NHS Greater Glasgow and Clyde

Administration of respiratory syncytial virus vaccine for protection of infants through maternal vaccination and older adults

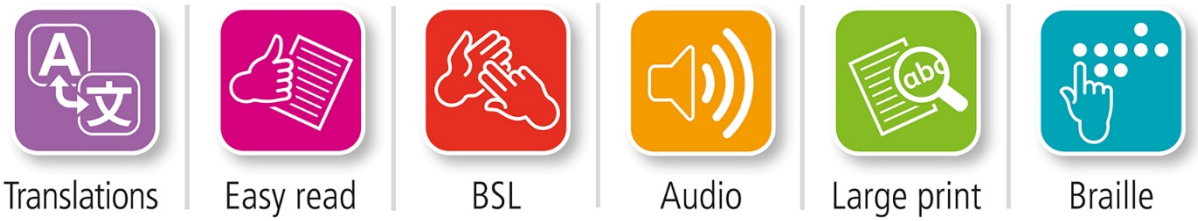
Patient group direction (PGD) template

Publication date: 23 August 2024

PGD No: 2024/2712

Expiry date: 31 July 2027

Version 1.2



Translations and other formats are available on request at:

phs.otherformats@phs.scot

0131 314 5300

Public Health Scotland is Scotland's national agency for improving and protecting the health and wellbeing of Scotland's people.

www.publichealthscotland.scot

Most recent changes

Version	Date	Summary of changes
1.2	23 August 2024	The following changes to v 1.1 of the PGD are as follows: Route of administration section updated.

Contents

Most recent changes 1

Authorisation 3

1. Clinical situation 4

2. Description of treatment 9

3. Adverse reactions 13

4. Characteristics of staff authorised under the PGD 165

5. Audit trail 187

6. Additional references 198

7. PGD for administration of respiratory syncytial virus vaccine for protection of infants through maternal vaccination and older adults v1.2 (valid from 23 August 2024 and expires 31 July 2027): authorisation **19**

8. Version history 221

Authorisation

PGD respiratory syncytial virus vaccine for protection of infants through maternal vaccination and older adults

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer respiratory syncytial virus vaccine for protection of infants through maternal vaccination and older adults under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD. NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS Greater Glasgow & Clyde by:

Professionals drawing up PGD/Authors	
*Name: Sarah Marshall  Signature: Date 30/08/2024	Designation: Specialist Public Health Pharmacist E-mail address: **sarah.marshall4@ggc.scot.nhs.uk**
Name: Tina McMichael  Signature: Date: 30/08/2024	Designation: Lead Nurse, Health Protection E-mail address **tina.mcmichael2@ggc.scot.nhs.uk**

Name: Iain Kennedy Signature: Date: 30/08/2024	Designation: Consultant in Public Health E-mail address: **lain.kennedy@ggc.scot.nhs.uk**

Approved on behalf of NHS Greater Glasgow and Clyde by ADTC Patient Group Direction Sub Committee representatives:

Chair	Dr Craig Harrow	
Senior Pharmacist	Elaine Paton, Senior Prescribing Adviser	
Nurse Director Representative	Kevin McAuley, Lead Nurse North Sector	

Valid from: 23 August 2024 Expiry date: 31 July 2027

1. Clinical situation

1.1. Indication

Active immunisation for protection of infants through maternal vaccination and older individuals against respiratory syncytial virus (RSV) in accordance with **Scottish Government RSV immunisation programme**, JCVI advice/recommendations given in Green Book **Chapter 27a** and subsequent correspondence/publications from Scottish Government.

1.2. Inclusion criteria

Individuals invited, or eligible in accordance with the recommendations in Green Book Chapter **Chapter 27a**, **Scottish Government RSV immunisation programme**

and/or in line with subsequent correspondence/publications from Scottish Government for the older persons programme or the maternal programme.

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- have had a confirmed anaphylactic reaction to any components of the vaccine (refer to relevant SmPC)
- pregnant women less than 28 weeks of gestation
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

1.4. Cautions/need for further advice/circumstances when further advice should be sought from a doctor

The Green Book advises there are very few individuals who cannot receive RSV vaccines.

When there is doubt, appropriate advice should be sought from the immunisation co-ordinator or health protection team rather than withholding the vaccine.

Individuals who are immunosuppressed may not make a full antibody response.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Co-administration of other vaccines/anti-D immunoglobulin

Older adults

RSV vaccines can be safely co-administered with Shingrix shingles vaccine and pneumococcal vaccines.

It is recommended that RSV vaccine is not routinely scheduled to be given to an older adult at the same appointment or on the same day as an influenza or COVID-19 vaccine. No specific interval is required between administering the vaccines. If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, Abrysvo® can be administered at the same time as influenza and/or COVID-19 vaccination.

Maternal vaccination

Pregnant women can safely have Abrysvo® co-administered with influenza vaccine, anti-D immunoglobulin or COVID-19 vaccine.

There is some data suggesting that coadministration of the RSV vaccine with pertussis-containing vaccines may reduce the response made to the pertussis components. The clinical significance of this is unclear and any impact on protection is likely to be small, the key pertussis component is least affected. Giving the vaccines separately at the typical scheduled times (around 20 weeks for pertussis and from 28 weeks for RSV) will avoid any potential attenuation of antibody response to the pertussis containing vaccine. If a woman has not received a pertussis containing vaccine at the time she presents for Abrysvo® RSV vaccine, both vaccines can and **should** be given at the same appointment to ensure prompt development of antibodies.

Reactogenicity for co-administered vaccines is expected to be consistent with the profiles of the individual products.

When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in

the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Syncope

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.

Pregnancy

Vaccination with RSV vaccination is authorised under this PGD for pregnant women from 28 weeks gestation. Please note the use in pregnant women from 36 weeks gestation is off-label but in line with recommendations in the Green Book Chapter **Chapter 27a** (See Section 2.10 Is the use outwith the SmPC)

1.5 Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated.

The risk to the individual and/or the baby of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

Advise individuals of preventative measures to reduce exposure to RSV such as covering coughs and sneezes, washing or sanitising hands often, and cleaning frequently touched surfaces.

Temporary exclusion

In case of postponement due to acute severe febrile illness, arrange a future date for immunisation.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Advise individuals of preventative measures to reduce exposure to RSV such as covering coughs and sneezes, washing or sanitising hands often, and cleaning frequently touched surfaces.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Respiratory syncytial virus vaccine (bivalent, recombinant):

Abrysvo® powder and solvent for solution for injection

2.2. Route of administration

Abrysvo ® vaccine is for intramuscular injection, preferably in the deltoid muscle.

The vaccine should not be mixed with any other vaccines or medicinal products.

Individuals with bleeding disorders may be immunised intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, immunisations 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 immunisation 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 or 25 gauge) should be used for the immunisation, followed by firm pressure applied to the site without rubbing for at least 2 minutes. The individual should be informed about the risk of haematoma from the injection.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration.

In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3. Dosage

0.5mls

2.4. Frequency

A single dose.

For the maternal immunisation programme a single dose should be offered in each pregnancy

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See frequency section.

2.8. ▼ black triangle medicines

Yes.

Abrysvo® powder and solvent for solution for injection is subject to additional monitoring and has been designated ▼

Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

The use of RSV vaccine in pregnant women is licensed from 28-36 weeks gestation but may be used off-label in pregnant women from 36 weeks gestation in accordance with **Chapter 27a** of the Green Book.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Vaccine should be stored according to the conditions detailed below.

However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines or national vaccine incident guidance.

Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Store in the original packaging to protect from light.

Do not freeze. Abrysvo® should be administered immediately after reconstitution or within 4 hours if stored at room temperature.

NHS Board guidance on Storage and Handling of vaccines should be observed.

In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.

2.12. Additional information

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.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

Maternal vaccination

The most commonly reported adverse reactions reported by pregnant women receiving Abrysvo® as part of a clinical trial were vaccination site pain (41%), headache (31%) and myalgia (27%). Most reactions were mild and resolved within a few days.

Older adult vaccination

A clinical trial of older adults receiving Abrysvo® found that the most common adverse events following immunisation was pain at the vaccination site (11% of recipients). Redness and swelling at the injection site were the next most commonly reported reactions. Most reactions were mild and resolved within 1-2 days.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of severe adverse reaction individual should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard**

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Supply immunisation promotional material as appropriate.

Individual advice/follow up treatment:

- Inform the individual/carer of possible side effects and their management
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the **Yellow Card reporting scheme**.
- When applicable, advise individual/parent/carer when the subsequent dose is due.

3.4. Observation following vaccination

Following immunisation, patients remain under observation in line with NHS board policy.

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

3.5. Follow up

As above.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists currently registered with the General Pharmaceutical Council (GPhC)
- pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)
- chiropodists/podiatrists, dieticians, 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
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- demonstrate appropriate knowledge and skills to work under this PGD.
- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.

- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/SmPC.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

- **Immunisation against Infectious Disease [Green Book]**:
    - **Immunisation against infectious disease - Chapter 27a - Respiratory syncytial virus**
- Current edition of British National Formulary.
- All relevant Scottish Government advice including the relevant CMO letter(s)
- **Marketing authorisation holders Summary of Product Characteristics.**
- **Professional Guidance on the Administration of Medicines in Healthcare settings 2019**.
- **Professional Guidance on the Safe and Secure Handling of Medicines**.

7. PGD for administration of respiratory syncytial virus vaccine for protection of infants through maternal vaccination and older adults v1.1 (valid from 23 August 2024 and expires 31 July 2027): authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's Summary of Product Characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction, you are indicating that you agree to its contents and that you will work within it.

I agree to administer respiratory syncytial virus vaccine for protection of infants through maternal vaccination and older adults only in accordance with this PGD.

Name of professional	Signature	Date

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 **NHS Greater Glasgow and Clyde** for the above-named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area:

Name ……

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

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

8. Version history

Version	Date	Summary of changes
1.0	15 July 2024	New PGD for protection of infants through maternal vaccination and older adult vaccination programme in Scotland
1.1	22 July 2024	Minor typographical inconsistency in Section 7 corrected.
1.2	23 August 2024	The following changes to v 1.1 of the PGD are as follows: Route of administration section updated.