NHS
Greater Glasgow and Clyde

Patient Group Direction (PGD)

Administration of pneumococcal polysaccharide vaccine (PPV) Pneumovax 23®

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Version 2.0
Effective from: 01 June 2022
Review date: 31 May 2024

Recent Changes

Version	Date	Summary of changes
2.0	01/06/22	• Inclusion criteria expanded to include other patient groups out with the Scottish immunisation programme • Frequency section updated to include dosing information for the other patient groups out with the Scottish immunisation programme

Contents

Authorisation

PGD pneumococcal polysaccharide vaccine (PPV) Pneumovax 23®

This Patient Group Direction (PGD) 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 pneumococcal polysaccharide vaccine (PPV) Pneumovax 23® 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 (SPC) 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. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

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

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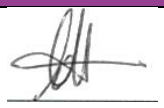
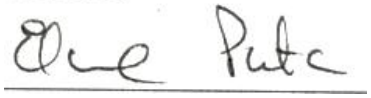
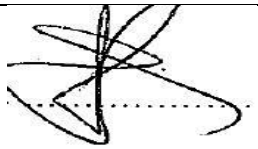
Pharmacist	Val Reilly, Public Health Pharmacist	
Nurse	Hilda Crookshanks (Health Protection Nurse Specialist)	

Date 04 July 2022

Approved on behalf of NHS Greater Glasgow and Clyde by ADTC Patient Group Direction Sub Committee representatives:

Chair	Dr Craig Harrow	
Senior Pharmacist	Elaine Paton, Senior Prescribing Adviser	
Nurse Director Representative	John Carson, Lead Nurse North Sector	

Signature

Date approved: 04/07/2022

Effective from: 01/06/2022 **Review date:** 31/05/2024

Clinical situation

Category	Description
Indication	Active immunisation against invasive disease caused by Streptococcus pneumoniae serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F

Category	Description
Inclusion criteria	• Adults aged 65 years and over not previously vaccinated with PPV23 • Individuals aged two years and over included in the clinical risk groups who should receive the PPV23 vaccine as defined in the Green Book Chapters 7 and 25 • Individuals with asplenia, splenic dysfunction or chronic kidney disease and who require a PPV23 booster (see Green Book chapter 25) • Individuals who are recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with **UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings** • Revaccination of individuals who have received a haemopoietic stem cell transplant • Valid consent has been given to receive the vaccine.
Exclusion criteria	• Children under 2 years of age • Anaphylactic reaction to a previous dose of PPV23 or any component of the vaccine • History of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free. • Individuals who have previously received PPV23 over the age of 2 years, except for individuals with asplenia, splenic dysfunction and chronic kidney disease • Have received pneumococcal conjugate vaccine (PCV13) in the preceding 8 weeks • Acute severe febrile illness - immunisation should be postponed until fully recovered
Cautions/need for further advice/ circumstances when further advice should be sought from a doctor	Chapter 25 of the Green Book advises that there are very few individuals who cannot receive PPV23 vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Category	Description
	Those requiring splenectomy or commencing immunosuppressive treatment should be vaccinated according to the age-specific advice in the Green Book chapter 25. Ideally, the vaccines should be given 4-6 weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to two weeks before treatment. If it is not possible to vaccinate beforehand, splenectomy, chemotherapy or radiotherapy should never be delayed. If it is not practicable to vaccinate two weeks before splenectomy, immunisation should be delayed until at least two weeks after the operation because functional antibody responses may be better from this time. If it is not practicable to vaccinate two weeks before starting chemotherapy/radiotherapy, immunisation should be delayed until at least three months after completion of therapy to maximise vaccine response. Immunisation of these patients should not be delayed if this is likely to result in a failure to vaccinate. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
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 at the clinic or GP as appropriate. If aged less than 2 years PPV23 is not indicated, ensure PCV immunisation is up-to-date. If PPV23 has previously been received over the age of 2 years and the individual does not have asplenia, splenic dysfunction or chronic kidney disease and the individual is not recommended vaccination for the public health management of clusters of serious pneumococcal disease in closed settings disease further PPV23 is not indicated. For those individuals who have received PCV in the preceding 8 weeks postpone immunisation until 8 weeks has elapsed. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
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

Category	Description
	Document advice given and decision reached. In NHS clinic setting, inform or refer to the clinician in charge. In GP practice setting, inform or refer to GP.

Description of treatment

Category	Description
Name of medicine	23-valent pneumococcal polysaccharide vaccine (PPV) Pneumovax 23® solution for injection
Form/strength	Pneumococcal polysaccharide vaccine 0.5ml solution for injection in a pre-filled syringe, with each 0.5ml dose containing 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.
Route of administration	Administer by intramuscular or subcutaneous injection. The preferred site is the deltoid region of the upper arm. The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by subcutaneous injection to reduce the risk of bleeding. The vaccine's normal appearance is a clear colourless solution. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.
Dosage	0.5ml
Frequency	Single dose for adults and children over the age of 2 years. Those with asplenia, splenic dysfunction or chronic kidney disease should receive a booster dose of PPV23 at five yearly intervals. **Revaccination of individuals who have received a haemopoietic stem cell transplant:** In accordance with the schedule recommended by the Scottish Haematology Society vaccination policy (Post HSC Transplantation): **http://scothaem.org/vaccination-policy-post-hsc-transplantation.asp** **Management of a pneumococcal disease clusters and outbreaks:** In accordance with advice from local Health Protection Team and informed by **Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals**

Category	Description
Duration of treatment	See Dose and frequency of administration above.
Maximum or minimum treatment period	See Frequency of administration above.
Quantity to supply/administer	See Dose
▼ black triangle medicines	No
Legal category	Prescription Only Medicine (POM)
Is the use out with the SPC?	No 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 under this PGD is allowed.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. Store in the original packaging to protect from light. Do not freeze. NHS board guidance on Storage and Handling of vaccines should be observed. 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.
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. Pneumococcal vaccines can be given at the same time as other vaccines such as DTaP/IPV/Hib/HepB, 4CMenB, MMR, MenACWY, Hib/MenC, Rotavirus and influenza. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If

Category	Description
	given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	Mild soreness and induration at the site of injection lasting one to three days and, less commonly, a low-grade fever may occur. More severe systemic reactions are infrequent. In general, local and systemic reactions are more common in people with higher concentrations of antibodies to pneumococcal polysaccharides. For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. In the event of severe adverse reaction individual should be advised to seek medical advice.
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.
Advice to patient or carer including written information	Written information to be given to individual • 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: • Individuals at especially increased risk of serious pneumococcal infection (such as asplenics and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need

Category	Description
	for early antimicrobial treatment in the event of severe, sudden febrile illness. • 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://yellowcard.mhra.gov.uk.
Observation following vaccination	Following immunisation patients remain under observation in line with NHS board policy.
Follow up	Not applicable
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.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)

Category	Description
	• pharmacists 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.
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 manufacturers product information/summary of product information, • 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.
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.

Audit trail

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that 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 • 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.

Additional references

Name	Description
Additional references	• Immunisation against Infectious Disease [Green Book] • Immunisation against Infectious Disease [Green Book] chapter 25 Pneumococcal disease • The Green book of immunisation - chapter 7 - Immunisation of immunocompromised individuals (publishing.service.gov.uk) • PHE Guidelines for the public health management of clusters of severe pneumococcal disease in closed settings • Scottish Haematology Society vaccination policy (Post HSC Transplantation) • Current edition of British National Formulary. • Marketing authorisation holder's Summary of Product Characteristics. • All relevant Scottish Government Health Directorate 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

PGD for administration of pneumococcal polysaccharide vaccine (PPV) Pneumovax 23® version 2.0 - Valid from: 01/06/2022 Expiry: 31/05/2024 - 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 pneumococcal polysaccharide vaccine (PPV) Pneumovax 23® 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 **[insert name of organisation]** 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.

Version History

Version	Date	Summary of changes
1.0	01/09/21	Version 1.0 new PGD
2.0	01/06/22	• Inclusion criteria expanded to include other patient groups out with the Scottish immunisation programme • Frequency section updated to include dosing information for the other patient groups out with the Scottish immunisation programme