza vaccine (QIVr).</p> <p>Egg-grown quadrivalent influenza vaccine (QIVe) may be offered only when every attempt to use QIVc or QIVr has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.</p>
All adults aged 65 years and over	<p>Offer adjuvanted quadrivalent influenza vaccine (aQIV) or recombinant quadrivalent influenza vaccine (QIVr).</p> <p>Cell-based quadrivalent influenza vaccine (QIVc) may be offered only when every attempt to use aQIV or QIVr has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.</p> <p>It is recommended that aQIV is offered 'off label' to those who become 65 before 31 March 2024.</p>

### Key for vaccine abbreviations:

aQIV – Adjuvanted Quadrivalent Influenza Vaccine

QIVc – Cell-based Quadrivalent Influenza Vaccine

QIVe – Influvac sub-unit Tetra Vaccine

QIVr - Supemtek Vaccine

# 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

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