



UKHSA Publications gateway number: GOV-20340

## Respiratory Syncytial Virus (RSV) vaccine Patient Group Direction (PGD)

This PGD is for the administration of RSV vaccine to individuals eligible for the national vaccination programme aged 75 years and over or resident in a care home for older adults and for individuals who are pregnant, from week 28 of pregnancy.

This PGD is for use by registered healthcare practitioners identified in [section 3](#), subject to any limitations to authorisation detailed in [section 2](#).

Reference no: RSV vaccine PGD  
Version no: v2.0  
Valid from: 1 April 2026  
Review date: 31 August 2028  
Expiry date: 28 February 2029

**The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.**

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 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)<sup>1</sup>. **The PGD is not legal or valid without signed authorisation in accordance with [HMR2012 Schedule 16 Part 2](#).**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter [section 3](#) (Characteristics of staff). **Sections 2 and 7 can be amended within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations. The legal validity of this PGD is contingent on those authorising sections 2 and 7 complying with the above.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

**Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.**

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. Current versions of the UKHSA PGD templates for authorisation can be found from:

[Immunisation patient group direction \(PGD\) templates](#)

<sup>1</sup> This includes any relevant amendments to legislation.

Any concerns regarding the content of this PGD should be addressed to:  
[immunisation@ukhsa.gov.uk](mailto:immunisation@ukhsa.gov.uk).

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to:

**For East Anglia email: [England.eaimms@nhs.net](mailto:England.eaimms@nhs.net)**

**For Essex email: [England.essexatimms@nhs.net](mailto:England.essexatimms@nhs.net)**

**For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: [England.immsga@nhs.net](mailto:England.immsga@nhs.net).**

## Change history

| Version number | Change details   | Date             |
|----------------|--|------------------|
| v1.0           | New UKHSA PGD for the vaccination of adults over 75 and under 80 years of age (including those turning 80 years of age in the <a href="#">catch-up campaign</a> ) and for pregnant individuals from week 28 of pregnancy, against respiratory syncytial virus (RSV)  | 24 July 2024     |
| v2.0           | <p>UKHSA RSV PGD updated as follows:</p> <ul style="list-style-type: none"> <li>• inclusion criteria extended for the older adults programme to include immunisation of individuals aged over 80 years and residents of older adult care homes, as recommended by <a href="#">JCVI</a></li> <li>• removal of the exclusion criteria for adults who have reached 80 years of age</li> <li>• reinforcing that the vaccine may be given to pregnant individuals of any age, including those aged under 18 years</li> <li>• adjustment of the dose and frequency of administration advice for older adults, to include residents in older adult care homes</li> <li>• inclusion of the <a href="#">MHRA Drug Safety Update</a> from July 2025, advising of a small increased risk of Guillain Barré syndrome in older adults aged over 60 years. Adverse drug reactions updated in line with the Abrysvo® summary of product characteristics</li> <li>• advice that COVID-19 vaccine may be safely co-administered with RSV vaccine in line with the update to the <a href="#">RSV chapter</a> of the Green Book</li> <li>• clarification that older adults immunised before the age of 75 years under the private market remain eligible for an NHS dose of vaccine.</li> </ul> | 16 February 2026 |

## 1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

| Developed by:   | Name  | Signature  | Date            |
|---|---|--|-----------------|
| <b>Pharmacist</b><br>(Lead Author)                                    | Christina Wilson<br>Lead Pharmacist - Immunisation<br>Programmes Division, UKHSA  |  | 9 February 2026 |
| <b>Doctor</b>   | Dr Mary Ramsay CBE<br>Director of Public Health<br>Programmes and Consultant<br>Epidemiologist, Immunisation and<br>Vaccine Preventable Diseases<br>Division, UKHSA |  | 9 February 2026 |
| <b>Registered Nurse<br/>and Midwife</b><br>(Chair of Expert<br>Panel) | Greta Hayward<br>Consultant Midwife– Immunisation<br>Programmes Division, UKHSA   |  | 9 February 2026 |

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

### Working Group advisory members

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| Dr Conall Watson | Consultant Epidemiologist and RSV programme lead, Immunisation and Vaccine Preventable Diseases Division, UKHSA |
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### Expert Panel (continued overleaf)

|                      |   |
|----------------------|---|
| Dr Nicholas Aigbogun | Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA  |
| Jess Baldasera       | Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA   |
| Helen Beynon         | Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London   |
| Alison Campbell      | Screening and Immunisation Coordinator, Clinical, NHSE Midlands   |
| Helen Eley           | Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA  |
| Jane Freeguard       | Deputy Director of Vaccination – Medicines and Pharmacy, NHSE   |
| Rosie Furner         | Advanced Specialist Pharmacist - Medicines Governance (Patient Group Directions and Medicines Mechanisms) NHS Specialist Pharmacy Service |
| Ed Gardner           | Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery                                      |
| Shilan Ghafoor       | Medicines Governance Pharmacist, Medicines Governance, UKHSA  |
| Michelle Jones       | Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board                   |
| Elizabeth Lockett    | Senior Screening & Immunisation Manager, NHSE South West  |
| Dr Vanessa MacGregor | Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA   |

|              |   |
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| Briony Mason | Vaccination Manager and Professional Midwifery Advocate,<br>Vaccination and Screening, NHSE West Midlands |
| Tushar Shah  | Lead Pharmacy Adviser, NHSE London  |

## 2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

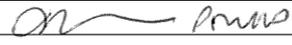
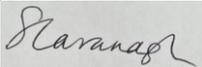
**The fields in this section cannot be used to alter, amend or add to the clinical or other PGD content (sections 3 to 6 inclusive). Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations. See page 1 for full details.**

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

**NHS England East of England** authorises this PGD for use by the services or providers listed below:

| Authorised for use by the following organisations and/or services  |
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| <b>NHS England East of England commissioned immunisation services or NHS Trust providing immunisation services covering Norfolk, Suffolk, Cambridgeshire, Peterborough, Essex, Southend-on-Sea, Thurrock, Bedfordshire, Hertfordshire, Luton and Milton Keynes local authorities, and Health and Justice facilities where NHS England East of England is the commissioner.</b> |
| Limitations to authorisation   |
| <b>None</b>  |

| Organisational Approval (legal requirement) |               |  |            |
|---|---------------|--|------------|
| Role  | Name          | Sign   | Date       |
| Medical Director                            | Dr Ian Gibson |  | 23/02/2026 |

| Additional signatories according to locally agreed policy |                   |  |            |
|---|-------------------|--|------------|
| Role  | Name              | Sign   | Date       |
| Screening and Immunisation Lead                           | Dr Eleanor Powers |  | 18/02/2026 |
| Pharmacist  | Sarah Cavanagh    |  | 18/02/2026 |
| Screening and Immunisation Coordinator                    | Lucy Blatch       |  | 18/02/2026 |
|   |                   |  |            |

Local enquiries regarding the use of this PGD may be directed to

For East Anglia email: [England.eaimms@nhs.net](mailto:England.eaimms@nhs.net)

For Essex email: [England.essexatimms@nhs.net](mailto:England.essexatimms@nhs.net)

**For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: [England.immsga@nhs.net](mailto:England.immsga@nhs.net)**

**For the Health Protection Team email: [eastofenglandhpt@phe.gov.uk](mailto:eastofenglandhpt@phe.gov.uk)**

[Section 7](#) provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

### 3. Characteristics of staff

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| <p><b>Qualifications and professional registration required</b></p>     | <p><b>All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the <a href="#">additional requirements</a> and <a href="#">continued training requirements</a> to ensure their competency is up to date, as outlined in the sections below.</b></p> <p>Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD:</p> <ul style="list-style-type: none"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>• dieticians, occupational therapists, paramedics, physiotherapists, podiatrists and radiographers currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>Check <a href="#">section 2</a> (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>  |
| <p><b>Additional requirements</b></p>                                   | <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply and administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework for health professionals using PGDs</a>)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the <a href="#">Green Book</a>) and national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines and management of the cold chain</li> <li>• must be competent in the appropriate administration method for the vaccine listed in this PGD</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.</b></p> |
| <p><b>Continued training requirements</b><br/>(continued over page)</p> | <p>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).</p>  |

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| <p><b>Continued training requirements</b><br/>(continued)</p> | <p>Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHS England and other sources of medicines information.</p> <p>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.</p> |
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#### 4. Clinical condition or situation to which this PGD applies

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| <p><b>Clinical condition or situation to which this PGD applies</b></p> | <p>Indicated for the active immunisation of individuals as detailed in the inclusion criteria, against RSV.</p> <p>Immunisation is indicated in accordance with the recommendations given in the <a href="#">RSV chapter</a> of Immunisation Against Infectious Disease: the Green Book, the <a href="#">JCVI statement</a> and the <a href="#">RSV letter</a>.</p>  |
| <p><b>Criteria for inclusion</b></p>                                    | <p><b>1. Pregnant individuals of any age:</b></p> <ul style="list-style-type: none"> <li>• from week 28 of pregnancy (see <a href="#">dose and frequency of administration</a> section for operational recommendations)</li> </ul> <p><b>2. Older adults programme:</b></p> <p><b>(i) from 1 April 2026, all individuals 75 years of age and over</b></p> <p>These individuals should be vaccinated on or after (but not before) their 75<sup>th</sup> birthday. <b>There is no upper age limit to the offer of vaccination.</b></p> <p><b>(ii) from 1 April 2026, all residents in a care home for older adults including those under 75 years of age</b></p>   |
| <p><b>Criteria for exclusion<sup>2</sup></b></p>                        | <p>Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the <a href="#">Mental Capacity Act 2005</a>, has not been obtained). For further information on consent, see <a href="#">chapter 2</a> of the Green Book. Several resources are available to inform consent (see <a href="#">written information to be given to individual or carer</a> section).</p> <p><b>Exclusion criteria for all individuals:</b></p> <ul style="list-style-type: none"> <li>• have had a confirmed anaphylactic reaction to Abrysvo<sup>®</sup> or to any of its active ingredients or excipients (see product <a href="#">SPC</a>)</li> <li>• are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)</li> </ul> <p><b>Exclusion criteria for pregnant individuals:</b></p> <ul style="list-style-type: none"> <li>• are less than 28 weeks pregnant</li> <li>• have already given birth, such that passive immunity is not possible</li> <li>• have already received a valid dose of RSV under the NHS programme during the current pregnancy</li> </ul> <p><b>Exclusion criteria for adults aged 75 years and over:</b></p> <ul style="list-style-type: none"> <li>• have not yet reached their 75<sup>th</sup> birthday</li> <li>• have already received a dose of RSV vaccine under the NHS programme</li> </ul> <p><b>Exclusion criteria for residents of care homes for older adults:</b></p> <ul style="list-style-type: none"> <li>• have already received a dose of RSV vaccine under the NHS programme</li> </ul> |

<sup>2</sup> 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.

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| <p><b>Cautions including any relevant action to be taken</b></p>               | <p>Facilities for management of anaphylaxis should be available at all RSV clinics (see <a href="#">Chapter 8</a> of the Green Book and advice issued by the <a href="#">Resuscitation Council UK</a>).</p> <p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with national recommendations.</p> <p>Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p>   |
| <p><b>Action to be taken if the individual is excluded</b></p>                 | <p>Individuals who have had a confirmed anaphylactic reaction to a previous dose of RSV vaccine or to any components of the vaccine should be referred to a clinician for specialist advice and appropriate management.</p> <p>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. However, vaccination should not be deferred in the presence of a minor infection, such as a cold.</p> <p>Pregnant individuals who have not yet reached week 28 of pregnancy should be advised that current evidence suggests protection for their baby is most effective when the RSV vaccine is given at week 28 of pregnancy (or as soon as possible after) and should be offered an appointment. The vaccine may be given up to birth.</p> <p>Individuals who are not of eligible age for the RSV vaccination programme should be advised when they will become eligible.</p> <p>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 <a href="#">also special considerations and additional information</a> - repeating doses).</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform or refer to the individual's GP or a prescriber as appropriate.</p> |
| <p><b>Action to be taken if the individual or carer declines treatment</b></p> | <p>Advise the individual or carer about the protective effects of the vaccine, the risks of infection and potential complications of the disease.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the individual's GP or a prescriber as appropriate.</p>   |
| <p><b>Arrangements for referral for medical advice</b></p>                     | <p>As per local policy.</p>  |

## 5. Description of treatment

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| <b>Name, strength and formulation of drug</b> | <b>Abrysvo<sup>®</sup></b> powder and solvent for solution for injection: respiratory syncytial virus vaccine (bivalent, recombinant)  |
| <b>Legal category</b>                         | Prescription Only Medicine (POM).  |
| <b>Black triangle▼</b>                        | <p>Yes.</p> <p>As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of associated adverse drug reactions. All suspected adverse drug reactions should be reported using the MHRA <a href="#">Yellow Card Scheme</a>.</p>  |
| <b>Off-label use</b>                          | <p>Administration of Abrysvo<sup>®</sup> by deep subcutaneous injection to individuals with a bleeding disorder is off-label, but appropriate where the intramuscular route is unsuitable and is in line with advice in <a href="#">Chapter 4</a> of the Green Book. See <a href="#">route and method of administration</a> section below.</p> <p>The vaccine should be stored according to the conditions detailed in the <a href="#">storage</a> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <a href="#">Vaccine Incident Guidance</a>. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label, as part of the consent process consider informing the individual or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.</p> <p><b>Pregnant individuals</b></p> <p>Abrysvo<sup>®</sup> is licensed for administration to pregnant individuals between weeks 28 and 36 of gestation. Offering Abrysvo<sup>®</sup> beyond 36 weeks gestation and up to birth, is off-label but in line with national guidance.</p> <p>For pregnant individuals, the Abrysvo<sup>®</sup> <a href="#">SPC</a> advises a 2 week minimum interval between administration of Abrysvo<sup>®</sup> and pertussis-containing vaccines, due to some evidence that co-administration of both vaccines may weaken the response to one of the pertussis components, although the clinical significance of this response is unclear. As the pertussis and RSV vaccines are recommended at different stages of pregnancy, RSV and pertussis vaccines should not be routinely scheduled for co-administration. However, where an individual becomes eligible for the RSV vaccine but has not yet had the pertussis-containing vaccine, it is recommended that the pertussis-containing vaccine should be given at the same time as the RSV vaccine to avoid further delay in conferring passive protection to the infant. Please also refer to the <a href="#">drug interactions</a> section.</p> <p>The advice to repeat the dose of Abrysvo<sup>®</sup> where it has been inadvertently administered to individuals who are less than 16 weeks pregnant is off-label but in line with recommendations in the relevant <a href="#">information for healthcare practitioners</a> document. See <a href="#">special considerations and additional information</a> section.</p> |

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| <p><b>Route and method of administration</b></p>                                | <p>The vaccine must be prepared in accordance with the manufacturer's instructions prior to administration.</p> <p>Following reconstitution, Abrysvo® should be given as a single dose by intramuscular (IM) injection, preferably into the deltoid muscle of the upper arm.</p> <p>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. The site at which each vaccine was given should be noted in the individual's records.</p> <p>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. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 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 carer should be informed about the risk of haematoma from the injection.</p> <p>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 Green Book <a href="#">chapter 4</a>). The vaccine must not be given via the intradermal or intravascular route.</p> <p>Abrysvo® forms a clear and colourless solution upon reconstitution. The vaccine components should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures.</p> <p>Do not mix the vaccine with other vaccines or other medicinal products. When adding the diluent to the powder, the vial should be gently swirled until the powder has completely dissolved.</p> <p>The vaccine <a href="#">SPC</a> provides further guidance on preparation and administration.</p> |
| <p><b>Dose and frequency of administration</b></p> <p>(continued over page)</p> | <p><b>Single 0.5ml dose per administration.</b></p> <p><b>Pregnant individuals</b></p> <p>Single 0.5ml dose of Abrysvo®, from week 28 of pregnancy. For clinical reasons, vaccination is best offered at the time of the antenatal appointment at week 28 of pregnancy.</p> <p>Individuals remain eligible up to birth.</p>   |

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| <p><b>Dose and frequency of administration</b></p> <p>(continued)</p> | <p>A dose of RSV vaccination is indicated for each pregnancy, irrespective of the interval between successive pregnancies.</p> <p><b>Adults aged 75 years and over or a resident of any age in a care home for older adults</b></p> <p>Single 0.5ml dose of Abrysvo®.</p>   |
| <p><b>Duration of treatment</b></p>                                   | <p><b>Pregnant individuals</b></p> <p>A dose of Abrysvo® is indicated for each pregnancy.</p> <p><b>Adults aged 75 years and over or a resident of any age in a care home for older adults</b></p> <p>A single dose of Abrysvo® should be given.</p>  |
| <p><b>Quantity to be supplied and administered</b></p>                | <p>Single dose of 0.5ml.</p>  |
| <p><b>Supplies</b></p>  | <p>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.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book <a href="#">chapter 3</a>).</p>  |
| <p><b>Storage</b></p>   | <p>Store between +2°C to +8°C.</p> <p>Store in original packaging to protect from light. Do not freeze.</p> <p>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.</p> <p>After reconstitution, chemical and physical in-use stability for Abrysvo® has been demonstrated for 4 hours between +15°C and +30°C. 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.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to <a href="#">Vaccine Incident Guidance</a>. Contact the manufacturer where more specific advice is required about managing a temperature excursion.</p> |
| <p><b>Disposal</b></p>  | <p>Follow local clinical waste policy and operating procedures to ensure safe and secure waste disposal.</p> <p>Equipment used for immunisation, including used vials, ampoules, or syringes, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local authority arrangements and NHS England guidance (<a href="#">HTM 07-01: safe and sustainable management of healthcare waste</a>).</p>   |

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| <p><b>Drug interactions</b></p>   | <p>The immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p><b>Interactions in older adults</b></p> <p>Influenza vaccines should not be routinely co-administered on the same day as RSV vaccines in individuals receiving the vaccine under the older adults programme. Studies suggest a lowered immune response to both RSV and influenza components when co-administered with adjuvanted influenza vaccines. No specific minimum interval is advised. If immediate protection is necessary or there are concerns the individual will not return for a second appointment, then Abrysvo® may be given at the same time as the influenza vaccine.</p> <p>Abrysvo® may be given with other vaccines routinely administered in older individuals eligible for the RSV vaccination programme, such as shingles, COVID-19 and pneumococcal vaccines.</p> <p><b>Interactions in pregnant individuals</b></p> <p>Abrysvo® should not be routinely scheduled for co-administration with the pertussis vaccine. However, if a pregnant individual presents from week 28 of pregnancy or beyond and has not received either Abrysvo® or Tdap (or dTaP/IPV), the benefit of offering both due vaccines at the same appointment outweighs the risk of not protecting the unborn infant against pertussis and RSV infection via passive immunity and avoids the risk of the individual not returning for a later appointment. This advice is outside the 2 week interval recommended between the vaccines in the Abrysvo® <a href="#">SPC</a> and as outlined in the <a href="#">off-label</a> section.</p> <p>RSV and influenza vaccines may be safely co-administered to pregnant individuals. Pregnant individuals eligible to receive the COVID-19 vaccine may also have this safely co-administered with the RSV vaccine.</p> <p>Pregnant individuals requiring treatment with Anti-D immunoglobulin at 28 to 30 weeks gestation may have their RSV vaccine administered at the same appointment.</p> <p>A detailed list of drug interactions associated with Abrysvo® is available from the product's <a href="#">SPC</a>.</p> |
| <p><b>Identification and management of adverse reactions</b></p> <p>(continued over page)</p> | <p>Very common reactions include vaccination site pain, headache and myalgia. Fatigue is reported in individuals aged 18 years and over.</p> <p>Other commonly reported reactions include injection site redness and swelling.</p> <p>Hypersensitivity reactions can occur but are very rare.</p> <p><b>Small increased risk of Guillan-Barre syndrome in older adults (over 60 years)</b></p> <p>In July 2025, the Medicines and Healthcare products Regulatory Agency (MHRA) <a href="#">advised</a> of a small increase in the risk of Guillain-Barré syndrome (GBS) following immunisation with RSV vaccines (including Abrysvo®) in adults aged 60 years and older. Healthcare practitioners are advised to be attentive to signs and symptoms of GBS in individuals who have been immunised with Abrysvo® to ensure early and correct diagnosis, rule out other causes and initiate adequate supportive care and treatment, as early</p>   |

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| <p><b>Identification and management of adverse reactions</b><br/>(continued)</p> | <p>medical care can reduce severity and improve outcomes. Individuals receiving the vaccine should be advised to seek immediate medical attention if they have symptoms such as tingling, numbness, weakness, sharp pain or pins and needles in their hands, feet, arms or legs. An MHRA Yellow Card should also be completed (see <a href="#">reporting procedure of adverse reactions</a>). Individuals should continue to be reassured that the benefits 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 1 case for every 40,000 to 100,000 administered doses.</p> <p>No such effect has been seen in pregnant women. A detailed list of adverse reactions associated with the vaccine is available from the product's <a href="#">SPC</a>.</p> |
| <p><b>Reporting procedure of adverse reactions</b></p>                           | <p>Healthcare professionals, individuals and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a>, or by searching for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.</p>   |
| <p><b>Written information to be given to individual or carer</b></p>             | <p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the medicine.</p> <p>Recommended patient information materials to accompany the RSV vaccination programmes are outlined on the <a href="#">RSV vaccination programme</a> website, including:</p> <ul style="list-style-type: none"> <li>• <a href="#">your guide to the RSV vaccine for older adults</a></li> <li>• <a href="#">a guide to RSV vaccination for pregnant women</a></li> </ul> <p>For resources in accessible formats and alternative languages, please visit <a href="#">Find public health resources</a>.</p> <p>Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility by providing the medicine name and product code number, as listed on the product <a href="#">SPC</a>.</p>                      |
| <p><b>Advice and follow up treatment</b></p>                                     | <p>Inform the individual or carer of possible side effects and their management.</p> <p>Give advice regarding normal reaction to the injection, for example redness and pain at the injection site.</p> <p>Individuals receiving vaccine should be advised to seek immediate medical attention if they have symptoms such as tingling, numbness, weakness, sharp pain or pins and needles in their hands, feet, arms or legs, as this may be suggested of GBS (see also <a href="#">identification and management of adverse reactions</a>, above).</p> <p>The individual or carer should be advised to seek medical advice in the event of a severe adverse reaction and report this via the <a href="#">Yellow Card reporting scheme</a>.</p> <p>When administration is postponed, advise the individual or carer when to return for vaccination.</p>   |

**Special considerations and additional information**

Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.

**Repeating doses**

There is no data on the effectiveness of Abrysvo® before week 24 of pregnancy, as outlined in the [SPC](#). However, if a dose has been inadvertently administered between week 16 and week 27+6 of pregnancy, the dose does not need to be repeated, as based on first principles, maternal antibodies should start to cross the placenta and confer passive immunity from a gestational age of 16 weeks. See the relevant [information for healthcare professionals](#) document for further information.

When a dose of Abrysvo® has been inadvertently administered before week 16 of pregnancy, a repeat dose should be given from 28 weeks gestation.

In both situations, local procedures for medicines error reporting should be followed.

Pregnant individuals should be offered a repeat dose of RSV vaccine for any subsequent pregnancies, regardless of the interval between pregnancies.

**Note:** administration of a dose of Abrysvo® before week 28 of pregnancy is outside the scope of this PGD and therefore must be administered under a different legal mechanism, such as a PSD.

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 also [criteria for exclusion](#).

**Timing of doses**

**(i) in individuals eligible under the older adults programme**

Administering Abrysvo® to eligible individuals before cases of RSV infection reach their seasonal peak maximises the efficacy of the vaccine. Individuals should be encouraged to take up the offer of vaccination as soon as reasonably possible, to reduce their chance of contracting the virus.

**(ii) in pregnant individuals**

When RSV vaccine is given late in pregnancy, whilst the potential for passive immunity is greatly reduced, the dose will help protect the mother from contracting RSV infection and thereby passing RSV infection onto the infant. Pregnant individuals should be encouraged to take up the offer of vaccination at week 28 of their pregnancy (or as soon as possible after) to maximise production and transplacental transfer of maternal antibodies to their baby.

**Records**

(continued over page)

The practitioner must ensure the following is recorded:

- 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](#))
- name of individual, address, date of birth and GP with whom the individual is registered
- name of the immuniser
- name and brand of vaccine

**Records**

(continued)

- date of administration
- dose, form and route of administration of the vaccine
- quantity administered
- batch number and expiry date
- anatomical site of vaccination
- advice given, including advice given if the individual is excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- the vaccine was supplied via PGD

Records should be signed and dated (or password-controlled on e-records).

All records should be clear, legible and contemporaneous.

This information should be recorded in the individual's GP record.

Where vaccination occurs outside the GP setting, appropriate health records should be kept and the individual's GP informed. When administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) using the appropriate documentation or pathway as required by any local or contractual arrangement.

PGD use should be audited as part of an organisation's medicines audit programme. An audit tool is available from [SPS](#).

## 6. Key references

|                       |  |
|-----------------------|--|
| <b>Key references</b> | <p><b>Respiratory syncytial virus</b></p> <ul style="list-style-type: none"><li>• Abrysvo® powder and solvent for solution for injection. Summary of Product Characteristics, last updated 8 January 2026<br/><a href="https://www.medicines.org.uk/emc/product/15309/smpc">https://www.medicines.org.uk/emc/product/15309/smpc</a></li><li>• Immunisation Against Infectious Disease: The Green Book, <a href="https://www.gov.uk/government/publications/respiratory-syncytial-virus-the-green-book-chapter-27a">RSV chapter</a>,<br/><a href="https://www.gov.uk/government/publications/respiratory-syncytial-virus-the-green-book-chapter-27a">https://www.gov.uk/government/publications/respiratory-syncytial-virus-the-green-book-chapter-27a</a></li><li>• Respiratory syncytial virus vaccination programme collection<br/><a href="https://www.gov.uk/government/collections/respiratory-syncytial-virus-rsv-vaccination-programme">https://www.gov.uk/government/collections/respiratory-syncytial-virus-rsv-vaccination-programme</a></li><li>• Respiratory syncytial virus (RSV) vaccination for older adults: expansion of eligibility, published 2 February 2026<br/><a href="https://www.gov.uk/government/publications/rsv-vaccination-for-older-adults-expansion-of-eligibility">https://www.gov.uk/government/publications/rsv-vaccination-for-older-adults-expansion-of-eligibility</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023<br/><a href="https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/">https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training, published 7 February 2018<br/><a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions, updated 27 March 2017 <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018<br/><a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration. Updated 7 July 2022<br/><a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul> |
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## 7. Practitioner authorisation sheet

**RSV vaccine PGD v2.0 Valid from: 1 April 2026 Expiry: 28 February 2029**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

### 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 PGD and that I am willing and competent to work to it within my professional code of conduct.

| Name | Designation | Signature | Date |
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### Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **[Insert name of organisation]**

for the above named healthcare professionals who have signed the PGD to work under it.

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |

### Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.