Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare 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. Healthcare professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

Respiratory Syncytial Virus (RSV) vaccine (Abrysvo▼®) for prevention of lower respiratory tract disease caused by RSV

by registered healthcare professionals in accordance with the

RSV vaccination programme for OLDER ADULTS

in Powys Teaching Health Board

Version number: PGD 0242B

Reference Number: PGD 0242B
Valid from: 01/04/2026
Review Date: 01/11/2028
Expiry Date: 31/03/2029

Change History		
Version number	**Change details**	**Date**
PGD 0242	Initial issue. Produced using Welsh Medicines Advice Service template version 1.0 (National reference: CYM-24010). Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs	01/09/2024
PGD 0242A	WMAS template version 2.0 (National reference – CYM- 25018) adopted: Inclusion criteria updated as per the CMO letter 2025/04 amendment to WHC/024/032. Individual or carer advice section updated with advice to seek medical attention if they develop signs of Guillain-Barre syndrome. Drug interaction section updated as per the GB chapter. RSV vaccine can be safely co-administered with COVID-19 vaccine. Reference section updated with reference to JCVI advice and CMO letter (CEM/CMO/2025/04).	01/09/2025
PGD 0242B	WMAS template version 3.0 (National reference – CYM- 26001) adopted: Inclusion criteria reviewed and updated as per the Welsh Health Circular (WHC/2025/053) to include individuals 80 years and over and individual in care homes for older adults, regardless of age. Reference to advisory document on ordering, storage and handling of vaccines section 5 removed. Adverse effects section updated as per the SmPC.	01/04/2026

PGD for the administration of Respiratory Syncytial Virus (RSV) vaccine (Abrysvo▼®) by healthcare professionals in accordance with the RSV vaccination programme for older adults and the recommendations in the Green Book.

This Powys Teaching Health Board PGD is based on the template (National reference CYM-26001, Respiratory Syncytial Vaccine (RSV) (Abrysvo▼®) older adults PGD, version no. 3.0) developed by the following health care professionals on behalf of NHS Wales and peer reviewed by the Vaccine Clinical Advisory Group in accordance with the Welsh Medicines Advice Service (WMAS) PGD policy and ratified by the All Wales PGD Advisory Board on 12 March 2026.

The WMAS template has been adapted for use in PTHB.
Local enquiries regarding the use of this PGD may be directed to Medicines Management: 01874 712641.

Assembly, final preparation and administration of vaccines supplied and administered under this PGD must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines should also be in accordance with the manufacturer's instructions in the product's UK Summary of Product Characteristics and / or in accordance with official national recommendations.

Developed by the following health professionals on behalf of NHS Wales:

Name	Designation
Expert reviewer – David Andrews	Medical Director for Primary Care and Community, Cwm Taf Morgannwg University Health Board. Member of the Vaccine Clinical Advisory Group
Main author – Dianne Burnett	National Lead pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB. Member of the Vaccine Clinical Advisory Group
Expert reviewer – Hawys Youlden	Lead Nurse/Practitioner VPDP, Health Protection Team, Public Health Wales

Expert panel

Name	Designation
Andrew Evans	Chief Pharmaceutical Officer
Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB
Christopher Johnson	Head of VPDP, Public Health Wales
Beverley Griggs	Consultant in Health Protection/Communicable Disease Control, Public Health Wales
David Andrews	Medical Director representative, Primary Care. Cwm Taf Morgannwg UHB
Siân Owen	Lead Doctor Immunisation, Associate Specialist in Community Paediatrics, Betsi Cadwaladr UHB
Heather Payne	Senior Medical Officer, Welsh Government
Paul Labourne	Senior Nursing Officer, Office of the CNO, Welsh Government
Nicola Bevan	Nurse Consultant, Deputy Head Vaccine Preventable Disease Programme

PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	3/24/2026
Senior Pharmacist **Jayne Price**	PTHB Community Pharmacy Services, Medicines Management	DocuSigned by: Jayne Price A9AFDC3B15294CC...	3/24/2026
Senior representative of professional group using the PGD **Paul Hooton**	Executive Director of Nursing and Midwifery for PTHB	Signed by: Paul Hooton EEABC83AC83F4B9...	3/26/2026
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	Signed by: Lucie Cornish 48844B7FC02A448...	3/27/2026

The PGD is not legally valid until it has had the authorisation of the organisation in which the practitioner using it operates.

It is the responsibility of the organisation, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Those using this PGD must ensure that it is authorised by the organisation in which they are operating and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human

Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

The final authorised copy of this PGD should be kept by the authorising organisation for 8 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 8 years after the PGD expires.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

[1] This includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178, 2015 No.323 and 2024 No.729).s

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Characteristics of staff

Qualifications and professional registration	**Practitioners must only work under this PGD where they are competent to do so.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC). • pharmacy professionals currently registered with the General Pharmaceutical Council (GPhC). • chiropodists/podiatrists, dietitians, 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 (GDC). • optometrists registered with the General Optical Council (GOC). Practitioners must also fulfil the Additional requirements. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be employed by, or providing services on behalf of, Powys Teaching Health Board or a PTHB GP Practice. • 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 have completed Patient Group Directions training (available via eLfH PGD eLearning programme. PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion.

	• must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A). • must be familiar with the vaccine product and alert to changes in the SmPC, Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes (the Welsh Health Circulars and Public Health Wales). • must have undertaken training appropriate to this PGD as required by local policy and health board standard operating procedures. • if new to immunising, the national minimum standards for immunisation training recommend a core curriculum of training should be completed. UKHSA provide this core immunisation training as an e-learning module called the Immunisation programme. Information about this module is available here: Immunisation eLearning - Public Health Wales. This page offers support on how to access the resource via ESR, or for staff outside of NHS Wales via the Learning@Wales platform. Training resources and guidance documents are also available to view here: Immunisation training resources and events - Public Health Wales (nhs.wales). A series of RSV recorded slides are also available to view here: Training (sharepoint.com). Please contact PTHB Immunisation coordinator for further information. • must be competent to undertake immunisation and to discuss issues related to immunisation. • must be competent in the injection technique appropriate for the vaccine (see route / method of administration section) • must be competent in the handling and storage of vaccines, and management of the cold chain. Completion of cold chain training (also available via ESR). • must be competent in procedures for the use of aseptic non-touch technique (ANTT) for drawing up the correct dose, following the procedure for mixing adjuvant/antigen. (see route / method of administration section). • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills.

	• 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.**
Ongoing training and competency	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). • be aware of any updates to relevant national guidelines from Public Health Wales, NHS Wales, Welsh Government Welsh Health Circulars (WHC) and other sources of medicines information. • be aware of any updates made to the product in its SmPC or BNF entries or in the Green Book. • as registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained. Practitioners must make a self-declaration of competency on PADR (if relevant). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. • have demonstrated competence in Basic Life Support skills including resuscitation skills and the management of anaphylaxis, in line with the published requirements for provision of this service. • Comply with all mandatory NHS training (if relevant). Note: The most current national recommendations should be followed. However, if updated recommendations mean that to vaccinate the individual would be outside the scope of this PGD, the individual should be referred to an appropriate clinician for vaccination. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Respiratory Syncytial Virus (RSV) vaccine is indicated for the immunisation of older adults in accordance with the RSV vaccination programme 2024 for older adults (WHC/2024/032), and the subsequent update on RSV vaccination programme WHC/2025/016 and WHC/2025/053, the recommendations given in the Green Book: respiratory syncytial virus (RSV) chapter, the information for healthcare professionals guidance and subsequent official correspondence / publications.
Inclusion Criteria	Respiratory Syncytial virus vaccine (Abrysvo▼®) can be given to: • individuals aged 75 years and over (with no upper age limit). • individuals in care homes for older adults, regardless of age. Medical and drug history taken, no reason for exclusion. Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below). **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.**
Exclusion Criteria[2]	Respiratory syncytial virus (RSV) vaccine (Abrysvo▼®) should not be given to: • individuals for whom no valid consent has been received or a 'best-interests' decision, in accordance

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

	with the Mental Capacity Act 2005, has not been obtained (for further information on consent see chapter 2 of the Green Book). The Patient Information Leaflet (PIL) for Abrysvo▼® should be available to inform consent. • individuals less than 75 years unless they are a resident in a care home for older adults. • individuals who have had a confirmed anaphylactic reaction to a previous dose of the vaccine. • individuals who have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process. See SmPC for the list of excipients. • individuals who have already received a dose of RSV vaccine under the NHS programme. • individuals who are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation). Refer to section action to be taken if the individual is excluded or the individual or carer declines.
Cautions	Refer to the SmPC for full details of special warnings and precautions for use. Facilities for management of anaphylaxis should be available at all vaccination sites (see chapter 8 of the Green Book) and advice issued by the Resuscitation Council. **Syncope** Syncope (fainting) can occur following, or even before, any vaccination 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. There is no routine requirement for observation following Abrysvo▼® administration but individuals should be observed for any immediate reactions whilst receiving any verbal post vaccination information and exiting the centre. However, as fainting can occur following vaccination, all those vaccinated with Abrysvo▼® should be advised to not drive for 15 minutes after vaccination.

	Immunocompromised Individuals with immunosuppression, HIV (regardless of CD4 count) or taking immunosuppressant medication may have a reduced response to vaccination. However, vaccination should proceed in accordance with national recommendations (see Green book). Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list). Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads
Action to be taken if the individual is excluded or the individual or carer declines	• Explain the reasons for exclusion and any advice or action taken and document in the individual's record in the Welsh Immunisation System (WIS). • Seek appropriate advice from the local Immunisation team or the individual's clinician as required. • In case of postponement due to acute illness and who are not at immediate risk of exposure, advise when the individual can be vaccinated and ensure another appointment is arranged. • 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 recovered fully. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Advise when the individual can be vaccinated and ensure another appointment is arranged.

	• Individuals who have not yet turned 75 years of age or who are not residents in care homes for older adults are not eligible for the RSV programme and should be advised when they will become eligible for immunisation. • In the older adult programme, there is no current evidence to support revaccination. If a dose of vaccine has been previously administered under the NHS older adult programme to an individual, they should be reassured that no further protection against RSV is currently advised. See special considerations section. • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a 'Best Interests' decision to vaccinate may be made for the individual and be equivalent to the requirement for informed consent for administration. For further information on consent, see chapter 2 of the Green Book. • If the individual declines, advise about the protective effects of the vaccine and the consequences of not receiving it. • The risk to the individual of not being immunised should be considered. • If a confirmed anaphylactic reaction has been experienced after a previous dose of respiratory syncytial virus vaccine or any of its components, specialist advice should be sought. • Document all advice given and the decision reached.
Arrangements for referral for medical advice	If there is any doubt about the administration of the vaccine or an individual's suitability to receive the vaccine, an appropriate medical professional should be consulted. Document any advice given.

Description of treatment

Name, strength and formulation of drug	Abrysvo▼® (respiratory syncytial virus vaccine (bivalent, recombinant) powder and solvent for solution for injection). After reconstitution each 0.5 mL dose contains: • 60 micrograms RSV subgroup A stabilised prefusion F antigen • 60 micrograms RSV subgroup B stabilised prefusion F antigen

Legal category	POM - Prescription Only Medicine
Black triangle▼	Yes. Being newer vaccines, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme. This information was accurate at the time of writing. See product SmPCs for indication of current black triangle status.
Off-label use	Yes. Administration by deep subcutaneous injection in individuals with a bleeding disorder is off-label. Administration into the anterolateral thigh is also off-label but may be necessary in certain circumstances—for example, in frail older adults with low muscle mass. In these types of situations, alternative routes of administration may be appropriate where the deltoid intramuscular route is unsuitable and is consistent with the advice in Immunisation procedures: the green book, chapter 4. See route / method of administration section below • 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 the UKHSA Vaccine Incident Guidance Where a 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, as part of the consent process, consider informing the individual or their parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Preparation	Abrysvo▼® must be reconstituted in accordance with the manufacturer's instructions prior to administration See appendix B for the preparation for administration instructions.

	An instructional video on the preparation of respiratory syncytial virus (RSV) vaccine (Abrysvo▼®) is available here: https://www.pfizerpro.co.uk/medicine/abrysvo/dosing/preparation When adding the vaccine solvent to the powder vial, the vial must be gently swirled for approximately 1-2 minutes. See SmPC for the full preparation instructions.
Route / method of administration	• Prior to administration inspect visually and ensure appearance is consistent with the description below and in the SmPC. • Abrysvo▼® is a white powder which comes with a clear, colourless solvent (water for injection). • Abrysvo▼® forms a clear and colourless solution upon reconstitution. The solution should be visually inspected for particulate matter and discoloration before use. Do not use if large particulate matter or discolouration is found. In the event of any damage to the pre-filled syringe, foreign particulate matter and/or variation of physical aspect being observed, the vaccine should be discarded. • After reconstitution, the vaccine should be used promptly (see storage section). • Abrysvo▼® is given as a 0.5 mL dose by intramuscular injection preferably into deltoid region of the upper arm or anterolateral thigh. See Green book chapter 4. • Do not inject the vaccine intravascularly or intradermally. • Do not mix the vaccine with other vaccines or other medicinal products. • Administration should be under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible. It is recommended that individuals should be observed for immediate adverse effects post vaccination. • Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. • If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. • Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their

	scheduled INR testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual or their carer should be informed about the risk of haematoma from the injection. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. • For individuals with an unstable bleeding disorder or where the intramuscular route is otherwise deemed unsuitable, vaccines normally given by the intramuscular route may be given by deep subcutaneous injection to reduce the risk of bleeding (see the off-label section and the Immunisation procedures: the green book, chapter 4 See Drug Interactions for co-administration interactions/ guidance. • RSV vaccines can be safely co-administered with the Shingrix® shingles vaccine, COVID-19 vaccines and pneumococcal vaccines. 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. Other vaccines should be given at separate sites, preferably into different limbs. If given into the same limb, they should be given at least 2.5cm apart. See drug interaction section below regarding co-administration with influenza vaccine. • The site at which each vaccine was given should be noted in the individual's records.
Dose and frequency of administration	• ONE single 0.5 mL dose of respiratory syncytial virus (RSV) vaccine (Abrysvo▼®) per administration for intramuscular injection. Individuals who received a dose of RSV more than 2 years ago (outside of the national programme) may receive a further dose provided they still meet the inclusion criteria. See special considerations section.
Duration of treatment	See dosage schedule above. This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be administered	Single 0.5 mL dose

Supplies	• Supplies for administration should be ordered through Immform. • PTHB standard operating procedures should be followed for appropriate ordering, storage, handling, recording, preparation, administration and waste minimisation • Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see storage section below and the Green Book, chapter 3).
Storage	Store in a refrigerator in the original packaging (+2°C to +8°C). Do not freeze. Do not use the vaccine after the expiry date shown on the label. Within the context of a temperature excursion, the unopened, unpunctured Abrysvo▼® vial is stable for 5 days when stored at temperatures between +8°C and +30°C. At the end of this period, the vial should be used or discarded. **After reconstitution**: Administer immediately after reconstitution or within 4 hours if stored between 15ºC and 30ºC. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the user's responsibility In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above (fridge failure/breaches in cold chain) should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to: ➢ storage, distribution and disposal of vaccines: the green book chapter 3, and relevant local vaccine policy or guidance.

	➢ UKHSA vaccine incident guidance: responding to vaccine errors. ➢ local Medicines Advice Service for advice. See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion. Any loss of vaccines due to expiry date, wastage or fridge failure/breaches in cold chain must be reported to the immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk) and senior pharmacy technician Immunisation/vaccination PTHB.VaccPharmacyStoreOrders@wales.nhs.uk and documented on WIS (if appropriate), ImmForm and via DatixCymru incident reporting system Once for Wales Reporting System.
Disposal	• Any unused product or waste material should be disposed of in accordance with local requirements. • Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	• Immunological responses may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. • It is recommended that RSV vaccine is not routinely scheduled on the same day as influenza vaccine, Respiratory syncytial virus (RSV): the green book says that in older adults, administering Abrysvo▼® at the same time as seasonal influenza vaccine may reduce the immune response to the RSV vaccine. The response to the influenza vaccine may be diminished when RSV and seasonal influenza vaccines are co-administered. The clinical significance of this is unknown but the influenza immune response is known to correlate with clinical protection. If it is thought that the individual is unlikely to return for their rescheduled appointment or immediate protection is necessary, they can be administered at the same time.

	• If co-administered with other vaccines, refer to their relevant PGDs Patient Group Directions (PGD) and the green book A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification and management of adverse reactions	If individuals or their carer are concerned about their health at any time, they should seek advice from their GP or NHS 111 Wales. **Hypersensitivity reactions and anaphylaxis** can occur after vaccination but are very rare. Signs include swelling of the face, lips, tongue or throat, hives, difficulty breathing or swallowing and dizziness. The most frequently reported adverse effects reported for adults 18 years of age and older affecting more than 1 in 10 people include: • injection site pain, headache, muscle pain and fatigue. Adverse effects affecting between 1 in 10 and 1 in 100 people include: • injection site redness, swelling and joint pain. • Most reactions were mild and resolved within 1-2 days of onset. Rare (affecting between 1 in 1000 people and 1 in 10,000 people): • Guillain Barré syndrome (GBS). In July 2025, the Medicines and Healthcare products Regulatory Agency (MHRA) Drug Safety Update advised of a small increase in the risk of Guillain-Barré Syndrome (GBS) following vaccination with RSV vaccines including Abrysvo▼® in individuals 60 years and over. Advise all recipients of Abrysvo▼® to seek immediate medical attention if they develop signs or symptoms of Guillain-Barré Syndrome. See individual or carer advice section. An MHRA Yellow Card should be completed. See reporting procedure below. Individuals should continue to be reassured that the benefit of vaccination against RSV outweigh the risk of developing GBS in older adults and that the incidence of occurrence is still very rare – the incidence of excess GBS cases is estimated to be 10-25 cases for every million doses of the vaccine administered. (post marketing).

	A detailed list of adverse reactions is available in the SmPC. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO Abrysvo▼® (respiratory syncytial virus vaccine (bivalent, recombinant))** • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system This list is not exhaustive. Refer to BNF or the vaccine's SPC for a detailed list of adverse reactions, which is available from the electronic medicines compendium website. Report any suspected adverse reactions to a doctor.
Reporting procedure for suspected adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records and their GP should be informed. Report ALL suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) or by using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App store. If immediate adverse event occurs document in the individual's electronic patient record. All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system Once for Wales Reporting System.
Patient or carer advice / follow up	Provide the individual or their carer with patient information leaflet (PIL). For information leaflets including those in accessible

	formats, please visit Imiwneiddio / Immunisation (nhs.wales). If applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/xpil accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC. Inform the individual or their carer: • with a full explanation of risks and benefits to the individual or their carer in order to obtain informed consent. • of any possible side effects and their management. • that they may experience injection site discomfort, redness and swelling, which usually resolves within 1-2 days. These are common, expected reactions. • to seek medical advice in the event of a severe adverse reaction or if common side effects do not spontaneously resolve 3 days after vaccination • to seek immediate medical attention if they develop tingling, numbness or pins and needles in the hands and feet, muscle weakness or difficulty moving the joints. • to talk to a doctor or pharmacist if they get any side effects, including side effects not listed in the leaflet. • that they can report side effects directly to the Yellow Card reporting scheme. • there is no routine requirement for observation following the respiratory syncytial virus (RSV) vaccine (Abrysvo▼®) administration but, they will be observed for any immediate reactions whilst receiving any verbal post vaccination information and exiting the centre. • not to drive for 15 minutes after vaccination as fainting can occur following vaccination. • that the vaccine cannot cause RSV infection. • when they can be vaccinated another time if they must postpone because of illness.
Special considerations / additional information	Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of RSV vaccine. The practitioner should have immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a working telephone at the time of vaccination.

	See chapter 8 of the Green Book and advice issued by the Resuscitation Council. An age appropriate protocol for the management of anaphylaxis and an anaphylaxis pack must always be available. Immediate treatment should include early treatment with: • 12 years and above: 500 micrograms IM (0.5 mL of 1:1000 or 1 mg/mL adrenaline). • with an early call for help and further IM adrenaline every 5 minutes. See chapter 8 of the Green Book and advice issued by the Resuscitation Council. **Repeating dose** Presently, there is no data to support revaccination of older adults following their first dose. Individuals who have received a dose of RSV vaccine on the private market are still eligible to receive a dose under the routine NHS programme and so there is no requirement to exclude them from invitations for vaccination at the appropriate time. See exclusion criteria section. 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. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing signs or symptoms to adverse effects of the vaccine.
• **Records**	• The Welsh Immunisation System (WIS) must be used to capture all RSV vaccination data. • Record: • that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate. • how the individual met or did not meet the inclusion/exclusion criteria of the PGD. • name of individual, address, date of birth and GP with whom the individual is registered. • medical and drug history taken, including any allergies and previous adverse events • printed name and signature of health care professional administering the vaccine (if recording on paper). If recording directly into electronic patient record, name only as signature will be replaced by electronic logging of the user.

	• name and brand of vaccine. • date of administration. • dose, form and route of administration of vaccine. • quantity administered. • batch number and expiry date of vaccine. • anatomical site of vaccination. • information provided to the individual or their carer, including side effects and advice given if excluded or declines immunisation. • details of any adverse drug reactions and actions taken. • referral arrangements (if any). • administered via PGD, record PGD title and version number • Records should be signed and dated (or password-controlled immuniser's record on e-records). • All records should be clear, legible and contemporaneous. • All records electronically or otherwise must be kept in accordance with NHS Wales record keeping. See: records management code of practice for health and social care 2022. • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

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Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of registered health professional	Signature of registered health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 8 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comments "	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

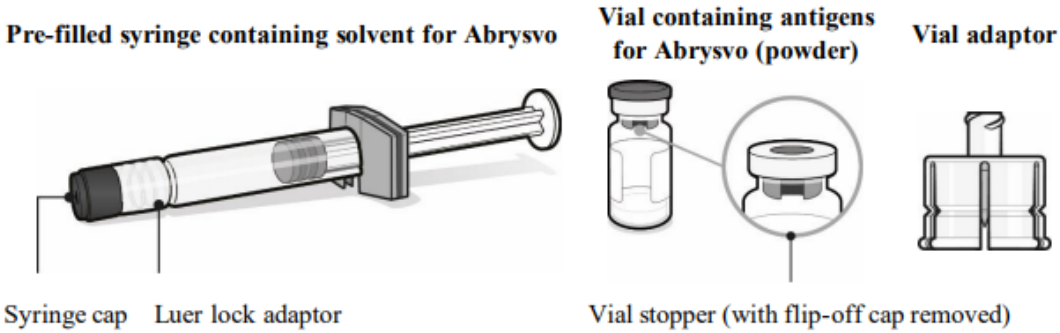
Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.

Appendix B: *Preparation for administration*

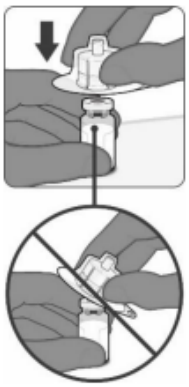
Please refer to the SmPC for full administration details

Preparation for administration



Step 1. Prepare vial adaptor

- Remove plastic flip off cap from vial and wipe the rubber stopper.
- Open the packaging containing the vial adaptor by peeling the top cover off.
- Do not remove the vial adaptor from its package.



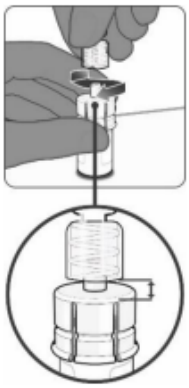
Step 2. Attach the vial adaptor to the vial containing antigens for Abrysvo

- Hold the base of the vial on a flat surface.
- Keep the vial adaptor in the packaging and orient it vertically over the centre of the vial so that the adaptor spike aligns with the centre of the vial's rubber stopper.
- Connect the vial adaptor to the vial with a straight downward push. The vial adaptor will lock into place.
- Do not push vial adaptor in at an angle as this may result in leaking during use.
- Remove the vial adaptor packaging.

Step 3. Remove syringe cap

- For all syringe assembly steps, hold the syringe only by the Luer lock adaptor located at the tip of the syringe. This will prevent the Luer lock adaptor from detaching during use.
- Remove the syringe cap by slowly turning the cap anti-clockwise while holding the Luer lock adaptor.

(continued over page)



Step 4. Connect syringe to the vial adaptor

- Hold the syringe's Luer lock adaptor and connect it to the vial adaptor by turning clockwise.
- Stop turning when you feel resistance, overtightening the syringe may result in leaking during use.
- Once the syringe is securely attached to the vial adaptor, there will be a small space between the top of the vial adaptor and the Luer lock adaptor of the syringe.

Step 5. Inject solvent and gently swirl

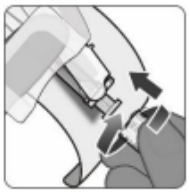
- Inject the entire contents of the syringe containing the solvent into the vial.
- Do not remove the empty syringe.
- While holding the plunger rod down, gently swirl the vial in a circular motion until the powder is completely dissolved (approximately 1-2 minutes).
- Do not shake.

Step 6. Withdraw the contents

- Invert the vial completely with the vial adaptor and syringe still attached.
- Slowly withdraw the entire contents into the syringe.
- Drawing up all obtainable content ensures a complete 0.5 mL dose for administration.
- Do not pull the plunger rod out.

Step 7. Disconnect syringe

- Hold the Luer lock adaptor of the syringe and disconnect the syringe from the vial adaptor by turning anti-clockwise.



Step 8. Attach needle

- Attach a sterile needle suitable for intramuscular injection to the pre-filled syringe by turning clockwise.
- Do not overtighten the needle as this may result in leaking during use.

Step 9. Visual inspection

- The prepared vaccine is a clear and colourless solution.
- Visually inspect the vaccine for large particulate matter and discolouration prior to administration. Do not use if large particulate matter or discolouration is found.

Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.