This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration of

23-valent pneumococcal polysaccharide vaccine (PPV23)

By registered health care professionals for

individuals from 65 years of age and individuals from 2 years of age in a clinical risk group in accordance with the national immunisation programme for active immunisation against pneumococcal disease and UK guidelines for the public health management of clusters of serious pneumococcal disease in closed setting

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 75

1. Change history

Version number	Change details	Date
V01.00	New PHE PGD template	01/09/2016

V02.00	PPV PGD amended to: • include vaccination in accordance with UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings • include 64 year olds who may be immunised during the influenza season and who will turn 65 years by the 31 March • include both vial and pre-filled syringe presentations of PPV • include additional healthcare practitioners in Section 3 • refer to PHE vaccine incident guidance within the off- label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	08/08/2018
V03.00	PPV PGD amended to: • clarify abbreviation from PPV to PPV23 as used in the Green Book • Recommend vaccination contacts if not received PPV23 in the preceding 12 months • Insert a note on immunisation of welders in the inclusion section and remove mention elsewhere • Update off-label section in line with revised SPC • Include minor wording, layout and formatting changes for clarify and consistency with other PHE PGD templates	19/05/2020
V04.00	PPV PGD amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1st July 2022 • remove NHS England DES (2020/21) cohort 64 years turning 65 years old by 31 March statement and related footnote from criteria for inclusion as PPV is now part of General Medical Services Statement of Financial Entitlements Directions 2022/23 (GMS SFE) • remove the generic pneumococcal polysaccharide vial from name, dose and strength section as it has been discontinued by manufacturer • update supplies section following the change to supply route on 1 July 2021 • remove from special considerations section the generic statement from Green Book Chapter 7 regarding the timing of the vaccination in immunosuppressive treatments and aligned it to the specific guidance in Chapter 25 • update references • delete Appendix A for consistency	29/06/2022

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Pre Signatures			
Job Title	**Name**	**Signature**	**Date**
Pharmaceutical Adviser			
Head of Ambulance Services			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	Dr Rizwan Khan	N/A	N/A
Final signatures			
Medical Director	Dr Marina Hudson		
Director of Nursing	Paul Moore		

5. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration *(continued)*	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) • The practitioners above must also fulfil the Additional requirements detailed below. • Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD. Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis

Qualifications and professional registration *(continued)*	• must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	• The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years • Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). • Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSE and other sources of medicines information. • Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

6. Clinical Conditions

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals from 65 years of age and individuals from 2 years of age in a clinical risk group, for the prevention of pneumococcal disease in accordance with the national immunisation programme and UK guidelines for the public health management of clusters of severe pneumococcal disease in closed settings (see Managing clusters of pneumococcal disease in closed settings) and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the 'Green Book'.

Inclusion criteria	Individuals who: • are aged 65 years and over • are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book Chapter 25 Table 25.2. • have asplenia, splenic dysfunction or chronic kidney disease (see Chapter 25 Table 25.2) and require a pneumococcal polysaccharide vaccine (PPV23) booster • are recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing clusters of pneumococcal disease in closed settings Note: Individuals at risk of frequent or continuous occupational exposure to metal fumes (such as welders) should be considered for immunisation taking into account exposure control measures in place. This indication is outside the remit of this PGD.
Exclusion criteria **Criteria for exclusion**[1]	Individuals for whom no valid consent has been received. Individuals who: • are less than 2 years of age • have previously received PPV23 over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see Green Book Chapter 25) and those recommended vaccination for the public health management of clusters of severe pneumococcal disease in closed settings • have had a confirmed anaphylactic reaction to a previous dose of PPV23 or to any component of the vaccine • have received pneumococcal conjugate vaccine (PCV) in the preceding 8 weeks • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions (including any relevant action to be taken)	Antibody response may be impaired in those with immunological impairment and those with an absent or dysfunctional spleen (see Special considerations / additional information section regarding appropriate timing of vaccination)
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded *(continued …)*	• 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 (see Green Book Chapter 25) and the individual is not recommended vaccination for the public health management of clusters of severe pneumococcal disease in closed settings, further PPV23 is not indicated

[1]Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Action to be taken if patient excluded *(… continued)*	• 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 at the earliest opportunity • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required • The risk to the individual of not being immunised must be taken into account • Document the reason for exclusion and any action taken in the individual's clinical records • Inform or refer to the GP or a prescriber as appropriate
Action to be taken if patient declines treatment	• Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. For further information on consent see Chapter 2 of the 'Green Book' • Any patient who declines care must have demonstrated capacity to do so (see the Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty) • Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease • Document advice given and the decision reached • Inform or refer to the GP as appropriate

7. Details of the medicine

Name, form and strength of medicine	Pneumovax® 23 solution for injection in a pre-filled syringe Each 0.5ml dose contains 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.
Legal category	Prescription only medicine (POM)
Indicate any off-label use (if relevant)	• Administration of a further dose of PPV23 to high-risk individuals who have already received a dose of PPV23 more than 12 months previously is off-label but may be recommended in accordance with the Managing clusters of pneumococcal disease in closed settings • Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD • 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

Route/method 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 in accordance in the Green Book Chapter 4 • 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 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 • 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 • The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website
Dose and frequency	• Single 0.5ml dose. • Individuals with asplenia, splenic dysfunction or chronic kidney disease (see Chapter 25) should be revaccinated at 5 year intervals. • PPV23 should be offered to high-risk individuals recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with Managing clusters of pneumococcal disease in closed settings, unless they have received PPV23 in the previous 12 months. • Revaccination is not routinely indicated for other individuals.
Quantity to be administered	Single 0.5ml dose (see Dose and frequency of administration regarding indications for revaccination)
Maximum or minimum treatment period	Single 0.5ml dose (see Dose and frequency regarding indications for revaccination)
Storage	• Store at +2°C to +8°C • Store in original packaging in order to protect from light • Do not freeze • 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. Refer to PHE Vaccine Incident Guidance

Adverse effects	• Local reactions following vaccination are very common including pain, swelling, soreness, warmth, induration and/or redness at the injection site • A low-grade fever may occur • The most common systemic adverse events reported are asthenia/fatigue, myalgia and headache. Hypersensitivity reactions and anaphylaxis can occur but are very rare • Rarely, injection site cellulitis has been reported • Other adverse events have been reported in clinical trials and post-marketing surveillance but the frequency of these is not known • A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website. **Reporting procedure of adverse reactions:** • Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store • Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed
Records to be kept	• The administration of any medication given under a PGD must be recorded within the patient's medical records • See Appendix C for more details

8. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request • Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. • Immunisation promotional material may be provided as appropriate: Splenectomy leaflet • Available from: www.gov.uk/government/collections/immunisation

Follow-up advice to be given to patient or carer	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • Inform the individual/parent/carer of possible side effects and their management • Vaccination may not result in complete protection in all recipients • Individuals at especially increased risk of serious pneumococcal infection (such as individuals with asplenia, splenic dysfunction and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness • The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction • When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due

9. Appendix A

References

- British National Formulary (BNF) available online: https://bnf.nice.org.uk
- Nursing and Midwifery "The code" available online: https://www.nmc.org.uk
- Current Health Care Professions Council standards of practice
- General Pharmaceutical Council standards
- Electronic medicines compendium available online: https://www.medicines.org.uk
- Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty http://edrmgi/sites/hospital/Clinical%20Policies%20and%20Procedures/Policy%20for%20Capacity,%20Best%20Interests%20Decisions%20and%20Deprivation%20of%20Liberty.pdf#search=deprivation

Pneumococcal polysaccharide vaccine

- Immunisation Against Infectious Disease: The Green Book Chapter 25 last updated 13 January 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Summary of Product Characteristic for Pneumovax® 23vaccine, Merck Sharp & Dohme Limited. Last updated 29 January 2021. https://www.medicines.org.uk/emc/product/9692/smpc
- Guidelines for the public health management of clusters of severe
- pneumococcal disease in closed settings. Updated 21 February 2020. https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings
- Pneumococcal polysaccharide vaccine: change to the supply route from June 2021 letter https://www.gov.uk/government/publications/pneumococcal-polysaccharide-vaccine-change-to-the-supply-route-from-june-2021-letter

General
• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. March 2017. https://www.nice.org.uk/guidance/mpg2/resources • Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

10. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

11. Appendix C

Supplies	• From 1 July 2021 changes were made to the supply route of PPV23 for the use in the NHS pneumococcal polysaccharide immunisation programme to bring the supply in line with the other national immunisation programmes. • Vaccines are available to order from the ImmForm website for the routine immunisation programme and immunisation of those with underlying medical conditions (see Change to the supply route of Pneumococcal Polysaccharide Vaccine (Pneumovax®23), vaccine for the national immunisation programme). • Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).

Disposal	• Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013) • Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in an UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the • Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	• Immunological response may be diminished in those receiving immunosuppressive treatment but it is important to still immunise this group • PPV23 may be given at the same time as other vaccines • PPV23 can also be given at the same time as shingles vaccine, Zostavax®, as recommended in the 'Green Book' following assessment of the evidence, concluding that there is no reduction in the effectiveness of Zostavax®
Special considerations/ additional information *(continued …)*	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. • 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. • Individuals who are a contact of pneumococcal disease do not usually require PPV23. Immunisation may be indicated for close contacts where there is a confirmed cluster of serious pneumococcal disease in a closed setting and should be on the advice of your local Health Protection Team. • 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. **Timing of vaccination** • Individuals with immunosuppression and HIV infection (regardless of CD4 count) should be given pneumococcal vaccines according to the recommendations. • Wherever possible, immunisation or boosting of immunosuppressed or HIV-positive individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen. The optimal timing for any vaccination should be based upon a judgement about the relative need for rapid protection and the likely response. For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least two weeks before commencement. In some

Special considerations/ additional information *(… continued)*	cases, this will not be possible and therefore vaccination may be carried out at any time and re-immunisation considered after treatment is finished and recovery has occurred. Ideally, PPV23 should be given four to six 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 (see Green Book Chapter 25). • If it is not practicable to vaccinate two weeks or more before splenectomy, immunisation should be delayed until at least two weeks after the operation. • If it is not practicable to vaccinate two weeks or more before initiation of chemotherapy and/or radiotherapy, immunisation should be delayed until at least three months after completion of therapy in order to maximise the response to the vaccine. • Immunisation of these individuals should not be delayed if this is likely to result in failure to vaccinate. • Splenectomy, chemotherapy or radiotherapy should never be delayed to allow time for vaccination.
Records to be kept	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and 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 via PGD Records should be signed and dated (or a password controlled immuniser's record on e-records) All records should be clear, legible and contemporaneous: • This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed • The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate • documentation/pathway as required by any local or contractual arrangement A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy

12. Appendix D

Clinical risk groups who should receive the pneumococcal immunisation
(Green Book Chapter 25 Table 25.2)

Clinical risk group	Examples (decision based on clinical judgement)
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction. (Re-immunisation is recommended every 5 years)
Chronic respiratory disease	This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neurological disease (e.g. cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless so severe as to require continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below)
Chronic heart disease	This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure
Chronic kidney disease	Nephrotic syndrome, chronic kidney disease at stages 4 and 5 and those on kidney dialysis or with kidney transplantation. (Re-immunisation is recommended every 5 years)
Chronic liver disease	This includes cirrhosis, biliary atresia and chronic hepatitis
Diabetes	Diabetes mellitus requiring insulin or oral hypoglycaemic drugs. This does not include diabetes that is diet controlled
Immunosuppression	Due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, asplenia or splenic dysfunction, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO) Individuals on or likely to be on systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day
Individuals with cochlear implants	It is important that immunisation does not delay the cochlear implantation
Individuals with cerebrospinal fluid leaks	This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery (does not include CSF shunts)