Consensus statement / recommendation on the prevention of respiratory syncytial virus (RSV) infections with the monoclonal antibody Nirsevimab (Beyfortus®)

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For the protection of infants against RSV there is a monoclonal antibody (mAB) authorized and available in Switzerland (**Palivizumab** – Synagis®) which must be administered monthly during the RSV season. Swiss Consensus recommendations for use of Palivizumab in infants at high risk of severe RSV disease were first published in 1999, and updated in 2017 (*Agyeman 2017*).

This consensus statement centers on the new **mAB Nirsevimab (Beyfortus®)**, which received market authorization by Swissmedic in December 2023. Additionally, an unadjuvanted **RSV-vaccine** (**Abrysvo**® by Pfizer) is currently authorized in some countries for use in pregnant women to protect their newborns during the first 3 to 4 months of life. Authorization in Switzerland is expected soon.

Acceptance is expected to be high: In a survey of physicians about Nirsevimab use for infants, 69% were in favour or somewhat in favour in German-speaking Switzerland (while 8% had no clear opinion yet), and in French-speaking Switzerland 78% were in favour or somewhat in favour (with 8% who had no clear opinion yet).

1. Burden of RSV in infants and toddlers:

Nearly all children contract RSV within the first two years of life. In high-income countries, RSV is one of the primary reasons for hospitalization among children (*Munro 2023*). Most of the RSV-burden affects healthy children during their first year. A systematic review revealed variations in the annual incidence of infant hospitalization, ranging from 11 to 23 per 1000, depending on the methodology used for measurement and calculation (*McLoughlin 2022*).

In **Switzerland**, the RSV season usually lasts from November through April, with a peak in January. **Hospitalization rates** (per 1'000 population) in 2016-2019 / 2020 / 2021 were 43 / 30 /56 at age 0 months, 51 / 29 / 63 at age 1-2 mo., 21 / 11 /26 at age 3-5 mo., 11 / 6/ 15 at age 6-11 mo. and 4 / 3 /7 in the 2nd year of life. (*Stucki 2023*). Using a slightly broader definition for RSV-related hospitalization, rates in 2022 were ≥67 at age 0-2 mo., ≥28 at age 3-5 mo., ≥18 at age 6-8 mo., ≥14 at age 9-11 mo., and ≥9 in the 2nd year of life. There were at least 5 deaths due to RSV in < 2-year-old children in 2022 (*BFS / OFS 2023*).

Around 90% of children <1 year of age hospitalized due to RSV are otherwise healthy term or late preterm infants without medical risk factors. During their 2nd year of life, this proportion of healthy children drops to 60-75%. A recent review of U.K. data showed an increased RSV hospitalization risk for children aged less than 3 months. (*Munro 2023*).

The most recent guidelines for administering Palivizumab in Switzerland, published in 2017 (*Agyeman 2017*), restricted its use to high-risk patients with moderate to severe bronchopulmonary dysplasia (BPD) and hemodynamically significant congenital heart disease (CHD) in the first year of life. However, the literature has identified additional medical conditions that increase the risk of hospitalization in relation to RSV lower respiratory tract infection (LRTI).

Kristensen et al. conducted a study utilizing a **Danish national register** comprising more than 391,000 children aged under 2 years. They identified **additional congenital and acquired health conditions** associated with an

increased risk of RSV hospitalization (*Kristensen 2012*). Presence of a co-morbidity, CHD, prematurity, and younger age at the time of RSV diagnosis were linked to more severe outcomes. A systematic review of 27 studies and meta-analyses, involving over 109,000 patients with RSV LRTI, also demonstrated that co-morbidities, CHD, prematurity with a gestational age (GA) < 37 or ≤ 32 weeks, and age less than 3 or 6 months at the time of RSV diagnosis were associated with a more severe outcome (*Shi 2022*). However, the study had limitations in assessing other specific risk factors due to the absence of standardized definitions or small population sizes in some studies.

In **Switzerland**, Stucki et al. identified the **following risk factors for hospitalization** (Odds ratio in parentheses): multiple birth (1.30), birth month (vs. Apr.-Sep): Oct-Dec (1.97), Jan.-Mar. (1.38), birth weight (vs. ≥3000g): 2000-2499 (1.28), <2000g (1.43), gest. age: 32-36 weeks (1.50), 29-31 w. (2.07), <29 w. (2.13), malformation of great vessels (1.42), malformation of heart (1.81), respiratory malformation (2.08), biliary atresia (4.15), hemophilia (1.94), bronchopulmonary dysplasia (1.28), down syndrome (2.66), immuno-deficiency (1.60 n.s. (not statistically significant)), liver disease (1.14 n.s.), nervous system disease (2.33), renal failure (1.49 not statistically significant), lung and heart disorders (1.17), vit.D deficiency (1.60 n.s.), cerebral palsy (1.60 n.s.), and cystic fibrosis (4.99) (*Stucki 2023*).

It is also important to highlight the **ambulatory and social impact** of RSV LRTI, as well as the potential mid- to long-term complications. A prospective cohort study in the USA involving 5067 children revealed that RSV accounted for 15% of all pediatric office visits for respiratory infections during November to April (*Hall 2009*). In children under 5, there were three times more RSV-related visits to pediatric offices than visits to emergency departments. Caregivers of children with RSV infections in the USA miss over 700,000 workdays annually, surpassing the number of workdays missed due to influenza (*Bourgeois 2009*). In the UK, it is estimated that RSV infections in children under 5 result in direct medical and indirect societal costs of £80.5 million. Around 19% of these total cost to RSV are due to loss of productivity (£14.0 million) and out-of-pocket expenses (£1.5 million) (*Fusco 2022*). Finally, several studies found an association between early-life RSV LRTI and recurrent wheezing / asthma-symptoms (*Fauroux 2017, Baraldi 2020*), and infants with RSV-LRTI have a 2- to 12-fold higher risk of later developing pediatric asthma (*Esposito 2022, Feldman 2015*).

There is no specific data on the burden of **second-year infections**. However, existing literature indicates that the highest burden of these infections is associated with the presence of co-morbidities. Consistently, literature data reveals that hospitalized patients with risk factors tend to be older than healthy children. (*Shmueli 2020, Moreno-Perez 2014, Mori 2011, Pockett 2013, Kirsensen 2012*). In an Israeli cohort, the median age of patients with co-morbidities hospitalized for RSV LRTI was 9.6 months, compared to 3.1 months for healthy children. Additionally, a higher proportion of hospitalized children with co-morbidities were older than 12 months (38.5% vs 12.8% among healthy children) (*Shmueli 2020)*. Similarly, a study in Australia found a higher incidence of hospitalization in children aged 12 to 24 months with co-morbidities compared to healthy children (*Homeira 2016*). Another study in the United States analyzed the cost of hospital care and outpatient consultations, revealing an increased proportion of co-morbidities among hospitalized and outpatient children aged 12-23 months in comparison to younger children (*Choi 2023*). A systematic review on the risk of severe LRTI in patients with CHD also observed a broader age range in these patients compared to children without CHD (*Chaw 2020*). The authors of this review determined that there is a requirement for enhanced RSV prophylactics in children aged over 1 year. Finally, a birth cohort study in Scotland showed that premature or chronically ill children had an increased risk of hospitalization for RSV infection throughout the first 3 years of life (*Hardelid 2019*). These findings suggest that these high-risk patients should be prioritized for protection after the first year of life.

2. Characteristics of Nirsevimab:

2.1. Background and product description:

Nirsevimab (Beyfortus®) is a human recombinant monoclonal antibody against RSV developed by AstraZeneca and Sanofi. It binds to the F (fusion) protein on the surface of the RSV virus and inhibits virus-host cell fusion. It has a modified F_c-region, extending the elimination half-life. Thus, one dose offers protection for about 6 months. It was authorized for use in neonates and infants in the E.U. and the U.K. in Nov. 2022, Canada in Apr. 2023, and the USA in July 2023. Market authorization in Switzerland was granted in December 2023, but the antibody is anticipated to be available in autumn of 2024. Nirsevimab is administered as a single intramuscular injection. Dosage depends on body weight (<5 kg: 50 mg purple syringe; ≥5 kg: 100 mg blue syringe).

2.2. Effectiveness:

The **MEDI8897 Ph2b trial** in 2019/2020 examined efficacy, safety, pharmacokinetics and antidrug-antibody responses as a placebo-controlled, multicenter RCT in the USA, Canada, Europe and the Southern hemisphere. Subjects were **healthy preterm infants (29-35 weeks GA)** aged ≤12 months, of whom 969 received Nirsevimab and 484 placebo. After follow-up of 150 days, **medically attended (MA) RSV LRTI** (objective clinical LRTI criteria and +RSV-PCR) were observed in 2.6% of the treatment-group, and in 9.5% of the placebo-group, which translates to an efficacy of **70.1%** (52.3-81.2). **RSV LRTI hospitalizations** occurred in 0.8% of subjects in the treatment- and in 4.1% of the placebo-group (efficacy of **78.4%** (49.6-90.3)) (*Griffin 2020*).
The **MELODY trial** in 2021/2022 a placebo-controlled, multicenter RCT in the USA, Canada, and countries across Europe, Asia and the Southern hemisphere included ≤ 12 month old **term and late preterm infants** (≥35 weeks GA): 2009 received Nirsevimab and 1003 placebo. At follow-up after 150 days, **medically attended (MA) RSV LRTI** were seen in 1.2% of participants of the treatment- and 5.4 % of participants of the placebo-group, for an efficacy of **76.4%** (62.3-85.2). **RSV LRTI hospitalizations and very severe MA RSV LRTI** occurred in 0.4 and 0.3% of participants of the treatment- and in 2 and 1.7% of participants of the placebo-group with an efficacy of **76.8%** (62.3-85.2) and **78.6%** (48.8-91), respectively (*Hammitt 2022, Muller 2023*).
In the **HARMONIE** trial, 8058 infants, aged under 12 months, with a GA of at least 29 weeks and experiencing their first RSV season, were randomly assigned in a 1:1 ratio to receive either Nirsevimab or standard care. The measured efficacy of Nirsevimab on the risk of hospitalization for RSV-associated LRTI was **83.2% (95%CI 67.8-92, p<0.001).** 11 infants (0.3%) in the Nirsevimab group vs 60 infants (1.5%) in the control group were hospitalized. The efficacy on severe cases (oxygen saturation below 90% and oxygen administration) was **75.7% (95%CI 58.8-98-7, p=0.004).** 5 (0.1%) and 19 (0.5%) met the severity criteria in the intervention and control groups, respectively (*Drysdale 2023*).
Initial real-world data for Nirsevimab are available from the Galicia region in Spain: they confirm the effectiveness found in the studies and support its medical and public health benefits. There is a monitoring system in place showing weekly RSV hospitalizations across various age groups, along with vaccination rates. With most infants receiving Nirsevimab, a substantial decrease in cases within this age group can be observed, while the epidemiology remains relatively normal in older age groups. The English version of the weekly report can be accessed here: https://www.sergas.es/Saude-publica/Virus-Sincitial-Respiratorio

2.3. Adverse events (AE) and safety:
There are no post-marketing data available yet, but studies are ongoing in several countries. In the clinical trials described above, AEs were assessed for up to 360 days. The **MEDLEY trial** in 2021/2022 investigated immunogenicity and safety, in a Palivizumab-controlled, multicenter RCT in the USA, Canada, Europe and the Southern hemisphere in ≤ 24 mo. old preterm infants and in infants with chronic lung disease (CLD) of prematurity or CHD (these remain vulnerable to severe RSV in their 2nd RSV season). 614 received 1 dose Nirsevimab and then monthly placebo, 304 received Palivizumab monthly. After 360 days of follow-up, incidence of adverse events (AE) was similar across treatment groups in the preterm and CHD–CLD cohorts. Serious aEs in the preterm cohorts were seen in 5.3% vs. 6.9% (Palivizumab vs. Nirsevimab). Serious adverse events (SAEs) occurred more frequently in the CHD–CLD compared to the preterm cohort (20.4% with palivizumab vs. 19.2% with Nirsevimab), but no SAEs related to the treatment were reported. Two AEs of special interest were reported in the Nirsevimab group: heparin-induced thrombocytopenia in an infant with CHD and maculopapular rash following a placebo dose in a preterm infant. No treatment-related deaths were observed (*Domachowske 2022*). In another publication of children with CLD/CHD entering their second RSV season, the safety profile of Nirsevimab was also favorable and like that of palivizumab (*Domachowske 2023*).
Overall, Nirsevimab demonstrated a favorable safety profile. The safety database of all the trials included 3'751 pediatric patients under Nirsevimab. At least one treatment-emergent AE was seen in 86.2% of the treatment and in 86.8% of the placebo groups. No AE was reported with a frequency difference of ≥5% between Nirsevimab and control arms. The most common treatment-emergent AEs were: upper respiratory tract infection, fever, and nasopharyngitis. Serious AEs were reported in ≥1% of subjects of any of the 3 trials: respiratory infections (pneumonia, bronchitis, bronchiolitis) or gastroenteritis. Hypersensitivity skin reactions within 3 days – all Grade 1 and self-limited – were more

frequent in the treatment groups, with <1%. No systemic symptoms were seen in combination with hypersensitivity skin reactions. In the **HARMONIE** trial only 2.1% of infants receiving Nirsevimab experienced treatment-related AEs related to Nirsevimab. There were 3 children with an AE of special interest: 1 drug reaction (reported as fever and rash), 1 maculopapular rash, and 1 allergic dermatitis. These 3 reactions were of low grade severity.

3. Aims of the recommendation:

The main goals are to: 1. prevent severe RSV disease and RSV-related hospitalizations in all infants during their first RSV season 2. prevent severe RSV disease and RSV-related hospitalizations in vulnerable children during their second RSV season 3. reduce the impact on the healthcare system (hospital overload, transfer of patients, cancelling of elective procedures, etc.) 4. reduce costs associated with outpatient RSV cases in children aged <1 year, including indirect non-medical costs for the society.

4. Recommendations for use of Nirsevimab in infants and toddlers in Switzerland

The Nirsevimab expert working group, the EKIF/CFV and the FOPH jointly recommend that all infants receive a **single dose** of the **monoclonal antibody (mAB) for Respiratory syncytial virus (RSV) disease known as Nirsevimab** as a (passive) basic immunization during their first year of life, **provided that the costs (including administration in private practice and maternity ward) are covered by compulsory health insurance**. It should be given in the following manner:

a. **Born April to September → give Nirsevimab in October or as soon as possible thereafter.** Nirsevimab can be given concurrently with regular vaccines (DTPa-IPV-Hib-HBV, PCV, meningococcal vaccines, MMR, MMRV) in a separate area of the body (at least 2.5 cm apart).
b. **Born October to March → give Nirsevimab in the first post-natal week**, ideally **at maternity ward** or, if hospitalized after birth, preferentially before discharge or earlier at the discretion of the treating physician. Ideally, information about Nirsevimab should be provided to future parents in advance before birth by the gynaecologists/obstetricians, midwives and/or or general practitioners.

Additionally**, a second dose of Nirsevimab** is **recommended for children aged 24 months or younger entering their 2nd RSV season, with chronic congenital or acquired medical conditions associated with a persistent high risk of severe RSV disease, as determined by the attending specialist physician**. These include, but are not limited to:

- Hemodynamically significant congenital or acquired heart disease (such as cyanotic heart defects)
- Pulmonary arterial hypertension
- Chronic lung disease (such as moderate to severe BPD, lung malformations and cystic fibrosis)
- Inborn error of metabolism with repercussion on cardiac or pulmonary function
- Congenital or acquired neurological diseases (such as epilepsy and cerebral palsy) and neuromuscular diseases.
- Immune deficiency (congenital, acquired or drug-induced)
- Down syndrome and other chromosomal abnormalities
- Prematurity: with a GA <33 weeks
- Other chronic conditions likely to result in severe RSV disease (such as chronic liver disease or organ malformations)

For children undergoing cardiac surgery with cardiopulmonary bypass or extracorporeal membrane oxygenation or plasmapheresis, an additional dose of Nirsevimab is recommended as soon as the child is stable to ensure adequate Nirsevimab serum levels (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf and Fachinformation Beyfortus® (swissmedicinfo.ch)

Nirsevimab is contra-indicated in case of a history of serious allergic reactions to Nirsevimab or any of the ingredients in Beyfortus®.

Nirsevimab should not be administered during the same season in which the eligible patient has already experienced an RSV infection unless there is a risk of loss of humoral immunity (cardiopulmonary bypass or extracorporeal membrane oxygenation or plasmapheresis).

In situations with **limited Nirsevimab supply**, Nirsevimab should be **prioritized** to the high-risk patient groups described above during their 1st and 2nd RSV season and to healthy children born between October and March with an increased risk of RSV-related hospitalization.

5. Nirsevimab for infants born from RSV-vaccinated mothers

Vaccination of pregnant women offers high protection against medically attended severe LRTI during the first months of life (*Kampman 2023*).

Infants born during the RSV season, whose mothers had received Abrysvo® during pregnancy, will generally be considered adequately protected. The administration of Nirsevimab should therefore be considered only in very specific situations where there is a risk of inefficient transplacental transfer of antibodies (Abrysvo® administered less than 14 days prior to birth, birth at GA <37 weeks, maternal immunosuppression including HIV infections with unsuppressed viral load), a risk of loss of humoral immunity (after cardiopulmonary bypass or extracorporeal membrane oxygenation or plasmapheresis) or a co-morbidity conferring a risk of life-threatening RSV disease as determined by the attending specialist physician.

The FOPH/Federal Commission for Immunization will release a global recommendation for preventing RSV infections in infants, which will encompass the vaccination of pregnant women (Abrysvo®) and the immunization of infants with Nirsevimab (Beyfortus®).

7. Literature:

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