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To the Minister of Health, Welfare and Sport
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2025020635

Date 5 September 2025
Subject GVS advisory report on nirsevimab (Beyfortus®) for children with an increased risk of illness caused by the RS virus

National Health Care Institute

Research, Development and Medicinal Products
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Our reference

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Dear Mr Bruijn,

The National Health Care Institute is hereby advising you about including nirsevimab (Beyfortus®) in the Medicine Reimbursement System (hereinafter also "GVS") for children at an increased risk of illness caused by the RS (respiratory syncytial) virus. This advice was prompted by the request from your predecessor in the letter of 15 July 2025 (CIBG-25-08443). The National Health Care Institute advises you to include nirsevimab (Beyfortus®) for the preventive treatment for children aged up to 24 months who remain vulnerable to severe RSV disease during their second RSV season on List 1A of the GVS, in a new cluster to be created with palivizumab.

RS virus is the most common cold virus in children, occurring mainly in the winter months from November to March. This period is also referred to as the "RSV season". Infection usually causes mild symptoms but can lead to severe respiratory tract infections such as bronchiolitis or pneumonia in high-risk groups. Very young children and certain groups of children with pre-existing medical conditions have a higher risk of developing severe illness from infection with the RS virus. As a result, hospital admission may be required.

Nirsevimab is a monoclonal antibody (immunoglobulin) administered by intramuscular injection. This injection against the RS virus can be used in children aged younger than 2 years. For all children younger than 6 months, nirsevimab is already offered through the Dutch National Immunisation Programme. For proper protection against the RS virus, they should receive nirsevimab in the autumn, before the start of the RSV season.

Licensed indication(s)

Nirsevimab (Beyfortus®) is indicated for the prevention of lower respiratory tract conditions caused by respiratory syncytial virus (RSV) 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.

Claim by the marketing authorisation holder

Nirsevimab (Beyfortus®) has a therapeutic effect comparable to palivizumab (Synagis®) for preventing lower respiratory tract conditions caused by RSV in children up to 24 months of age who remain vulnerable to severe RSV disease during their second RSV season.

The marketing authorisation holder requests the inclusion in List 1A of the Healthcare Insurance Regulation for the indication claimed.

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Advice

The National Health Care Institute advises you to include nirsevimab (Beyfortus®) on List 1A of the GVS as a preventive treatment for children aged up to 24 months who remain vulnerable to severe RSV disease during their second RSV season, in a new cluster to be created with palivizumab.

The standard dose of nirsevimab has been set at 0.55 mg.
The standard dose of palivizumab has been set at 2.3 mg.

In addition, we advise you to place nirsevimab (Beyfortus®) on List 2 of the GVS with the same additional conditions as palivizumab:

Conditions for nirsevimab:

only for an insured person who:

1. is younger than one year old and has bronchopulmonary dysplasia; or
2. is younger than one year old and has a severe immunodeficiency; or
3. is younger than one year old and has severe pulmonary pathology resulting from cystic fibrosis; or
4. is younger than two years and has a congenital heart defect that is haemodynamically significant; or
5. is younger than two years old and requires oxygen therapy for the treatment of bronchopulmonary dysplasia, or
6. is younger than two years old and has Down's syndrome.

We explain this recommendation in more detail below.

Substantive assessment

Assessment of interchangeability

Based on the criteria for interchangeability, the National Health Care Institute has concluded that nirsevimab is interchangeable with palivizumab, which is currently included in List 1B of the GVS.

Therapeutic value

The National Health Care Institute has concluded that nirsevimab has a therapeutic effect comparable to the standard treatment with palivizumab for preventive treatment of children aged up to 24 months who remain vulnerable to severe RSV disease during their second RSV season.

The efficacy of nirsevimab has been demonstrated in a placebo-controlled trial and is comparable to that of palivizumab. In addition, nirsevimab was directly

compared against palivizumab in the MEDLEY study; comparable efficacy was also observed there.

The clinical trials conducted with nirsevimab did not include all the high-risk groups for which nirsevimab is indicated. It is highly probable that the efficacy of nirsevimab is also comparable to that of palivizumab in the other high-risk groups (younger than 1 year with severe immune deficiencies or younger than 1 year with cystic fibrosis).

The MEDLEY study also examined the safety of nirsevimab compared against palivizumab. This showed that the adverse effects of nirsevimab are similar to those of palivizumab.

The preventive effect of nirsevimab is based on a single (one-time) injection; palivizumab has to be administered every month for 5 months.

The National Health Care Institute has concluded that nirsevimab complies with established medical science and medical practice and thus has a therapeutic effect comparable to treatment with palivizumab for preventive treatment of children aged up to 24 months who remain vulnerable to severe RSV disease during their second RSV season.

Should you need any further information, please do not hesitate to contact us. The assessment reports have been added as appendices (assessment of interchangeability and pharmacotherapeutic report).

Yours sincerely,

M.J. Janssen
Chair of the Executive Board

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Institute**
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