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RECOMMENDATIONS

Prevention of respiratory syncytial virus infection in children. Recommendations of the Polish Society of Paediatrics and the National Paediatric Consultant

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ABSTRACT

Respiratory syncytial virus (RSV) is one of the most important etiological agents of acute lower respiratory tract infections in children (LRTI-RSV). RSV infection occurs in almost all children during the first 2 years of life. RSV is one of the main causes of hospitalisation in the first year of life and especially in the first months of life.

In Poland, the monoclonal antibody palivizumab (Synagis®) is currently available to protect infants against RSV as part of a drug programme. It is provided exclusively for premature infants and children at risk and should be administered monthly during the RSV season.

Two new methods of prophylaxis against RSV infection are currently available worldwide: a vaccine (Abrysvo®, Pfizer) and a monoclonal antibody (nirsevimab, AstraZeneca and Sanofi Pasteur).

The Abrysvo® vaccine is administered to mothers to give their babies protection against RSV infection. The Abrysvo® vaccine is recommended for women at 32–36 weeks of pregnancy. In Poland, it is already available in pharmacies, at full price.

The monoclonal antibody nirsevimab (AstraZeneca and Sanofi Pasteur) is used in newborns and infants to protect against severe RSV infection. It is currently not available in Poland, although it is registered in Europe.

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The paper presents current recommendations for the use of palivizumab (Synagis®) in Poland, as well as current studies and recommendations from scientific societies and expert groups on the use of the Abrysvo® vaccine and the monoclonal antibody nirsevimab (Beyfortus®).
The paper also presents the rationale for the introduction of the health policy programme "Nationwide health prevention programme: single passive immunisation with a monoclonal antibody for the prevention of lower respiratory tract infections caused by RS virus for 2025–2030", submitted by the Polish Paediatric Society to the Ministry of Health in March 2024.

KEY WORDS:
respiratory syncytial virus, RSV, palivizumab, Abrysvo®, nirsevimab.

INTRODUCTION

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections (LRTIs) in children and the leading cause of infant hospitalisation worldwide. Most children become ill in the first year of life [1, 2].

A characteristic feature of RSV infections is their seasonality. In the northern hemisphere, RSV infections occur from September-October to April-May, with a peak incidence in the winter months of January-February [3, 4].

Statistics on RSV-related morbidity are mainly based on hospitalisation data, which are significantly underestimated [5]. The true burden of RSV in the outpatient setting remains unknown.

EPIDEMIOLOGY OF RSV IN INFANTS AND YOUNG CHILDREN

Mandatory reporting of RSV cases in Poland started in February 2023 [6]. In 2024, by the end of June (6 months), the incidence in children in the first 2 years of life was 2903.51 per 100,000 population [7]. Mazela *et al.* [8] reported that the highest hospitalisation rate is in children aged 2–3 months.

CLINICAL PRESENTATION OF RS VIRUS INFECTION

The clinical picture of RSV infection can vary from mild upper respiratory tract infection to severe LRTIs such as bronchitis, bronchiolitis or pneumonia [1, 9]. The course of infection is unpredictable even in healthy, full-term infants [10–12]. The most severe course of RSV infection is bronchiolitis, which often requires hospitalisation in the youngest children. Complications of RSV infection are common, affecting more than 60% of hospitalised children [13, 14].

There is no causal treatment for RS virus-induced bronchiolitis, and management is based on hydration and possible oxygen therapy.

If hospitalised, RS virus infection contributes significantly to quality of life (QALY) [15]. Hospitalisation for RSV also has a significant impact on parents' quality of life, with anxiety and depression being the most reported problems [16].

This article presents methods of passive prophylaxis in infants with both products registered in Poland and those already registered by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

(1) PASSIVE IMMUNISATION WITH SPECIFIC MONOCLONAL ANTIBODIES (PALIVIZUMAB)

In Poland, passive immunisation with a specific monoclonal antibody, palivizumab (Synagis®; AstraZeneca), is available and reimbursed under the B.40 drug programme for high-risk infants [17] (Table 1). Prophylaxis of RS virus infection with palivizumab is given to approximately 1.5% of children under one year of age.

Palivizumab is administered intramuscularly at a dose of 15 mg/kg body weight monthly (3–5 doses) during the RS virus infection season (1 September to 30 April) [18].

RECOMMENDATION 1

1. **We recommend the use of palivizumab in all infants during the first and second seasons according to the current drug programme B.40.**
2. **Continuation of the drug programme with palivizumab should be based on parental decisions and pharmacoeconomic analysis.**

(2) VACCINE FOR PREGNANT WOMEN (ABRYSVO®)

The vaccine Abrysvo® (Pfizer) is indicated for:

a) **passive protection** against lower respiratory tract disease caused by RSV in infants from birth to 6 months of age following maternal vaccination during pregnancy;
b) **active immunisation** of persons 60 years of age and older against lower respiratory tract disease caused by RSV [19, 20].

The Abrysvo® vaccine was registered by the FDA on 21 August 2023 with an indication for administration to women at 32–36 weeks' gestation for the prevention of LRTIs and severe LRTIs caused by RSV in infants from birth to 6 months of age [21]. According to the vaccine characteristics (10 September 2024), it is recommended between 24 and 36 weeks of pregnancy [19].

The Abrysvo® (RSVpreF) vaccine has been shown to be effective in preventing severe RSV-associated disease in infants from birth to 6 months of age. The efficacy of

TABLE 1. Eligibility criteria for the RS virus infection prevention programme according to drug programme B.40 [12]

1.1. Neonatal patients
1. Not older than 6 months at the start of immunisation and meeting the following criteria:
a) gestational age of 29–32 weeks
or
b) gestational age ≤ 35 weeks and low birth weight of 1500 g or less.
2. Failure to reach the age of 1 year at the start of the vaccination and birth at a gestational age ≤ 28 weeks.
3. Less than 2 years of age at the start of the vaccination and a diagnosis of bronchopulmonary dysplasia.
1.2. Patients with a diagnosis of cystic fibrosis
1. Not older than 1 year of age at the start of vaccination.
1.3. Heart patients
1. Less than 2 years of age at the start of vaccination and diagnosed with a hemodynamically significant cardiac defect with
a) overt heart failure that persists despite pharmacological treatment
or
b) moderate or severe secondary pulmonary hypertension
or
c) cyanotic heart defects with transcutaneous arterial blood oxygenation < 90%.
1.4. Patients diagnosed with spinal muscular atrophy
1. Not older than 2 years of age at the time of vaccination.

the vaccine in preventing severe RSV-associated lower respiratory tract disease in infants was 81.8% (99.5% CI: 40.6–96.3) at 90 days of age and 69.4% (97.58% CI: 44.3–84.1) at 180 days of age. The efficacy of the vaccine in preventing RSV-related lower respiratory tract infection (LRTI-RSV) was 57.1% (99.5% CI: 14.7–79.8) at 90 days after birth and 51.3% (97.58% CI: 29.4–66.8) at 180 days after birth. The RSVpreF vaccine had a favourable safety profile and efficacy against severe LRTI-RSV and RSV-related hospitalisations in infants up to 6 months of age [22].

Clinical trials showed a small increase in preterm births in vaccinated pregnant women. Therefore, the vaccine is recommended for use in women at 32–36 weeks' gestation to prevent LRTI-RSV in infants while minimising the risk of preterm birth.

Interactions of Abrysvo® with other vaccines [19]: the Abrysvo® vaccine may be administered concomitantly with quadrivalent seasonal influenza vaccine. However, an interval of at least two weeks is recommended between Abrysvo® and tetanus, diphtheria and pertussis (Tdap) vaccine.

For most infants, co-administration of nirsevimab and vaccine is not indicated. It is recommended that nirsevimab be given only to those born to:

- unvaccinated mothers;
- prematurely (< 30 weeks);
- within two weeks of administration of the Abrysvo® vaccine.

The Abrysvo® vaccine is a milestone in RSV prophylaxis because it is safe and effective in preventing severe RSV infection in an at-risk population.

The Advisory Committee on Immunization Practices (ACIP) and the American College of Obstetricians and Gynecologists (ACOG) recommend that pregnant women be vaccinated with a single dose of the vaccine at 32 weeks and zero days to 36 weeks and six days of gestation during the infection season (September–January) [22, 23].

The Australian Technical Advisory Group (ATAGI) and the National Health and Medical Research Council (NHMRC) recommend that pregnant women receive a single dose of the Abrysvo® vaccine at 28–36 weeks' gestation. Administration of the vaccine from 24 to less than 28 weeks' gestation is not routinely recommended [24].

In the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) licensed the Abrysvo® vaccine on 21 November 2002 for vaccination of women at 28–36 weeks' gestation [40]. The Joint Committee on Vaccination and Immunisation (JCVI) issued a position statement on 7 June 2023 recommending both passive immunisation and vaccination to ensure high performance in the delivery of RS infection prevention programmes. The JCVI does not express a preference for either product [25].

The Polish Society of Vaccinology (PTW) [26] recommends vaccination with the RSV vaccine between 32 and 36 weeks of gestation due to the potentially greater benefit and better safety profile.

RECOMMENDATION 2

1. **We recommend that mothers be vaccinated with a single dose of the RSV vaccine at 32–36 weeks' gestation to protect their infants (ACIP), and in special cases as early as 28 weeks' gestation. We do not recommend vaccination before 28 weeks' gestation.**
2. **We recommend vaccination of women who are due to give birth between the beginning of September and the end of March.**
3. **The RSV vaccine protects against RS virus infection for approximately 2 weeks after vaccination.**
4. **We recommend that the Abrysvo® vaccine be provided and fully reimbursed for pregnant women.**

(3) PASSIVE IMMUNISATION WITH THE SPECIFIC MONOCLONAL ANTIBODY NIRSEVIMAB (BEYFORTUS®)

Nirsevimab (Beyfortus®; AstraZeneca and Sanofi Pasteur) is the first monoclonal antibody with an extended half-life. A single dose of 50 mg intramuscularly is recommended for infants weighing less than 5 kg and 100 mg for infants weighing 5 kg or more. Nirsevimab is recommended to be administered before the start of the RSV infection season or from birth for infants born during the RSV infection season. Nirsevimab is shown to protect for at least 5 months [27].

Nirsevimab was approved by the EMA on 31 October 2022 [28] and by the FDA on 17 July 2023 [29].

The safety and efficacy of nirsevimab have been confirmed in three clinical trials (ClinicalTrials.gov numbers NCT02878330; NCT03979313; NCT03959488).

The 2019–2020 Griffin trial [30] included 1453 healthy preterm infants (born at 29–35 weeks' gestation) born during or before the first RSV season. Efficacy against medically attended RSV lower respiratory tract infection (MA-LRTI-RSV), classified as very severe, was 87.5% (95% CI: 62.9–95.8) in the nirsevimab group compared to placebo.

In the MELODY study conducted in 2021–2022 and published by Hammitt *et al.* [31], the study group included 1490 infants under 12 months of age born at a gestational age of 35 weeks or less. At 150 days, the efficacy of nirsevimab in preventing MA-LRTI-RSV was 74.5% (95% CI: 49.6–87.1) and in preventing severe progression was 64.2% (95% CI: 12.1–88.6). The efficacy of nirsevimab in preventing hospitalisation for LRTI-RSV was 62.1% (95% CI: 8.6–86.8). A post-hoc analysis of all participants in the study confirmed that 150 days after nirsevimab administration, the efficacy against LRTI-RSV hospitalisation was 76.8% (95% CI: 49.4–89.4) and against very severe LRTI-RSV was 78.6% (95%CI: 48.8–91.0) [32].

In the HARMONIE study published in 2023 by Drysdale *et al.* [33], which was conducted before or during the RSV season in three countries – France, Germany and the UK – a group of 8058 infants under 12 months of age, born at a gestational age of at least 29 weeks, received a single dose of nirsevimab (4037) or patients received standard care (4021). The efficacy of nirsevimab in preventing hospitalisation for LRTI-RSV was 83.2% (95% CI: 67.8–92.0) and in preventing severe cases of LRTI-RSV 75.7% (95% CI: 32.8–92.9). The effectiveness of nirsevimab in preventing hospitalisation for LRTI-RSV was 89.6% in France, 74.2% in Germany and 83.4% in the UK. The HARMONIE study showed that nirsevimab protects infants from hospitalisation and very severe LRTI-RSV in a near real-world setting.

The MEDLEY study, conducted in 2021–2022 in the US, Canada, Europe and the southern hemisphere, evaluated the immunogenicity and safety of nirsevimab compared with palivizumab. The study was conducted in preterm infants born before 35 weeks' gestation and in infants with chronic lung disease or congenital heart disease. After 360 days of follow-up, the incidence of adverse events was similar between the study groups. The safety profile of nirsevimab was shown to be like that of palivizumab in infants with congenital heart disease or chronic lung disease and in premature infants [34].

Nirsevimab can be given with childhood vaccines. Nirsevimab is a monoclonal antibody and does not interfere with the immune response when given concomitantly with vaccines. The safety and reactogenicity profiles were similar in children vaccinated without and with nirsevimab [27].

Current recommendations and RSV prevention programmes implemented in other countries: the US Advisory Committee on Immunization Practices (ACIP) recommends a single dose of nirsevimab in 2023 infants [35, 36]:

a) under 8 months of age born during or at the beginning of the first RSV season;
b) born during the RSV season (between November and March) before discharge from the neonatal unit;
c) born before the start of their first RSV season (between April and October) at the start of the RSV season in the outpatient clinic;
d) aged 8 to 19 months who are at increased risk of severe RSV infection and who are starting their second RSV season (200 mg).

The recommendations of the American College of Obstetricians and Gynaecologists [37] emphasise that in most neonates and infants it will not be necessary to give the vaccine to the mother and nirsevimab to the infant. Infants born at less than 34 weeks' gestation should receive nirsevimab regardless of maternal vaccination status due to incomplete transplacental transfer of maternal IgG.

In the US, the effectiveness of nirsevimab against RSV-related hospitalisations in infants during the first RSV season (between 1 October 2023 and 29 February 2024) was 90% (95% CI: 75–96%). The ACIP recommends both active and passive immunisation because both confer immunity and therefore may have similar effects on the risk of infection and the severity and duration of illness. ACIP experts believe that there is strong evidence to support both passive and active immunisation and to include them in childhood immunisation schedules [35, 36].

Many European countries have already included passive immunisation in childhood vaccination programmes (Spain [38–43], France [44–48], Luxembourg [49, 50], Switzerland [51], the United Kingdom [52, 53], Ireland [54], Belgium [55], the Netherlands [56], Germany [57]).

RECOMMENDATION 3

1. **Nirsevimab is a monoclonal antibody licensed for the prevention of RSV-induced lower respiratory tract infection in neonates, infants and young children during the first RSV season. RSV prophylaxis by passive immunisation with once-daily nirsevimab can significantly reduce the incidence of severe RSV-induced illness and even death. The inclusion of nirsevimab in prophylaxis will reduce the burden on paediatric wards and the number of outpatient visits during the high seasonal burden of RSV-induced disease in infants and young children.**
2. **Nirsevimab is administered as a single dose, intramuscularly into the anterolateral thigh, at a dose of 50 mg for neonates and infants weighing less than 5 kg and 100 mg for those weighing 5 kg or more.**
3. **Nirsevimab is recommended for all neonates and infants under 12 months of age:**
   a) **neonates born during the RSV season from October to March should receive nirsevimab during the first month of life, preferably while in the neonatal unit; neonates with prolonged hospitalisation should receive nirsevimab during their hospital stay, shortly before discharge (bearing in mind that peak serum concentrations are reached 6 days after administration);**
   b) **infants born between April and September should receive nirsevimab before the start of the RSV season (September–November), i.e. between 2 and 6 months of age, depending on the month of birth;**
   c) **in addition, a second dose of nirsevimab is recommended for infants under 24 months of age entering their second RSV season, born at less than 33 weeks' gestation, in infants with chronic congenital or acquired diseases associated with a high risk of severe RSV-related disease (in a total dose of 200 mg, i.e. two intramuscular injections of 100 mg each).**
4. **Nirsevimab infants born during the RSV season whose mothers received the Abrysvo vaccine during pregnancy should be considered protected. Administration of nirsevimab should only be considered in very specific situations where there is a risk of ineffective transplacental antibody transfer (Abrysvo® given less than 14 days prior to delivery, delivery < 37 weeks gestation, maternal immunosuppression including HIV infection with viral load, risk of loss of humoral immunity). Note that the RSV vaccine protects against infection for approximately 2 weeks after administration.**
5. **RSV prophylaxis with nirsevimab in infants born out of season can be incorporated into the immunisation calendar. Nirsevimab can be given at the same time as vaccines (DTPa-IPV-Hib-HBV, PCV, meningococcal, MMR) but at separate sites. Concomitant administration of nirsevimab is well tolerated and does not interfere with the immune response to the vaccines.**
6. **Information on recommendations for RSV prophylaxis in newborns and infants should be provided to prospective parents during pregnancy and before delivery by gynaecologists/obstetricians, midwives or other health professionals.**

(4) NATIONAL HEALTH PREVENTION PROGRAMME

The Polish Paediatric Society (PTP) prepared and submitted to the Ministry of Health in March 2024 the "National Health Prevention Programme: single passive immunisation with a monoclonal antibody for the prevention of lower respiratory tract infections caused by RS virus for 2025–2030". The rationale for the public health programme is as follows:

a) RSV infection is one of the most common causes of LRTI in infants and children under 1 year of age worldwide, often associated with complications and life-threatening, requiring medical intervention and hospitalisation;
b) Polish data indicate that up to 70% of hospitalisations due to RSV occur in children in the first year of life;
c) there is currently no effective causal treatment for LRTI-RSV, and the only therapeutic option available once infection is established is symptomatic treatment, which is not always effective;
d) the only form of reducing the incidence of LRTI-RSV (including hospitalisations) is passive immunoprophylaxis, consisting of direct administration to the child or transplacental transfer of antibodies against RSV by vaccination of the pregnant woman, which prevents the virus from entering the cells, thus preventing the development of the disease; and
e) currently in Poland, palivizumab (Synagis®) is used for passive prophylaxis of RSV infections in the B.40 drug programme, but this prophylaxis covers only a limited population of the so-called high-risk group; 98% of children in their first season of RSV infection do not have access to immunoprophylaxis;
f) other products with proven efficacy and safety are already registered in Europe for once-daily passive immunoprophylaxis to prevent RSV infection – the Abrysvo® vaccine and the monoclonal antibody Beyfortus®.

SUMMARY OF RECOMMENDATIONS

1. **We recommend that mothers who are 32–36 weeks pregnant be vaccinated to protect their baby, and that women who are due to give birth between the beginning of September and the end of March be vaccinated. We recommend that the Abrysvo® vaccine for pregnant women be included in the recommended vaccination programme, which is fully reimbursed.**
2. **We recommend passive immunisation with a single dose of nirsevimab for all newborns and infants born during the RSV season and for those born out of season to be immunised by the end of 12 months of age.**
3. **We recommend that at-risk infants (under 2 years of age) with underlying conditions associated with an increased risk of severe infection also receive nirsevimab during the second season.**
4. **The results of a study on the burden of RSV in paediatric wards and outpatient care during the RSV season, presented at the European Health Management Association (EHMA), showed that prevention programmes can improve the healthcare system and meet one of the objectives of the European Health Union to improve preparedness and response to health crises. In addition, the EHMA study showed that the majority of infants are not optimally treated and routinely undergo unnecessary tests and treatments (e.g. antibiotics) of questionable efficacy, potentially contributing to antibiotic resistance [58].**
5. **Nirsevimab was 88.4% (95% CI: 84.70–91.21) effective in preventing hospitalisation due to LRTI-RSV [59].**
6. **The Polish Paediatric Society recommends prophylaxis of RSV infection in all children, advocating the use of a vaccine in pregnant women and a monoclonal antibody in infants, while leaving the choice to parents and healthcare providers, based on analyses of the implementation of both prophylaxis programmes and data from cost-effectiveness analyses.**

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