18a Respiratory Syncytial Virus (RSV)

Content last updated: 18 November 2025

NOTIFIABLE

In some circumstances, advice in these guidelines may differ from that in the Summary of Product Characteristics (SmPC) of the immunisation product. When this occurs, NIAC advises that the recommendations in these guidelines, which are based on current expert advice from NIAC, are followed.

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Acronyms used in this chapter

ADA	anti-drug antibodies
ARI	acute respiratory illness
CHD	congenital heart disease
CI	confidence interval
CLD	chronic lung disease
COPD	chronic obstructive pulmonary disease
EMA	European Medicines Agency
EU	European Union
F protein	fusion glycoprotein
GMT	genomic mean titres
HPSC	Health Protection Surveillance Centre
ICU	intensive care unit
IIV	inactivated influenza vaccine
IM	intramuscular
LRTD	lower respiratory tract disease
mRNA	messenger ribonucleic acid
PCR	polymerase chain reaction
RSV	respiratory syncytial virus
$Sp0_2$	peripheral oxygen saturation
SmPC	summary of product characteristics
Tdap	tetanus, diphtheria, acellular pertussis
VE	vaccine efficacy

Terms used for frequency of adverse events

Very common	≥1/10
Common	1/100 and <1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000 and <1/1,000
Very rare	<1/10,000

18a.1 Introduction

Respiratory syncytial virus (RSV) causes annual epidemics during autumn and winter in temperate climates and continues to exert a significant toll on public health and healthcare systems. It is a leading cause of respiratory tract infections and places vulnerable populations, including infants, older adults, and immunocompromised individuals, at increased risk.

Globally, RSV is estimated to cause 33 million cases of lower respiratory tract disease (LRTD) per year, 3.6 million hospitalisations in children less than five years of age and is responsible for one third of deaths resulting from acute LRTD in the first year of life.

Most children experience at least one RSV infection by the age of two years. Those aged less than six months are at highest risk of severe disease and up to 30% of RSV infections occur in infants aged less than six weeks. While most infections cause only mild symptoms, RSV is the most important cause of viral LRTD in infants and the leading cause of infant hospitalisation in Europe. Infection-induced immunity is not fully protective and repeated lifelong infections are common. RSV causes a considerable socioeconomic burden, due to the impact of infant infections and hospitalisations on healthcare systems and caregivers.

RSV is also a significant cause of severe respiratory illness, hospitalisation and death in older adults. Adults aged 60 years and older with medical conditions including chronic lung disease, chronic heart disease, diabetes mellitus, chronic kidney disease, obesity and immunocompromising conditions, as well as those who are frail or in long-term care settings, are at greatest risk for RSV-associated hospitalisation.

There are no effective treatments available for RSV infection in either adults or children — supportive care is the mainstay of treatment.

A long-acting monoclonal antibody (nirsevimab, Beyfortus, Sanofi) and a maternal vaccine (RSVpreF, Abrysvo, Pfizer) have been approved by the European Medicines Agency (EMA) for the prevention of RSV LRTD in infants. A shorter-acting monoclonal antibody (palivizumab, Synagis, AstraZeneca) is authorised by the EMA. It was previously available for use in Ireland in selected high-risk infants. Three vaccines (RSVPreF3, Arexvy, GSK; RSVpreF, Abrysvo, Pfizer; and the mRNA-1345 vaccine, mResvia, Moderna) have been approved by the EMA for the prevention of RSV LRTD in adults (Table 18a.1).

These products aim to prevent severe RSV-related disease in their target populations, thereby alleviating the associated healthcare burden.

Table 18a.1 RSV vaccine and RSV monoclonal antibody products authorised by the European Medicines Agency

	RSV vaccine	RSV monoclonal antibody
Infants (<12 months)	▪ RSVpreF, Abrysvo, Pfizer ▪ Maternal vaccine to protect infants	▪ Nirsevimab, Beyfortus, Sanofi
Second year of life (where recommended)		▪ Nirsevimab, Beyfortus, Sanofi
Adults	▪ RSVPreF3, Arexvy, GSK ▪ RSVpreF, Abrysvo, Pfizer · mRNA-1345, mResvia®, Moderna	

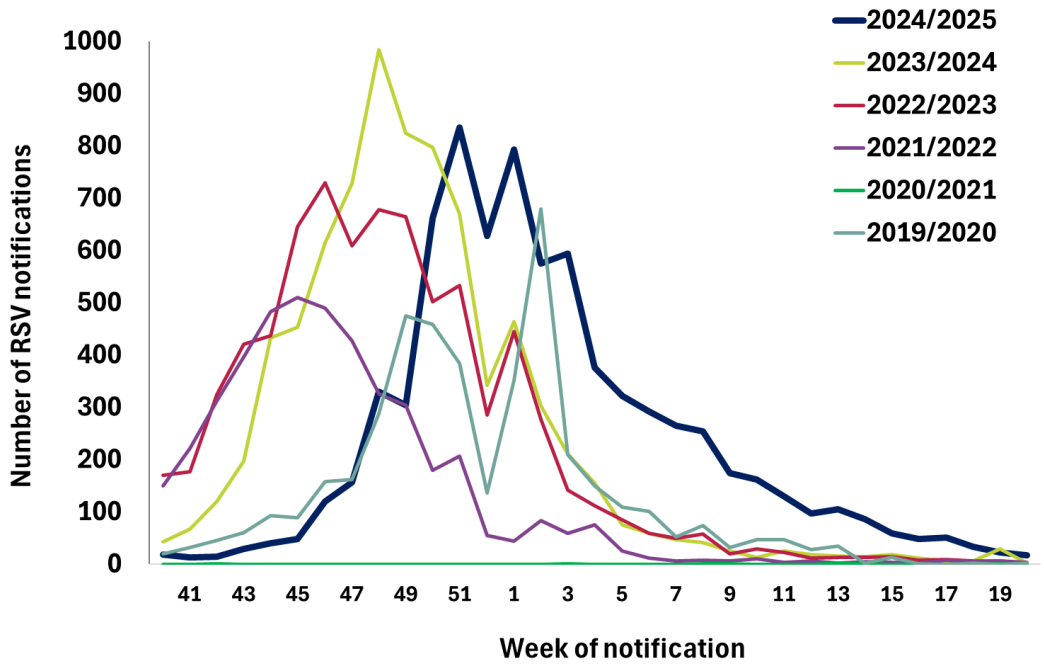
18a.2 Epidemiology

RSV infections typically occur in a seasonal pattern in temperate climates. The RSV season in Ireland usually begins in October and subsides in February. However, in Ireland, as in many other countries, the 2022/2023 and 2023/2024 RSV seasons started earlier, lasted longer and were more severe in terms of case numbers and hospitalisations compared to previous seasons (Figure 18a.1).

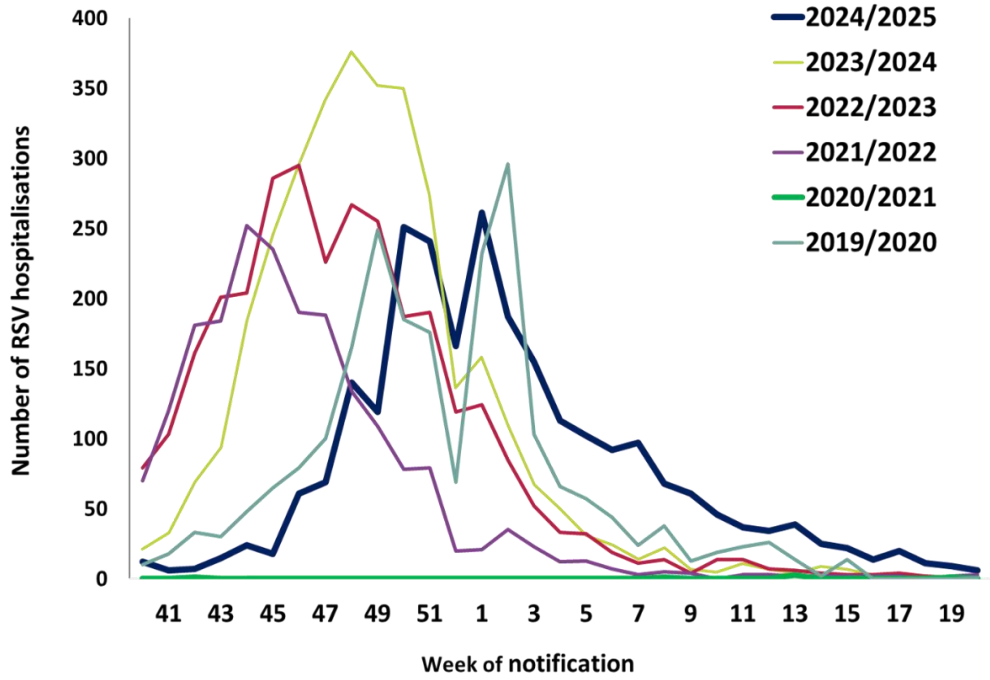
Those aged less than one year have the highest incidence of hospitalisation from RSV, followed by those aged one to four years and those aged 65 years and older (Figure 18a.2). In winter 2023/2024, which was a severe RSV season in relation to hospitalisations, the age-specific incidence rate of hospitalisation per 100,000 for those aged less than one year was 2,475.9 and for those aged one to four years was 376.7 (Table 18a.2). Nirsevimab, a long-acting monoclonal antibody that provides passive protection against RSV, was introduced in 2024 for infants born during the 2024/2025 RSV season (1 September 2024 to 28 February 2025). Nirsevimab was also offered to high-risk infants and children previously eligible for palivizumab. The overall uptake among babies born during the RSV season was 83% and among high-risk infants was 99%. Compared with the 2023/2024 RSV season, among infants born on or after 1 September, the incidence rate of RSV-related hospitalisation per 100,000 in the 2024/2025 season declined from 4,764.3 to 1,263.4 and hospitalisation rates declined from 2,837 to 545 per 100,000 population. The number of eligible infants requiring ICU admission due to RSV declined from 89 to 23.

Figure 18a.1 Number of laboratory-confirmed RSV notifications (A) and hospitalisations (B) to HPSC by week of notification, 2019/2020 to 2024/2025 season

A. Notifications



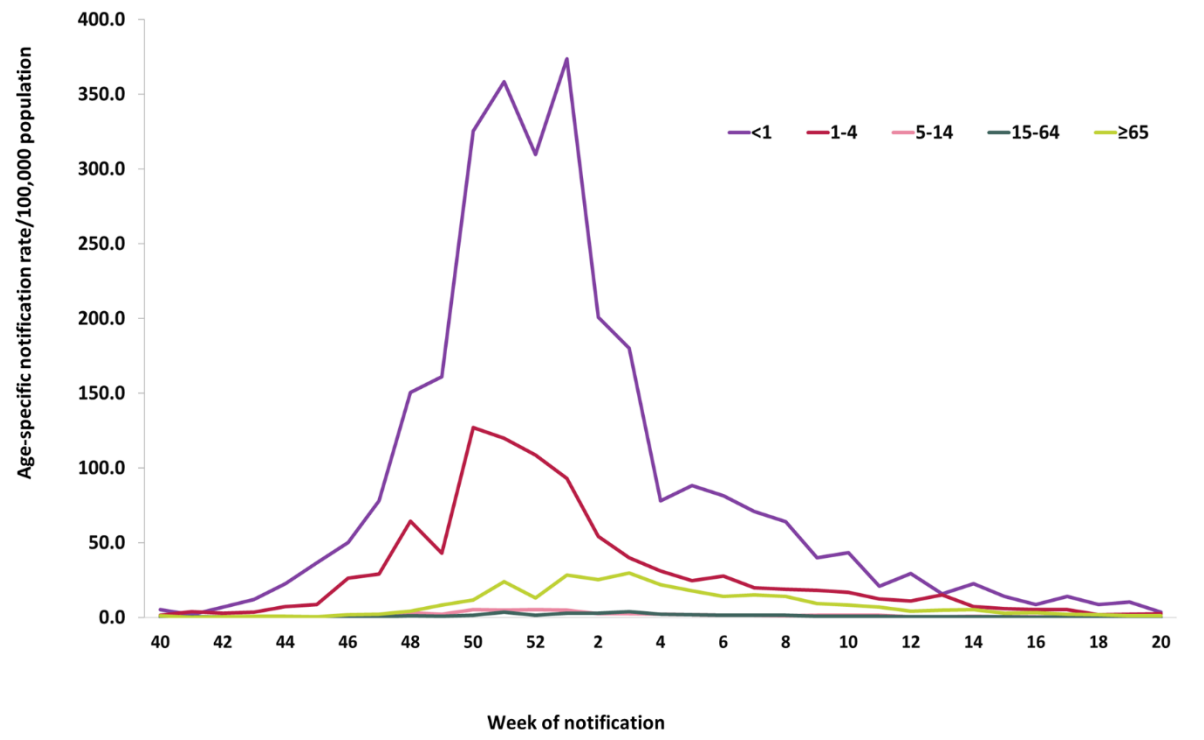
B. Hospitalisations



Source: Ireland's Computerised Infectious Diseases Reporting System via the HSE-HPSC

Among adults, the burden of RSV disease increases with increasing age. In the 2024/2025 RSV season, rates of hospitalisation were 59.6, 96.6 and 208.8 per 100,000 population for those aged 70-74 years, 75-79 years and ≥80 years old, respectively. The number of patients aged 65 years and older requiring ICU admission was 13 in 2024/2025 and there were 47 RSV-related deaths, 80% of which were in those aged 75 years and older. The incidence of RSV is likely to be underestimated due to underrecognition, undertesting and potentially low sensitivity of standard diagnostic testing among adults.

Figure 18a.2 Age-specific rates per 100,000 population for laboratory-confirmed RSV notifications to HPSC by week of notification for the 2024/2025 season



Source: Ireland's Computerised Infectious Disease Reporting System via the HSE-HPSC

Table 18.a.2 Age-specific number, percentage and rate per 100,000 population of notified laboratory-confirmed RSV hospitalised cases notified in 2023/2024 and 2024/2025 RSV season (week 40 to week 20)

Age (years)	Hospitalised (Week 40 2023 to week 20 2024)			Hospitalised (Week 40 2024 to week 20 2025)		
	Number	% of all hospitalisa-tions	Age-specific incidence rate per 100,000 population	Number	% of all hospitalisa-tions	Age-specific incidence rate per 100,000 population
<1	1431	43.2	2475.9	569	22.5	984.5
1-4	895	27.0	376.7	792	31.3	333.3
5-14	189	5.7	26.4	136	5.4	19
15-24	29	0.9	4.5	34	1.3	5.3
25-34	31	0.9	6.2	37	1.5	5.9
35-44	39	1.2	4.9	54	2.1	6.8
45-54	52	1.6	7.3	62	2.5	8.7
55-64	95	2.9	16.4	118	4.7	20.4
65-69	71	2.1	29.8	77	3.0	32.3
70-74	101	3.0	49.8	121	4.8	59.6
75-80	109	3.3	70.7	149	5.9	96.6
≥80	271	8.2	149.7	378	15.0	208.8
Total	3313	100.0	64.3	2527	100.0	49.1

Source: Ireland's Computerised Infectious Disease Reporting System via the HSE-HPSC

Transmission

RSV is highly contagious. Transmission occurs through contact with aerosolised viral particles generated through sneezing and coughing, or from contaminated surfaces or fomites. Large-particle droplets can survive on contaminated surfaces for up to six hours, making handwashing the most effective infection control procedure. The frequent occurrence of mild or asymptomatic infection in otherwise healthy individuals makes infection control challenging.

Incubation period

Incubation is usually 2-8 days.

Infectious period

Infected individuals shed RSV for 3-8 days, but immunocompromised patients with severe infection may shed virus for up to four weeks.

18a.3 Effects of RSV

Symptoms of RSV in infants

RSV typically causes a self-limiting upper respiratory tract infection with rhinorrhoea, pharyngitis, nasal congestion, coughing, sneezing, tachypnoea, and decreased appetite. LRTD occurs as bronchiolitis or pneumonia, with fever in <50% of infections, increased work of breathing, hyperinflation, croup (laryngotracheobronchitis), and wheeze. Typically, in the absence of immunisation, between 1% and 3% of infected infants require hospitalisation. Treatment is supportive (supplemental oxygen and feeding support). Some infants require admission to intensive care for ventilation support.

Symptoms of RSV in adults

For most healthy adults, RSV causes a mild self-limiting cold-like illness. RSV is a significant cause of severe respiratory illness, hospitalisation and occasionally death in older adults. Adults aged over 60 years with medical conditions including chronic lung disease (CLD), chronic heart disease (CHD), diabetes mellitus, chronic kidney disease, obesity and immunocompromising conditions, as well as those who are frail or in long-term care settings, are at greatest risk for RSV-associated hospitalisation.

Diagnosis

RSV can be detected in nasopharyngeal aspirate, bronchoalveolar lavage, sputum, or swabs from the nose and throat by using real-time polymerase chain reaction (PCR), immunofluorescence, enzyme-linked immunosorbent assay and growth in cell culture. PCR is the most sensitive test, and the current gold standard.

18a.4 RSV immunisations

18a.4.1 RSV immunisation of infants and children

Prior to 2022, only one product was available for the prevention of RSV disease in infants: palivizumab (SmPC), a monoclonal antibody which provides passive immunity against RSV. Palivizumab requires administration of five doses, given monthly during the RSV season to maintain protection and was recommended only for a cohort of high-risk infants in Ireland.

In recent years, the characterisation of the RSV fusion glycoprotein (F protein) in its prefusion state has enabled the development of vaccines and antibody-based therapies for prevention of RSV-induced disease in infants. One maternal vaccine,

RSVpreF (Abrysvo, Pfizer), and one long-acting monoclonal antibody, nirsevimab (Beyfortus, Sanofi) are authorised by the EMA. A second long-acting monoclonal antibody, clesrovimab (Enflonsia, Merck) has been recommended for authorisation by the EMA. RSVpreF (Abrysvo, Pfizer) and nirsevimab (Beyfortus, Sanofi) have been reviewed by NIAC for the prevention of RSV in infants.

18a.4.1.1 Nirsevimab (Beyfortus, Sanofi) (SmPC)

Nirsevimab is a long-acting monoclonal antibody which is administered directly to the infant, providing passive immunity against RSV. Nirsevimab inhibits the essential membrane fusion step in the viral entry process, neutralising the virus and blocking cell-to-cell fusion.

Nirsevimab was authorised by the EMA in October 2022 for the prevention of RSV LRTD in infants during their first RSV season by administering a single dose at the beginning of the season and to those born during the RSV season. Protection is expected to last approximately five months, similar in duration to an average RSV season.

Licenced indications: (SmPC)

Nirsevimab (Beyfortus, Sanofi) is licenced for the prevention of RSV LRTD in:

- neonates and infants during their first RSV season
- children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Storage

Nirsevimab should be stored at between +2°C and +8°C. Store in original packaging and protect from light. If nirsevimab has been frozen, it should not be used.

Nirsevimab may be kept at room temperature (+20°C to +25°C) when protected from light for a maximum of eight hours. After this time, the syringe must be discarded.

Immunogenicity and efficacy

Nirsevimab was authorised by the EMA based on data from three clinical trials (MEDLEY, D5290C00003 and MELODY trials). Since authorisation, a further pragmatic clinical trial (HARMONIE) was conducted over the 2022/2023 season.

Immunogenicity and pharmacokinetics

Serum concentrations of nirsevimab decrease linearly over time, with a mean half-

life of 69 days. The MEDLEY and MELODY trials found that serum concentrations of nirsevimab were similar at 151 days in preterm, CHD/CLD, and term cohorts. Antidrug antibodies (ADAs) were low in these trials, (5.6-6.1% in nirsevimab groups, 1.1-3.8% in treatment groups) and no effect on pharmacokinetics was observed through the first 151 days. However, on day 361, serum nirsevimab concentrations were generally lower in infants with ADAs compared to those without. In the MELODY trial, RSV-neutralising antibodies in infants who received nirsevimab were approximately 50-fold higher at 150 days post-dose compared to baseline pre-dose levels.

Efficacy and effectiveness

In the MELODY trial, efficacy against medically-attended RSV LRTD and hospitalisation in late preterm and term infants born after 35 weeks' gestation was 75% and 62%, respectively. In the D5290C0003 trial, efficacy against medically-attended RSV LRTD and hospitalisation was 70% and 78%, respectively among infants born between 29 weeks 0 days' and 34 weeks 6 days' gestation. The HARMONIE trial reported an efficacy of 83% against RSV hospitalisation and a 58% reduction in all-cause LRTD hospitalisation in healthy infants born after 29 weeks' gestation.

A systematic review conducted in 2025 synthesised all published real world effectiveness studies incorporating data from 28 studies across five countries: France, Italy, Luxembourg, Spain, and the United States. The meta-analysis demonstrated that nirsevimab significantly reduced the risk of RSV-related hospitalisation compared with control groups, with an odds ratio (OR) of 0.14 (95% CI:0.11-0.20, $p<0.001$), corresponding to an estimated effectiveness of 86%. The risk of ICU admission was also significantly lower among infants who received nirsevimab, with an OR of 0.17 (95% CI:0.10-0.31, $p<0.001$), indicating an effectiveness of 83%. Additionally, the pooled analysis found a significantly reduced risk of RSV-related lower respiratory tract infection (LRTI), with an OR of 0.27 (95% CI:0.23-0.32, $p<0.001$), equating to an effectiveness of 73%.

Dose, schedule and route of administration

Nirsevimab is for intramuscular (IM) injection only and should be administered as follows:

- Infants <5kg: A single dose of 50mg administered intramuscularly.
- Infants ≥5kg: A single dose of 100mg administered intramuscularly.
- Children up to 24 months entering their second season: 200mg given as two 100mg IM injections.

For additional dosing recommendations in patients post cardiac surgery requiring cardiopulmonary bypass, please consult the Summary of Product Characteristics (SmPC).

Nirsevimab should be administered preferably in the anterolateral aspect of the thigh.

Multiple IM injections given at the same visit must be given at least 2.5cm apart, where administered in the same limb, and if necessary, in different limbs.

Interchangeability

If an infant has received palivizumab initially, they can receive nirsevimab rather than complete the remaining monthly doses of palivizumab. There is no minimum interval between the last dose of palivizumab and the dose of nirsevimab. Given protection from palivizumab wanes after 30 days, nirsevimab should be administered no later than 30 days after the last palivizumab dose, when possible.

Contraindications

- Anaphylaxis to any of the monoclonal antibody constituents listed in the SmPC.
- Serious hypersensitivity reaction to previous immunisation with nirsevimab or palivizumab.

Precautions

- Serious hypersensitivity reactions, including anaphylaxis, have been observed with monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medicinal products and or supportive therapy.
- As with any other IM injections, nirsevimab should be given with caution to infants with thrombocytopenia or any coagulation disorder.

Concomitant administration with vaccines

Since nirsevimab is a monoclonal antibody (a passive immunisation specific for RSV), it is not expected to interfere with the active immune response to co-administered vaccines. There is limited experience of co-administration with vaccines. In clinical trials, when nirsevimab was given with routine childhood vaccines, the safety and reactogenicity profile of the co-administered regimen was similar to the childhood vaccines given alone. Nirsevimab can be given concomitantly with childhood vaccines. Nirsevimab should not be mixed with any vaccine in the same syringe or vial. When administered concomitantly with injectable vaccines, they should be given with separate syringes and at different injection sites.

Adverse reactions

The most frequent adverse reaction was rash (0.7%) occurring within 14 days post-dose. The majority of cases were mild to moderate in intensity. Additionally, pyrexia and injection site reactions were reported at a rate of 0.5% and 0.3% within seven days post-dose, respectively. Injection site reactions were non-serious.

Adverse reactions of nirsevimab	
Local	Common: injection site reactions
General	Common: rash, pyrexia

18a.4.1.2 Palivizumab (Synagis AstraZeneca) (SmPC)

Palivizumab, a humanised mouse monoclonal antibody specific for the F protein of RSV, provides passive immunity against RSV. It inhibits RSV binding to host cells and prevents fusion of infected cells with adjacent cells. Palivizumab prophylaxis reduces the absolute risk of RSV hospitalisation from about 10% to about 5% for infants born prematurely, for infants with CLD, and for infants with haemodynamically-significant CHD, particularly when complicated by large left-to-right shunts and pulmonary hypertension.

Palivizumab is authorised for use in the EU but is no longer available in Ireland.

18a.4.2 RSV maternal vaccination during pregnancy

18a.4.2.1 RSVpreF (Abrysvo, Pfizer) (SmPC)

RSVpreF contains two recombinant stabilised RSV prefusion F antigens representing subgroups RSV A and RSV B. Prefusion F is the primary target of neutralising antibodies that block RSV infection. Following IM administration, the prefusion F antigens elicit an immune response, which protects against RSV-associated LRTD.

In infants born to mothers who were vaccinated with RSVpreF between 24- and 36-weeks' gestation, protection against RSV-associated LRTD is due to transplacental transfer of RSV-neutralising antibodies.

RSVpreF was authorised by the EMA in August 2023 for passive protection against LRTD caused by RSV in infants from birth through six months of age following maternal immunisation during pregnancy.

Immunogenicity and vaccine efficacy

A phase 3, multicentre, randomised (1:1), double-blind, placebo-controlled study was undertaken to assess the efficacy of a single dose of RSVpreF in the prevention of RSV-associated LRTD in infants born to pregnant individuals vaccinated between

24- and 36-weeks' gestation.

RSV-associated LRTD was defined as a medically-attended visit with a PCR-confirmed RSV illness accompanied by one or more of the following: fast breathing, low oxygen saturation (SpO_2 <95%) and chest wall indrawing.

RSV-associated severe lower respiratory tract illness was defined as an illness that met the lower respiratory tract illness-RSV criteria plus at least one of the following: very fast breathing, low oxygen saturation (SpO_2 <93%), high-flow oxygen supplementation via nasal cannula or mechanical ventilation, ICU admission for >4 hours and or failure to respond/unconscious.

Vaccine efficacy (VE) was defined as the relative risk reduction of the endpoint in the RSVpreF group compared to the placebo group for infants born to pregnant individuals who received the assigned intervention. There were two primary efficacy endpoints, assessed in parallel, severe RSV-positive medically-attended lower respiratory tract illness and RSV-positive medically-attended lower respiratory tract illness, occurring within 90, 120, 150 or 180 days after birth.

RSVpreF VE against severe medically-attended lower respiratory tract illness caused by RSV in infants from birth through six months of age by active immunisation of pregnant individuals ranged from 82.4% (95% CI: 57.5 to 93.9) at 90 days after birth to 70% (95% CI: 50.6 to 82.5) at 180 days after birth.

RSVpreF VE against medically-attended lower respiratory tract illness caused by RSV in infants from birth through six months of age by active immunisation of pregnant individuals ranged from 57.6% (95% CI: 31.3 to 74.6) at 90 days after birth to 49.2% (95% CI: 31.4 to 62.8) at 180 days after birth.

Immunogenicity data from the phase 2b SAVVY trial included just over 400 vaccine recipients (73 of whom had received the exact vaccine composition coming to market) and over 100 placebo recipients, vaccinated between 24- and 36-weeks' gestation. The 50% neutralisation geometric mean titres were higher in both maternal and infant samples at birth in vaccine recipients compared to placebo recipients. A geometric mean titre ratio of 2.1 was reported in infants of vaccine recipients compared to infants of placebo recipients. Of note, the levels of RSV-neutralising titres in the umbilical cord blood did not vary substantially according to the gestational age at which the vaccine was administered, supporting a three-month immunisation window. Infant RSV-neutralising titres declined over the first six months of life in both groups, while the vaccine recipient group continued to have consistently higher titres compared to the placebo recipients.

Dose, schedule and route of administration

A single dose of 0.5ml should be administered.

RSVpreF is for IM injection into the deltoid region of the upper arm.

The need for revaccination with a subsequent dose has not been established.

Contraindications

Anaphylaxis to any of the vaccine constituents listed in the SmPC.

Precautions

1. Acute febrile illness, defer until recovery.
2. RSVpreF should be given with caution to individuals with thrombocytopenia or any coagulation disorder.
3. The efficacy and safety of the vaccine have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of RSVpreF may be lower in immunosuppressed individuals.
4. RSVpreF has not been studied in pregnant individuals less than 24 weeks' gestation. Since protection of the infant against RSV depends on the transfer of maternal antibodies across the placenta, RSVpreF should be administered between 24- and 36-weeks' gestation.

Adverse reactions

A full list of adverse reactions may be found in the SmPC.

Adverse reactions of RSVpreF (Abrysvo) vaccination during pregnancy	
Local	Very common: vaccination site pain Common: vaccination site redness, vaccination site swelling
General	Very common: headache, myalgia

Co-administration

RSVpreF can be administered concomitantly with the seasonal inactivated influenza vaccine (IIV). In a randomised study in adults aged 65 years and older, the criteria for non-inferiority of the immune responses in the co-administration versus the separate administration group were met. However, numerically lower RSV A and B neutralising titres and numerically lower influenza A and B haemagglutination inhibition titres were observed when RSVpreF and adjuvanted inactivated influenza vaccine were co-administered than when they were administered separately. The

clinical relevance of this finding is unknown.

A minimum interval of two weeks is recommended between administration of RSVpreF and administration of a tetanus, diphtheria and acellular pertussis vaccine (Tdap). There were no safety concerns when RSVpreF was co-administered with Tdap in healthy non-pregnant women. Immune responses to RSV A, RSV B, diphtheria and tetanus on co-administration were non-inferior to those after separate administration. However, the immune responses to the pertussis components were lower on co-administration compared to separate administration and did not meet the criteria for non-inferiority. The clinical relevance of this finding is unknown.

18a.4.3 RSV vaccination of adults

There are three vaccines authorised by the EMA for the prevention of RSV lower respiratory tract disease (LRTD) in adults. Of these, two are recombinant subunit vaccines RSVPreF3 (Arexvy) and RSVpreF (Abrysvo), and one is an mRNA vaccine (mRNA-1345, (mResvia).

18a.4.3.1 RSVPreF3 (Arexvy, GSK) (SmPC)

RSVPreF3 (Arexvy) combines the RSV-specific antigen, F-protein in prefusion conformation, with an adjuvant ($AS01_E$). It is designed to enhance antigen-specific cellular immune response and neutralising antibodies in individuals with pre-existing immunity against RSV.

Licensed indications

RSVPreF3 is indicated for:

- Active immunisation for the prevention of LRTD caused by respiratory syncytial virus in adults aged 60 years and older.
- Active immunisation for the prevention of LRTD in adults aged 50 to 59 years who are at increased risk for RSV disease.

Immunogenicity and vaccine efficacy

Efficacy against RSV-associated LRTD in adults 60 years and older was evaluated in an ongoing, phase 3, randomised, placebo-controlled, observer-blind clinical study conducted in 17 countries from Northern and Southern Hemispheres. Participants were followed for up for 36 months.

The primary objective was to demonstrate efficacy in the prevention of a first episode of confirmed RSV A and or B-associated LRTD during the first season.

Confirmed RSV cases were determined by PCR on nasopharyngeal swab. LRTD was defined based on the following criteria: the participant must have experienced at least two lower respiratory symptoms and or signs including at least one lower respiratory sign for at least 24 hours, or experienced a minimum of three lower respiratory symptoms for at least 24 hours. Lower respiratory symptoms included: new or increased sputum, new or increased cough, new or increased dyspnoea (shortness of breath). Lower respiratory signs included new or increased wheezing, crackles/ronchi, respiratory rate ≥20 respirations/min, low or decreased oxygen saturation (O_2 saturation <95%, or ≤90% if baseline is <95%) or need for oxygen supplementation.

Efficacy in preventing RSV-associated LRTD in season one following vaccination was 82.6% (96.95% CI: 57.9 to 94.1) in participants aged 60 years and older. VE against RSV A-associated LRTD cases and RSV B-associated LRTD cases was 84.6% (95% CI: 32.1 to 98.3) and 80.9% (95% CI: 49.4 to 94.3), respectively. Season two and three VE was 56.1% and 48%, respectively.

VE was similar against the RSV A and B subtypes and was consistently high among participants aged 60 to 69 years and those aged 70 to 79 years, among prefrail older adults, and among those with coexisting conditions.

Data on revaccination has been reported for RSVPreF3 (Arexvy) which demonstrates an overall similar safety profile as for a single dose, however no additional cumulative efficacy or additional efficacy in season two was demonstrated.

Dose, schedule and route of administration

RSVPreF3 is administered as a single dose of 0.5ml.

This is for IM injection only, preferably in the deltoid muscle.

The need for revaccination with a subsequent dose has not been established.

Contraindications

Anaphylaxis to any of the vaccine constituents listed in the SmPC.

Precautions

1. Do not administer the vaccine intravascularly or intradermally. No data are available on subcutaneous administration of RSVPreF3.
2. Exercise caution for individuals with thrombocytopenia or any coagulation disorder.
3. Safety and immunogenicity data on RSVPreF3 are not available for immunocompromised individuals. Patients receiving immunosuppressive

treatment or patients with immunodeficiency may have a reduced immune response to RSVPreF3.

4. The safety and efficacy of RSVPreF3 in children have not been established.

Co-administration

RSVPreF3 may be administered concomitantly with IIV (standard dose unadjuvanted, high dose unadjuvanted, or standard dose adjuvanted), COVID-19 vaccine, pneumococcal conjugate vaccine and with herpes zoster vaccine (Shingrix).

Upon concomitant administration of RSVPreF3 with influenza vaccines, numerically lower RSV A and B-neutralising titres and numerically lower influenza A and B haemagglutination inhibition titres were observed as compared to the separate administration. This was not observed consistently across studies. The clinical relevance of these findings is unknown.

Adverse reactions

A full list of adverse reactions may be found in the SmPC.

Adverse reactions of RSVpreF3 (Arexvy)	
Local	Very common: vaccination site pain Common: vaccination site redness, vaccination site swelling
General	Very common: headache, myalgia, arthralgia, fatigue Common: fever, chills Very rare: Guillain-Barré syndrome

18a.4.3.2 RSVpreF (Abrysvo, Pfizer) (SmPC)

RSVpreF contains two recombinant stabilised RSV prefusion F antigens representing subgroups RSV A and RSV B. Prefusion F is the primary target of neutralising antibodies that block RSV infection.

Following IM administration, the prefusion F antigens elicit an immune response, which protects against RSV-associated LRTD.

Licensed indications

RSVpreF is indicated for:

- Active immunisation of individuals aged 18 years and older for the prevention of LRTD caused by RSV.
- Passive protection against LRTD caused by RSV in infants from birth through six months of age following maternal immunisation during pregnancy.

Immunogenicity and vaccine efficacy

A phase 3, multicentre, randomised (1:1), double-blind, placebo-controlled study assessed the efficacy of RSVpreF in the prevention of RSV-associated lower respiratory tract illness in individuals aged 60 years and older. RSV-associated lower respiratory tract illness was defined as PCR-confirmed RSV illness with two or more, or three or more, of the following respiratory symptoms within seven days of symptom onset and lasting more than one day during the same illness: new or increased cough, wheezing, sputum production, shortness of breath or tachypnoea (≥25 breaths/min or 15% increase from resting baseline).

The primary objective was assessment of VE, defined as the relative risk reduction of first episode of RSV-associated lower respiratory tract illness in the RSVpreF group, compared to the placebo group in the first RSV season.

RSVpreF VE within season one in individuals aged 60 years and older was 65.1% (95% CI: 35.9 to 82.0) against first episode of RSV-associated lower respiratory tract illness with ≥2 symptoms and 88.9% (95% CI: 53.6 to 98.7) against first episode of RSV-associated lower respiratory tract illness with ≥3 symptoms. VE was similar against RSV-LRTD among participants aged 60 to 69 years, 70 to 79 years and among those with one or more co-morbidities. Season two VE was 55.7%. Season two VE was 55.7%.

Dose, schedule and route of administration

A single dose of 0.5ml should be administered.

RSVpreF is for IM injection into the deltoid region of the upper arm.

The need for revaccination with a subsequent dose has not been established.

Contraindication

Anaphylaxis to any of the vaccine constituents listed in the SmPC.

Precautions

1. Acute febrile illness, defer until recovery.
2. Exercise caution for individuals with thrombocytopenia or any coagulation disorder.
3. The efficacy and safety of RSVpreF have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of RSVpreF may be lower in immunosuppressed individuals.
4. RSVpreF has not been studied in pregnant individuals less than 24 weeks' gestation. For transfer of maternal antibodies, administer between 24- and 36-

weeks' gestation.

Co-administration

RSVpreF can be administered concomitantly with IIV (standard dose, high dose, adjuvanted) and COVID-19 vaccine. In a randomised study in adults aged 65 years and older, the criteria for non-inferiority of the immune responses in the co-administration versus the separate administration group were met. However, both RSV A and B-neutralising titres and influenza A and B haemagglutination inhibition titres (most pronounced for influenza strain A (H3N2)), were observed to be numerically lower when RSVpreF and adjuvanted inactivated influenza vaccine were co-administered, than when they were administered separately. The clinical relevance of this finding is unknown.

A minimum interval of two weeks is recommended between administration of RSVpreF and administration of a tetanus, diphtheria and acellular pertussis vaccine (Tdap). There were no safety concerns when RSVpreF was co-administered with Tdap in healthy non-pregnant women. Immune responses to RSV A, RSV B, diphtheria and tetanus on co-administration were non-inferior to those after separate administration. However, the immune responses to the pertussis components were lower on co-administration compared to separate administration and did not meet the criteria for non-inferiority. The clinical relevance of this finding is unknown.

Adverse reaction

A full list of adverse reactions may be found in the SmPC.

Adverse reactions of RSVpreF (Abrysvo) vaccination in adults	
Local	Very common: vaccination site pain Common: vaccination site redness, vaccination site swelling
General	Very common: headache, myalgia, fatigue Common: arthralgia Very rare: Guillian-Barré Syndrome (<1/10,000)

18a.4.3.3 mRNA-1345 (mResvia, Moderna) (SmPC)

The RSV mRNA vaccine, mRNA-1345 (mResvia) contains a single-stranded 5' capped mRNA encoding the RSV-A glycoprotein F stabilised in the prefusion conformation.

Licenced indications

RSV mRNA-1345 vaccine is licenced for:

- Active immunisation of individuals aged 60 years and older for the prevention of lower respiratory tract disease caused by RSV.

Immunogenicity and vaccine efficacy

Efficacy against RSV-associated LRTD in adults aged 60 years and older (with or without underlying medical conditions), was evaluated in an ongoing phase 2 of 3 randomised, observer-blind, placebo-controlled, study in 22 countries in the Northern and Southern hemispheres. The primary efficacy analysis population included 35,088 participants (17,572 mRESVIA, 17,516 placebo), of whom 6.9% had a protocol-defined LRTD risk factor such as congestive heart failure or chronic obstructive pulmonary disease, while 29.3% had ≥1 comorbidity of interest, and 21.8% were defined as vulnerable or frail.

The primary efficacy endpoints were the prevention of first episode RSV-LRTD with ≥2 or ≥3 symptoms occurring between 14 days and 12 months post injection. VE, assessed at 3.7 months of follow-up, when at least 50% of the anticipated cases of RSV-LRTD had occurred, was 83.7% (95.8% CI: 66.0 to 92.2%) against RSV-LRTD defined by ≥2 symptoms and 82.4% (96.36% CI: 34.8 to 95.3%) against RSV-LRTD defined by ≥ 3 symptoms. After a median of 8.6 months of follow-up, VE for RSV LRTI with ≥2 symptoms and ≥3 symptoms was 63.3% (95% CI: 48.7 to73.7%) and 63.0% (95% CI: 37.3 to78.2%) in season one, respectively. Vaccine efficacy was similar against RSV-LRTD among participants aged 60 to 69 years, 70 to 79 years and among those with one or more co-morbidities. Protection was observed against both RSV A and B.

Dose, schedule and route of administration

A single dose of 0.5ml should be administered.

mRNA-1345 vaccine (mResvia) is for IM injection into the deltoid region of the upper arm.

The need for revaccination with a subsequent dose has not been established.

Contraindications

Anaphylaxis to any of the vaccine constituents listed in the SmPC.

The vaccine is not indicated in women of childbearing potential. It is not to be used in women who are or may be pregnant or breastfeeding. There are no or limited data from the use of mRNA-1345 vaccine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy.

Precautions

1. Acute febrile illness, defer until recovery.
2. Exercise caution for individuals with thrombocytopenia or any coagulation disorder.
3. The safety and efficacy in children have not been established.
4. Safety and immunogenicity data are not available for immunocompromised individuals. Individuals receiving immunosuppressant therapy or patients with immunodeficiency may have a diminished response to this vaccine.

Co-administration

mRNA-1345 (mRESVIA) can be administered concomitantly with IIV and mRNA COVID-19 vaccines. In a randomised study in medically stable adults 50 years and older, the reactogenicity profiles of co-administered vaccines were similar to when the vaccines were administered alone. When mRNA-1345 was administered with either standard dose IIV or mRNA COVID-19 vaccines, the criteria for non-inferiority of the immune responses in the co-administration versus the separate administration group were met.

Adverse reactions

A full list of adverse reactions may be found in the SmPC.

Adverse reactions of mRNA-1345 (mResvia) vaccination in adults	
Local	Very common: vaccination site pain Common: vaccination site redness, vaccination site swelling
General	Very common: fatigue, chills, lymphadenopathy, headache, myalgia, arthralgia, nausea/vomiting Common: fever Rare: facial paralysis, including Bell's palsy

18a.5 Recommendations

NIAC's recommendations and advice are informed by extensive review of the latest clinical and scientific information. Recommendations for the immunisation of infants and high-risk children were updated on 25 March 2025 with the underpinning evidence available here. Recommendations for the immunisation of older adults were updated on 2 October 2025, with the underpinning evidence available here.

18a.5.1 RSV immunisation of infants and high-risk children

1. NIAC recommends the passive immunisation with nirsevimab of all infants who

are born during the RSV season. These infants should receive nirsevimab ideally prior to discharge home from a maternity hospital.

2. NIAC recommends the passive immunisation with nirsevimab of all infants who are aged ≤6 months at the start of the RSV season. These infants should receive nirsevimab prior to the start of the RSV season.

3. NIAC recommends the passive immunisation with nirsevimab of all high-risk infants aged ≤12 months at the start of their first RSV season (Table 18a.3). These infants should receive nirsevimab prior to the start of the RSV season.

4. NIAC recommends the passive immunisation with nirsevimab of all ex-preterm infants aged under 24 months with CLD[†] in their second RSV season. Infants who will be severely immunocompromised during the RSV season may also be considered for nirsevimab in consultation with their treating specialist. These infants should receive nirsevimab prior to the start of the RSV season.

5. In the event of short supply or programmatic limitations, the youngest infants (those born during the RSV season) and high-risk infants in their first RSV season should be prioritised.

6. Neonates[‡] with prolonged hospitalisation from birth due to prematurity or other reasons should receive nirsevimab shortly before discharge from hospital if they are being discharged during or shortly before the RSV season.

7. The RSV season in Ireland typically starts in calendar weeks 38-40 and ends around calendar week eight of the following year. Immunisation of the birth cohort (that is, infants born during the RSV season) should aim to start shortly before the onset of the RSV season and finish at the end of the RSV season. Immunisation of infants aged ≤6 months at the start of the RSV season and of high-risk infants and children should aim to be completed shortly before the onset of the RSV season.

[†] CLD is defined as those who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) for six months preceding the RSV season.
[‡] Earlier inpatient administration may be considered if infant is considered at risk of RSV exposure in hospital. Dosing in infants with a body weight from 1.0 kg to <1.6 kg is based on extrapolation; no clinical data are available. There are no data to inform dosing in infants <1kg and the benefits and risks of nirsevimab use in infants <1kg should be carefully considered.

Table 18a.3 Categories of high-risk infants recommended to receive passive immunisation with Nirsevimab if aged <12 months at the start of their first RSV season

High-risk infants*
▪ Infants born before 30 weeks, 0 days' gestation.
▪ Preterm infants with CLD of prematurity (defined as birth at <32 weeks' gestation and a requirement for >21% oxygen for at least 28 days after birth).
▪ Certain infants with haemodynamically-significant heart disease, specifically those with acyanotic heart disease requiring medication for congestive cardiac failure and or moderate to severe pulmonary hypertension, and infants with cyanotic heart disease (in consultation with cardiology specialist).
▪ Infants with a pulmonary abnormality or neuromuscular disease that impairs their ability to clear upper airways secretions may be considered for prophylaxis.
▪ Children younger than one year who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.

*Categories of high-risk infants align with those previously eligible to receive palivizumab prophylaxis in Ireland. These categories were adapted using guidance from the American Academy of Pediatrics.

18a.5.2 RSV immunisation of adults

1. NIAC recommends RSV vaccination with either RSVPreF3 (Arexvy), RSVpreF (Abrysvo) or mRNA-1345 (mRESVIA) for those:

   (a) aged 75 years and older.

   (b) aged 60-74 years with any additional risk factors for severe RSV disease, as outlined in Table 18a.4.

   (c) aged 60 years and older living in long-term care facilities for older adults.

2. A single dose is recommended; the need for booster doses has not yet been established.

3. RSV vaccines may be given at any time of the year, but vaccination will have the most individual benefit if administered just before the RSV season. The impact of any vaccination programme will depend on uptake and thus implementation factors should also be considered in determining the optimal RSV vaccination strategy for adults.

4. RSV vaccines may be given at the same time as other vaccines, such as COVID-19, inactivated influenza, herpes zoster and pneumococcal vaccines. However, co-administration studies on RSV and influenza vaccines have shown slightly lower immune responses to certain strains of influenza compared with when these vaccines are administered separately. The clinical significance of these decreased immune responses is uncertain. The benefits of giving the vaccines at the same time where there is an opportunity to do so may outweigh such concerns.

Table 18a.4 Medical conditions associated with an increased risk of RSV-related hospitalisation, severe disease and death

Medical conditions*
Chronic heart disease
Chronic respiratory disease
Chronic kidney disease
Chronic liver disease
Chronic neurological disease
Chronic metabolic disorders
Immunocompromise due to disease or treatment
Obesity

*This list is not exhaustive, and the medical practitioner should apply clinical judgment to consider the risk of RSV exacerbating any medical condition that a patient may have, as well as the risk of serious illness from RSV.

An up-to-date list of licensed vaccines can be accessed on the HPRA website www.hpra.ie.

A list of the vaccines currently available from the National Cold Chain Service can be found at www.immunisation.ie.

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