NHS Greater Glasgow and Clyde

Supply for immediate administration or administration of live attenuated intranasal influenza vaccine (LAIV)

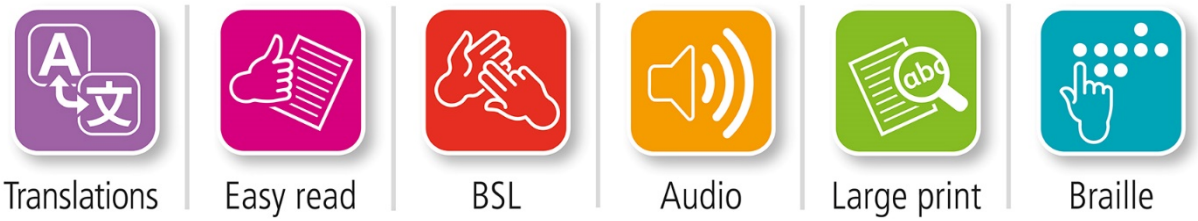
Patient group direction (PGD) template

Publication date: 23 August 2024

PGD No: 2024/2710

Expiry date: 31 August 2025

Version 1.1



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Most recent changes

Version	Date	Summary of changes
V1.1	23 August 2024	The following changes to version 1.0 have been made: • Is the use outwith the SmPC section updated as Fluenz is licensed for a second dose in those not previously vaccinated against seasonal influenza.

Contents

Authorisation

PGD Live Attenuated Intranasal Influenza Vaccine (LAIV)

This specimen PGD template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer LAIV under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD. NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. If the PGD is used for supply, the subsequent immediate self-administration or administration by another healthcare worker is outside the remit of this PGD and should only take place in well-defined local circumstances covered by protocols and training. Administration under this PGD must be directly by the named registered health professional who has assessed the patient under the PGD.

This PGD has been produced for NHS Greater Glasgow and Clyde by:

Professionals drawing up PGD/Authors	
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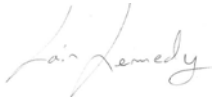
Name: Iain Kennedy  Signature: Date: 30/08/2024	Designation: Consultant in Public Health E-mail address: **Iain.kennedy@ggc.scot.nhs.uk**

Effective from: 1 September 2024 Expiry date: 31 August 2025

1. Clinical situation

1.1. Indication

Active immunisation against disease caused by influenza virus in line with Scottish Government immunisation programme and JCVI advice/recommendations as set out in **Green Book Chapter 19** and subsequent correspondence/publications from Scottish Government.

1.2. Inclusion criteria

Valid consent has been given to receive the vaccine.

Vaccine should be offered to individuals invited, or eligible in accordance with the recommendations in Green Book **Chapter 19**, and/or in line with **Scottish Government seasonal influenza vaccination programme** and subsequent correspondence/publications from Scottish Government.

National policy must be followed in relation to the groups eligible for vaccination at a particular point in time.

1.3. Exclusion criteria

Individuals who:

- Are aged under 2 years.
- Are aged 18 years and over unless attending secondary school – see section 2.10 below.
- Have had a confirmed anaphylactic reaction to a previous dose of influenza vaccine.
- Have had a confirmed anaphylactic reaction to any component of the vaccine including gelatin and gentamicin. Practitioners must check the marketing authorisation holder's SmPC for details of vaccine components.
- Have required admission to intensive care for a previous severe anaphylaxis to egg. JCVI has advised that children with an egg allergy – including those with previous anaphylaxis to egg – can be safely vaccinated with LAIV in any setting (including primary care and schools).
- Have severe asthma or active wheezing including those:
    - with evidence of active wheezing in the previous 72 hours
    - with evidence of increased use of bronchodilators in the previous 72 hours
    - those who require regular oral steroids for maintenance of asthma control
    - those who have previously required intensive care for asthma exacerbation
- Are known to be clinically severely immunocompromised due to conditions or immunosuppressive therapy such as acute and chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy; cellular immune deficiencies; and high dose corticosteroids until at least three months after treatment has stopped including adults on more than 40mg prednisolone per day or 2mg/ kg/day in children under 20kg for more than one week, or adults on more than 20mg prednisolone per day or 1mg/kg/day in children under 20kg for more than 14 days.

- Are currently being treated for a malignant disease with immunosuppressive chemotherapy or radiotherapy, or those who have terminated such treatment within at least the last 6 months.

- Have received a solid organ transplant and are currently on or have received in the last 6 months' immunosuppressive treatment.

- Have received an allogenic (cells from a donor) stem cell transplant in the past 24 months and only then if they are demonstrated not to have on-going immunosuppression or graft versus host disease (GVHD).

- Have received an autologous (using their own stem cells) haematopoietic stem cell transplant in the past 24 months and only then if they are in remission.

- Are receiving or have received in the past 12 months immunosuppressive biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist.

- Are receiving or have received in the past 3 months high dose non-biological oral immune modulating drugs (e.g. methotrexate dose greater than 25mg per week in adults or 15mg/m2 in children, azathioprine dose greater than 3.0mg/kg/day or 6-mercaptopurine dose greater than 1.5mg/kg/day), for the treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease and other conditions.

- Are known to be a close contact of a very severely immunocompromised person (such as those who would normally be in isolation).

- Are known to be taking salicylate therapy (other than for topical treatment of localised conditions).

- Are known to be pregnant.

- Are known to be breastfeeding.

- Are currently taking or are within 48 hours of cessation of influenza antiviral agents.

- Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive LAIV. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation coordinator or health protection team.

There is a theoretical potential for transmission of live attenuated influenza virus in LAIV to immunocompromised contacts for 1 to 2 weeks following vaccination. In extensive use of the LAIV in the UK, there have been no reported instances of illness or infections from the vaccine virus among immunocompromised patients inadvertently exposed. However, where close contact with very severely immunocompromised patients (for example bone marrow transplant patients requiring isolation) is likely or unavoidable (for example, household members), appropriate alternative inactivated influenza vaccines should be considered.

There are no data on the effectiveness of LAIV when given to children with a heavily blocked or runny nose (rhinitis) attributable to infection or allergy. As heavy nasal congestion might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration until resolution of the nasal congestion or an appropriate quadrivalent inactivated influenza vaccine should be considered.

Long term stable low dose corticosteroid therapy, either alone or in combination with low dose non-biological oral immune modulating drugs (e.g. methotrexate 25mg per week in adults or up to 15mg/m2 in children, azathioprine 3.0mg/kg/day or 6-mercaptopurine 1.5mg/kg/day), are not considered sufficiently immunosuppressive and these patients can receive live vaccines.

1.5 Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

In case of postponement due to acute wheezing/increased use of bronchodilators offer/arrange for a suitable quadrivalent inactivated vaccine to avoid a delay in protection.

In case of exclusion due to regular oral steroids for maintenance of asthma control or having previously required intensive care for asthma due to limited safety data in these children advice from the child's specialist should be sought on the vaccine and circumstances under which it could be given.

In case of exclusion as result of immunosuppression, pregnancy or salicylate therapy (other than for topical treatment of localised conditions), consider use of an appropriate quadrivalent inactivated influenza vaccine.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached. Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Fluenz® nasal spray suspension, influenza vaccine (live attenuated, nasal)

Nasal spray, suspension in a prefilled nasal applicator.

2.2. Route of administration

Nasal administration only.

LAIV must not be injected.

The patient can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff.

If the PGD is used for supply, the subsequent immediate self-administration or administration by another healthcare worker is outside the remit of this PGD and should only take place in well-defined local circumstances covered by protocols and training.

Administration under this PGD must be directly by the named registered health professional.

2.3. Dosage

0.2ml (administered as 0.1ml per nostril).

LAIV is administered as a divided dose in both nostrils.

2.4. Frequency

Children not in clinical risk groups only require one dose of LAIV.

Unless otherwise excluded individuals in clinical risk groups aged two to under 9 years who have not received influenza vaccine before should receive two doses of LAIV with the second dose at least 4 weeks after the first.

2.5. Duration of treatment

See above.

2.6. Maximum or minimum treatment period

See above.

2.7. Quantity to supply/administer

See above.

2.8. ▼ black triangle medicines

No.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

Yes.

LAIV is licensed for administration to children and adolescents from 24 months to less than 18 years of age. It may be administered under this PGD to those individuals aged 18 years in secondary school accordance with the **Scottish Government seasonal influenza immunisation programme.**

The SmPC states that in children who have not previously been immunised against influenza, a second dose should be given after an interval of least four weeks. This is superseded by Green Book recommendations to give a single dose of LAIV to children not in a clinical at-risk group.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines or national Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration or supply under this PGD is allowed.

2.11. Storage requirements

Store at between +2°C to +8°C.

Store in original packaging in order to protect from light.

Do not freeze.

NHS Board guidance on storage and handling of vaccines should be observed.

Before use, the vaccine may be taken out of the refrigerator once for a maximum period of 12 hours at a temperature not above 25°C. Stability data indicate that the vaccine components are stable for 12 hours when stored at temperatures from 8°C to 25°C. If the vaccine has not been used after this 12-hour period, it should be disposed of.

In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

The patient can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff.

Administration of either dose does not need to be repeated if the patient sneezes or blows their nose following administration.

LAIV can be given at the same time as other vaccines including COVID-19 vaccine and live vaccines. No specific intervals need to be observed between LAIV and other live vaccines.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

Nasal congestion/runny nose, reduced appetite, weakness and headache are common adverse reactions following administration of LAIV. It is uncommon, but some children may experience a nosebleed following administration of LAIV.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of a severe adverse reaction individual should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://yellowcard.mhra.gov.uk/**

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.

- Supply immunisation promotional material as appropriate.

Individual advice/follow up treatment

- Inform the individual/carer of possible side effects and their management.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **http://www.mhra.gov.uk/yellowcard**
- When applicable, advise individual/parent/carer when the subsequent dose is due.
- Give general advice relating to good hygiene practice to prevent the spread of germs – always have tissues to hand, use a clean tissue to cover your mouth and nose when you cough and/or sneeze, bin any tissue after one use, wash your hands with soap and hot water or a sanitiser gel often.

3.4. Observation following vaccination

Following immunisation, patients remain under observation in line with NHS board policy.

3.5. Follow up

If appropriate remind parents/guardian that a further dose will be required to complete the course.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early

treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists currently registered with the General Pharmaceutical Council (GPhC)
- pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)
- dental hygienists and dental therapists registered with the General Dental Council
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it

- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/SmPC
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions
- must have access to the PGD and associated online resources
- should fulfil any additional requirements defined by local policy

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included.

If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- supplied or administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

- **Immunisation against Infectious Disease [Green Book]**
- **Immunisation against Infectious Disease [Green Book] chapter 19**
- Current edition of British National Formulary (BNF) and BNF for children
- Marketing authorisation holder's Summary of Product Characteristics
- **Educational resources for registered professionals produced by National Education for Scotland**
- All relevant Scottish Government advice including the relevant CMO letter(s)
- **Professional Guidance on the Administration of Medicines in Healthcare Settings 2019**
- **Professional Guidance on the Safe and Secure Handling of Medicines**
- **Framework for the Administration of Medicines**

7. PGD for administration or supply of live attenuated intranasal influenza vaccine for 2024–25 season (LAIV) v1.0 (valid from 1 September 2024 and expires 31 August 2025): authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction, you are indicating that you agree to its contents and that you will work within it.

I agree to administer the live attenuated intranasal influenza vaccine (LAIV) only in accordance with this PGD.

Name of professional	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **NHS Greater Glasgow & Clyde** for the above named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area:

Name ……..

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

8. Version history

Version	Date	Summary of changes
V1.0	19 August 2024	The following changes from the PGD used in 2023/24 have been made: • Vaccine changed from Quadrivalent (Fluenz Tetra) to Trivalent (Fluenz) • Dates for 2024-25 season updated throughout the document • Inclusion criteria section updated to generic inclusion criteria • Is the use outwith the SmPC section updated as Fluenz is licensed for a second dose in those not previously vaccinated against seasonal influenza.
V1.1	23 August 2024	The following changes to version 1.0 have been made: • Is the use outwith the SmPC section updated as Fluenz is licensed for a second dose in those not previously vaccinated against seasonal influenza.