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

Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13)

By registered health care professionals for

individuals from 12 weeks to under 2 years of age in accordance with the national immunisation programme for active immunisation against pneumococcal disease and to individuals from 6 weeks of age recommended PCV13 in response to an outbreak of pneumococcal disease

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

PGD NUMBER 76

1. Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19/01/2016
V02.00	PHE PCV PGD amended to: • include early administration from 6 weeks of age • include administration for the management of outbreaks • include additional healthcare practitioners in Section 3 • add paragraph on patient consent to the off-label section • reference the protocol for ordering storage and handling of vaccines • include additional stability data from products SPC • refer to PHE vaccine incident guidance within the off-label and storage sections • include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	28/11/2018
V03.00	PHE PCV PGD amended to: • reflect the 1+1 schedule for individuals born on or after 1 Jan 2020 and the immunisation from 12 weeks of age • refer to the PCV Risk Groups PGD for the immunisation of individuals with aspenia, splenic dysfunction, complement disorder and severe immunocompromise • include rewording, layout and formatting changes for clarify and consistence with other PHE PGDs	20/12/2019
V04.00	UKHSA PCV PGD amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGD and updated references • remove from actions following exclusion, off label and dose/frequency sections, information pertaining to the 2+1 schedule • add in the exclusion section the recommendation to have minimum 4 weeks interval between PCV13 vaccinations • include in the off-label the information for partially immunised as per the 'Green Book', Chapter 25 13 January 2020 • provide detail to primary dose and schedule for premature infant in cautions section • include in the dose and frequency section immunisation recommendations for premature infants and unimmunised or partially immunised children as per Green Book Chapter 25, 13 January 2020 • include to the special considerations information for immunisation for bone marrow transplant • update the dose and frequency in line with the Green Book Chapter 25, 13 January 2020	16/02/2022

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

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. 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	• 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 Additionally practitioners: • 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 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)

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

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of: • individuals from 12 weeks to under 2 years of age for the prevention of pneumococcal disease in accordance with the national immunisation programme and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the 'Green Book' • individuals from 6 weeks of age recommended PCV13 in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals
Inclusion criteria	Individuals from 12 weeks to under 2 years of age who: • require a primary dose of PCV13 • require a reinforcing booster dose of PCV13 against pneumococcal disease Individuals from 6 weeks of age recommended PCV13 in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Note: Individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease may require additional vaccination outside the inclusion criteria for this PGD - see PCV Risk Groups PGD and Chapter 25 of the 'Green Book'.

Exclusion criteria[1]	Individuals for whom no valid consent has been received. Individuals who: • are less than 12 weeks of age, unless PCV13 is recommended in response to an outbreak of pneumococcal disease • are aged 2 years and over, unless PCV13 is recommended in response to an outbreak of pneumococcal disease • have received a dose of PCV13 within the last 4 weeks (Note: national schedule recommends an 8-week interval, see Dose and frequency of administration section) • have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine, including diphtheria toxoid • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Individuals with asplenia, splenic dysfunction, complement disorder and who are severely immunocompromised should be vaccinated in accordance with Chapter 7 and Chapter 25 of the 'Green Book' an appointment needs to be arranged with the General Practitioner
Cautions (including any relevant action to be taken)	• The immunogenicity of the vaccine could be reduced in immunosuppressed individuals and additional doses may be recommended, see the 'Green Book' Chapter 7 and Chapter 25 and the PCV Risk Groups PGD. • Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. • The occurrence of apnoea following vaccination is especially increased in infants who are born very prematurely. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hrs.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment

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

Action to be taken if patient excluded	• Immunisation can be administered to infants from 6 weeks of age if at increased risk of exposure due to an outbreak (see Dose and frequency of administration) • If aged less than 6 weeks defer immunisation and provide an appointment as appropriate • If aged 2 years and over routine immunisation with pneumococcal vaccine is not indicated. If the individual is at increased risk of pneumococcal disease, in accordance with the 'Green Book' Chapter 7 and Chapter 25, refer to the PCV Risk Groups PGD • Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered. Immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged • 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 • Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications • Document advice given and the decision reached • Inform or refer to the GP as appropriate

8. Details of the medicine

Name, form and strength of medicine	Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed), PCV13, eg: Prevenar® 13 suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Indicate any off-label use (if relevant) *(continued)*	• Administration of a two-dose primary series of Prevenar®13 to pre-term infants <37 weeks gestation is contrary to the three-dose primary schedule detailed in the SPC but is in accordance with the recommendations for the Vaccination of premature infants and Chapter 25 of the 'Green Book' • Administration of a one-dose primary series of Prevenar®13 is contrary to the two or three dose primary schedule detailed in the SPC but is in accordance with the recommendations and Chapter 25 of the 'Green Book' • A single dose schedule for previously unvaccinated individuals between 12 months and up to 2 years of age is contrary to the 2-dose schedule detailed in the SPC but is in accordance with the

Indicate any off-label use (if relevant) *(continued)*	national recommendations for the Vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the 'Green Book' • A single dose schedule for partially immunised individuals between 12 months and up to 2 years of age is not consistent with the SPC but is in accordance with the national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and Chapter 25 of the 'Green Book' • 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 injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid region of the upper arm may be used in individuals over one year of age • For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be administered in accordance with the recommendations in the 'Green Book' Chapter 4 to reduce the risk of bleeding
Dose and frequency *(continued)*	Single 0.5ml dose per administration **Routine Childhood Immunisation Schedule** Infants, who do not have asplenia, splenic dysfunction, complement disorder or who are severely immunocompromised, (see Green Book Chapter 25, Table 25.2) should be offered a 1+1 PCV schedule, that is: • a single priming dose of PCV13 to be administered from 12 weeks of age, followed by • a PCV13 booster dose to be administered at one year old, on or soon after their first birthday and before 2 years of age. Routine immunisation with PCV13 is not offered after the second birthday. **Premature infants** Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age, no matter how premature they are (see 'Green Book' Chapter 25). Since the immunogenicity of PCV13 will be lower if given at a

Dose and frequency *(continued)*	younger age, any dose given before 12 weeks of age should not be counted as the single priming dose for the 1+1 schedule and the routine PCV dose should be given once the infant reaches 12 weeks of age, leaving a minimum 4-week interval between the priming dose and any preceding dose. **Unimmunised or partially immunised children** Unimmunised or partially immunised infants who do not have asplenia, splenic dysfunction, complement disorder or who are severely immunocompromised[2] who: • present late for vaccination, and before one year of age, should receive a primary dose of PCV13 before the age of one year, and a booster dose at one year of age, leaving an 8-week interval between the primary PCV13 dose and the booster. Where the infant is presented very late (such as at 11 months), then a minimum interval of four weeks should be observed before the booster dose • present for vaccination between one year and under two years of age should only have a single dose of PCV13 • do not have a reliable history of previous immunisation should be assumed to be unimmunised and the routine programme should be followed (see above) • have received one or more doses of PCV10 vaccine in another country should be offered PCV13 vaccination in accordance with the UK PCV13 vaccination schedule (see above) with a minimum interval of 4 weeks between PCV13 vaccination and any preceding PCV10 dose. Where the infant is presented very late (such as at 11 months), then a minimum interval of four weeks should be observed between the PCV13 priming dose and booster dose See flow chart for Vaccination of individual with uncertain or incomplete immunisation status. (Appendix D) **Management of a pneumococcal disease clusters and outbreaks in closed settings with high-risk individuals** A single dose of PCV 13 may be administered to adults and children from 6 weeks of age who have not received PCV13 vaccine in the preceding 4 weeks and who are identified as requiring PCV13 immunisation in accordance with Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Note: PPV23 would ordinarily be used in an outbreak with the exception of serotype 6A/6C disease, individuals under 2 years of age, and where PPV23 is unavailable or otherwise inappropriate.

[2] Examples of severe immunocompromised include bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO)

Quantity to be administered	Single 0.5ml dose per administration
Maximum or minimum treatment period	See dose and frequency of administration section above
Storage	• Store at between +2°C to +8°C • Store in original packaging in order to protect from light • Do not freeze • Prevenar®13 is stable at temperatures up to 25°C for four days. At the end of this period Prevenar®13 should be used or discarded. These data are intended to guide health care professionals in case of temporary temperature excursions • 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 Vaccine Incident Guidance
Adverse effects	• Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site • The most commonly reported adverse reactions include, fever, irritability, decreased appetite, increased and/or decreased sleep, rash, vomiting and diarrhoea • Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare • A detailed list of adverse reactions is available in the 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

9. 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 marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies 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 • Advise the individual/parent/carer when any subsequent immunisations are due • When administration is postponed advise the individual/parent/carer when to return for vaccination

10. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

Pneumococcal conjugate vaccine

- Immunisation Against Infectious Disease: The Green Book Chapter 25 January 2020 https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25
- Summary of Product Characteristics for Prevenar® 13 suspension for injection, Pfizer Ltd. 12 October 2021. http://www.medicines.org.uk/emc/medicine/22689
- Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. 26 August 2021. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status
- Changes to the infant pneumococcal conjugate vaccine schedule: Information for healthcare practitioners. Public Health England. 13 December 2019. https://www.gov.uk/government/publications/pneumococcal-vaccination-guidance-for-health-professionals
- Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Public Health England 21 January 2020 https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings

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. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- UKHSA 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

11. 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

12. Appendix C

Route/method of administration	• 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 uniform white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine • The vaccine should be visually inspected prior to administration and should not be used if discoloured or foreign particles are present • The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
Supplies	• Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge. • Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the '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 an UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the 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. Vaccination is recommended even if the antibody response may be limited • May be given at the same time as other vaccines • A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website

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 Services team 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
Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination • Individuals with asplenia, splenic dysfunction, complement disorder and severe immunosuppression are at increased risk of pneumococcal disease and require additional doses of PCV13 in accordance with the 'Green Book' Chapter 7 and Chapter 25. • Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 and Chapter 25 of the 'Green Book'). This is not covered by this PGD and should be provided through a Patient Specific Direction (PSD)

13. Appendix D