Live attenuated intranasal influenza vaccine (LAIV▼) 2018-19

For individuals 2 years up to and including 17 years
(N.B. Adjuvanted Inactivated Trivalent Vaccine (Fluad®▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

GG&C PGD ref no: 2018/1601

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition	
Indication:	Active immunisation against disease caused by influenza virus in line with Scottish Government Health Directorate seasonal influenza immunisation programme 2018-19
Inclusion criteria:	Individuals identified in Scottish Government's seasonal influenza vaccination programme 2018-19 in the following groups; All those aged 2 years to under 18 years in the clinical risk groups laid out in the latest iteration of the Chief Medical Officer letter on Seasonal Influenza Vaccination Programme at http://www.sehd.scot.nhs.uk/ All pre-school children aged 2 to 5 years of age on 1st September 2018 (i.e. born on or before 1st September 2016). All individuals of primary school age. Young carers, defined as, a child or young person under the age of 18 years carrying out significant caring tasks and assuming a level of responsibility for another person, which would normally be taken by an adult. Health and Social Care Workers
Exclusion criteria:	• Non-consent • Individuals under 2 years of age • Individuals aged18 years and over • Confirmed anaphylactic reaction to a previous dose of influenza vaccine • Confirmed anaphylactic reaction to any component of the vaccine including gelatin and gentamicin. Practitioners must check the marketing authorisation holder's summary of product characteristics (SmPC) for details of vaccine components. • Severe confirmed anaphylaxis to eggs/egg product or chicken proteins such as ovalbumin

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	Severe asthma or active wheezing: o Evidence of prescription of oral steroids for exacerbation of asthma symptoms currently or within the last 14 days o Currently taking a high dose inhaled steroid – Budesonide >800mcg/day or equivalent (in children 5-12 years, the definition of severe asthma corresponds to the British Thoracic Society BTS/SIGN step 5 o Evidence of active wheezing in the previous 72 hours o Evidence of increased use of bronchodilators in the previous 72 hours o Are being currently managed in a secondary care (hospital) clinic for asthma • Known to be severely or potentially severely immunosuppressed 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. This would include children who receive prednisolone, orally or rectally, at a daily dose (or its equivalent) of 2mg/ kg/day for at least one week, or 1mg/kg/day for one month. • Patients currently treated for a malignant disease with immunosuppressive chemotherapy or radiotherapy, or those who have terminated such treatment within at least the last 6 months • Patients who have received a solid organ transplant and are currently on immunosuppressive treatment. • Patients who have received a bone marrow transplant, until at least 12 months after finishing all immunosuppressive treatment, or longer where the patient has developed graft-versus-host-disease. • Therapy with higher-doses of methotrexate (>0.4 mg/kg/week), azathioprine (>3.0 mg/kg/day), or 6mercaptopurine (>1.5mg/kg/day) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions • Patients receiving other types of immunosuppressive

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	drugs (e.g. cyclosporine, cyclophosphamide, leflinomide, and the newer cytokine inhibitors) alone or in combination with lower doses of steroids until at least 6 months after terminating such treatment • Known to be a close contact of a very severely immunocompromised person (e.g. bone marrow transplant recipient) • Known to be taking salicylate therapy • Known to be pregnant • Heavy nasal congestion at the time of vaccination • At same time or within 48 hours of cessation of influenza antiviral agents • Acute systemic or febrile illness – consider postponing immunisation until patient has fully recovered • Evolving neurological condition, immunisation should be deferred until resolved or stabilised • History of severe (i.e. anaphylactic reaction) to latex where vaccine is not latex free
Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber:	• There is a theoretical potential for transmission of live attenuated virus in LAIV▼ to severely immunocompromised contacts (e.g. bone marrow transplant patients requiring isolation) for one to two weeks following vaccination. Where close contact with immunocompromised patients (e.g. household members) is likely or unavoidable, an appropriate alternative inactivated influenza vaccine should be considered. For individuals aged from 6 months the preferred vaccine is a suitable quadrivalent inactivated licensed for individuals from 6 months of age. • LAIV▼ can be given at the same time as other vaccines including live vaccines. Where protection against influenza is needed before the start of the seasonal increase of influenza, vaccination with LAIV▼ should not be delayed because of another live vaccine or administration with inactivated influenza vaccine should be offered. • 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

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	or an appropriate alternative intramuscularly administered influenza vaccine should be considered.
Action if patient declines or is excluded:	Refer to appropriate clinician e.g. GP, Public Health Consultant. If declined advise regarding protective effect of immunisation and potential disease complications. Document advice given and refer to appropriate clinician. Temporary exclusion: In case of postponement due to acute febrile illness, arrange a future date for immunisation. In case of exclusion as result of immunosuppression, severe asthma, wheezing at time of immunisation, pregnancy or salicylate therapy consider use of appropriate inactivated influenza vaccine For individuals six months and over the preferred vaccine is quadrivalent inactivated vaccine. N.B. not all brands of quadrivalent inactivated vaccine are recommended for use in children under three years of age.
Referral arrangements for further advice / cautions:	As above

Drug Details	
Name, form & strength of medicine:	Live attenuated intranasal influenza vaccine (LAIV®▼) Nasal spray, suspension in a prefilled nasal applicator
Route/Method 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.
Dosage (include maximum dose if appropriate):	0.2ml (administered as 0.1ml per nostril) LAIV▼is administered as a divided dose in both nostrils
Frequency:	Single dose for children not in clinical at risk group Children aged less than 9 years who are in a clinical at risk group who have not received influenza vaccine before should receive two doses of LAIV▼with the second dose at least 4 weeks after the first. If LAIV▼ is not available for the second dose e.g. due to batch expiry an inactivated influenza vaccine can be given.
Duration of treatment:	N/A
Maximum or minimum treatment period:	N/A

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Quantity to supply/administer:	N/A
Supply, Administer or Both:	Supply and Administer
▼Additional Monitoring:*	Yes
Legal Category:	POM
Is the use outwith the SPC:**	Yes The SPC states that in children aged less than 9 years who have not previously been immunised against influenza, a second dose should be given after an interval of at least four weeks. This is superceded by the Green Book recommendation to give a single dose of LAIV▼ to children **not** in a clinical at risk group.
Storage requirements:	Store between 2^0C-8^0C in locked storage. NHS GG&C Vaccine Ordering, Storage and Handling Guidelines should be observed http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/Pages/home_page.aspx Vaccine storage history e.g. temperature charts must be checked and deemed satisfactory before administration to patient.

*** The black triangle symbol has now been replaced by European "additional monitoring" (▼)**
**** Summary of Product Characteristics**

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Warnings including possible adverse reactions and management of these:	Nasal congestion/runny nose are the most common adverse reactions following administration of LAIV▼. Low grade fever, malaise, shivering, fatigue, headache, aching muscles and joint pain are among the commonly reported symptoms after vaccination. These symptoms usually disappear within one to two days without treatment. Please refer to current BNF, eBNF https://www.medicinescomplete.com/about/subscribe.htm or SPC at http://emc.medicines.org.uk/ for full details. Use the Yellow Card System to report adverse drug reactions directly to the CSM.CMS. Yellow Cards and guidance on their use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/
Advice to patient/carer including written information provided:	Explain treatment and course of action. Give patient a copy of relevant patient information leaflet. , if appropriate. PIL available at http://emc.medicines.org.uk/ Further Information available to patients at www.immunisationscotland.org.uk
Monitoring (if applicable):	N/A
Follow up:	See advice to patient/carer

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Staff Characteristics	
Professional qualifications:	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions and have current registration.
Specialist competencies or qualifications:	Has undertaken appropriate training and competence to undertake immunisation including recognition and treatment of anaphylaxis Has undertaken appropriate training for working under PGDs for the supply and administration of medicines
Continuing education & training:	All health care professionals working under the direction will be expected to maintain their competence as specified in hospital, local and national policies e.g. Nursing & Midwifery Council guidelines. The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development in all aspects of immunisation including recognition and treatment of anaphylaxis.
Referral Arrangements and Audit Trail	
Referral arrangements	Any prolonged reaction, whether mild or severe must be reported to an appropriate clinician for the department administering vaccination
Records/audit trail:	Consent forms Patient's name, address, date of birth and consent given; Contact details of GP (if registered); Dose, form administered and batch details. Advice given to patient (including side effects); Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment; Details of any adverse drug reaction and actions taken including documentation in the patient's medical record; Referral arrangements (including self-care) Depending on the clinical setting where immunisation is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate e.g.: • GP practice computer, • Individuals GP records, • Child Health Systems documentation • Consent Forms

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References/ Resources and comments:	Department of Health (2006): Immunisation against Infectious Disease [Green Book] http://immunisation.dh.gov.uk/category/the-green-book/ British National Formulary https://www.medicinescomplete.com/about/subscribe.htm Marketing authorisation holder's Summary of Product Characteristics http://emc.medicines.org.uk/ All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) http://www.sehd.scot.nhs.uk/index.asp?name=&org=%25&keyword=&category=9&number=10&sort=tDate&order=DESC&Submit=Go NMC (2015) Code of Professional Conduct. http://www.nmc-uk.org NMC (2010) Standards for Medicines Management http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf NHS GG&C Immunisation Best Practice Guideline http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/Pages/home_page.aspx NHS GG&C Vaccine Ordering Storage and Handling Guidelines http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/Pages/home_page.aspx

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This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at PPSU, 2nd Floor, Main Building, West Glasgow ACH. The PGD must be easily accessible in the clinical setting.

Organisation:	**NHS Greater Glasgow & Clyde**

Professionals drawing up PGD/Authors	
	Designation and Contact Details
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* Lead Author

AUTHORISATION:

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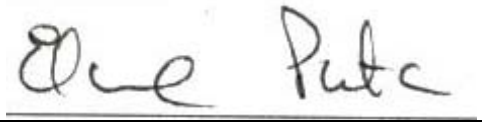
NHSGG&C PGD & Non-medical Prescribing Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		18/07/2018

Lead of the professional group to which this PGD refers:		
Professional Nurse Advisor, Primary Care Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Karen Jarvis		18/07/2018

Pharmacist representative of PGD & Non-Medical Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		18/07/2018

Antimicrobial use **If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT.**		
Microbiology approval	Name:	Designation:
	Signature:	Date:
	(on behalf of NHS GG&C AMT)	

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Local Authorisation:

Service Area for which PGD is applicable:			
I authorise the supply/administer medicines in accordance with this PGD to patients cared for in this service area.			
Lead Clinician for the service area (Doctor)			
Name:	**Signature:**	**Designation:**	**Date:**
E-Mail contact address:			

I agree that only fully competent, qualified and trained professionals are authorised to operate under the PGD. Records of nominated individuals will be kept for audit purposes.			
Name (Lead Professional)**:**	**Signature:**	**Designation:**	**Date:**
E-Mail contact address:			

Description of Audit arrangements:			
Frequency of checks: (Generally annually)		**Names of auditor(s):**	

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: 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.

I have read and understood the Patient Group Direction. I acknowledge that it is a legal document and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	**Signature**	**Date**