

Advisory document to support the delivery of Pneumococcal polysaccharide conjugate vaccine (adsorbed) in accordance with the National Immunisation Programme in Wales

We gratefully acknowledge UKHSA for their permission to use their PCV (13-valent or 15-valent adsorbed) PGD as a reference resource across NHS Wales, to be used alongside this associated advisory document.

Individual Summaries of Product Characteristics (SmPCs) may differ in their licensed indications from official vaccination policy as specified in the Green Book and Welsh Policy.

On these occasions, Green Book recommendations should take precedence and provides the rationale for any off-label use. Practitioners using authorised PGDs should also be familiar with the relevant chapters of the Green Book, SmPCs and Welsh Policy, and be constantly alert to any subsequent recommendations from Public Health Wales and/or Welsh Government and other sources of medical information.

Prepared by: the Welsh Medicines Advice Service (WMAS)

Any queries regarding the content of this advisory document should be addressed to: welshmedicines.information@wales.nhs.uk

The relevant amendments, governance and sign off for any PGD is the responsibility of the authorising organisation in Wales.

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Additional clinical conditions or situations to which this advisory document applies

Pneumococcal polysaccharide conjugate vaccine (adsorbed) PGD in accordance with the National Immunisation Programme

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Section 5. Description of treatment

Off Label use

Revised wording highlighted as follows:

Administration of a **2-dose schedule** of Prevenar[®]13 or Vaxneuvance[®] to pre-term infants <37 weeks gestation is contrary to the **4-dose schedule** detailed in the SmPC 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 or Vaxneuvance[®] is contrary to the 2 or 3 dose primary schedule detailed in the SmPC 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 Prevenar[®]13 and Vaxneuvance[®] SmPCs 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.

A single dose schedule for partially immunised individuals between 12 months and up to 2 years of age is not consistent with the SmPCs for Prevenar[®]13 or Vaxneuvance[®] 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.

Vaccines 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 the 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 or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.