Zorginstituut Nederland

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To the Minister of Health, Welfare and Sport
P.O. Box 20350
2500 EJ THE HAGUE

Date 26 March 2025
Re: GVS advice RSVPreF3 (Arexvy®) for the prevention of hospitalisations due to respiratory syncytial virus (RSV) respiratory tract infections in high-risk adults aged ≥ 60 years

Dear Ms Agema,

In the letter of 27 February 2024 (CIBG-24-06660), your predecessor requested the National Health Care Institute to carry out a substantive review to determine whether the RSVPreF3 vaccine (Arexvy®) can be included in List 1B of the Health Insurance Regulation for active immunisation for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in high-risk adults aged ≥ 60 years.

The National Health Care Institute has already completed this review, advised by its Scientific Advisory Board (WAR). The focus was on the effectiveness of the RSVPref3 vaccine in preventing hospitalisation.

RSV causes respiratory tract infections. It is particularly common in the winter months in the Netherlands. Almost all children experience RSV infection before their second birthday, sometimes resulting in hospitalisation. The Health Council of the Netherlands has advised that all children in their first year should be protected against RSV through the National Immunisation Programme. Adults aged ≥ 60 years are also generally at increased risk of severe RSV infections, especially if they have heart or lung disease. It is estimated that 1 to 2 in 1000 elderly patients end up in hospital each year due to RSV infection, with a mortality rate of 7.1%. RSV is a frequent cause of outbreaks among the elderly in nursing homes worldwide.

Registered indication
RSVPreF3 is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged 60 years and older, and in adults aged 50 through 59 years who are at increased risk for RSV disease.

Claim by the marketing authorisation holder:
The marketing authorisation holder claims that RSVPreF3 has added value in indicated patients at an increased risk of severe RSV infection compared to current practice where patients are not vaccinated.

The marketing authorisation holder is requesting reimbursement for the following patients:
"Adults aged 60 years and older with at least one relevant co-morbidity, consisting of: chronic obstructive pulmonary disease (COPD), asthma, chronic respiratory/lung disease, type 1 or 2 diabetes mellitus, chronic heart failure or advanced liver or kidney disease."

Advice
The National Health Care Institute recommends that the RSVPreF3 vaccine is not included in the Medicine Reimbursement System (GVS) for active immunisation for the prevention of lower respiratory tract disease caused by RSV in adults aged ≥ 60 years with at least one relevant co-morbidity, consisting of: chronic obstructive pulmonary disease (COPD), asthma, chronic respiratory/respiratory disease, type 1 or type 2 diabetes mellitus, chronic heart failure or advanced liver disease.

The considerations for this advice are explained below.

Substantive assessment
RSVPreF3 was studied in a randomised study (RCT; AResVi-006), comparing it to placebo in adult patients aged ≥ 60 years. Approximately 40% of them were at increased risk due to relevant co-morbidity. A total of ~12,500 participants were treated with RSVPreF3 and the same number with placebo. The effectiveness of RSVPreF3 in preventing hospitalisation due to respiratory disease was a secondary outcome parameter. Consequently, the results on this outcome parameter have not been specifically analysed for participants at increased risk due to relevant co-morbidity. These observations do not allow a scientifically valid and reliable assessment of the clinical relevance of the effect of RSVPreF3 vaccination on the prevention of hospitalisation in adults aged ≥ 60 years with relevant co-morbidity.

The results of a recent US observational study of the effect of active immunisation with an RSV vaccine[1] on the number of RSV-related hospitalisations in ~37,000 adults aged ≥ 60 years suggest that the risk of hospitalisation is lower if a patient has had an RSV vaccination. No data has been published on vaccine effectiveness in preventing RSV-related hospitalisations in patients aged ≥ 60 years at (demonstrated) increased risk. The same applies to data on quality of life. Since this study was carried out in the United States, it is uncertain whether the results can be generically applied to the Dutch population. As the participants in this study were not randomised, the results cannot be corrected for variables or circumstances that could affect them unless specifically taken into account at the start of the study. This study did not correct, for example, for the background, physical condition and willingness of individuals to (not) be vaccinated. According to the National Health Care Institute, supported by its Scientific Advisory Board (WAR), the results of the study in this context do not constitute adequate

[1] Namely RSVPreF3 (Arexvy®) or RSVPreF (Abrysvo®)

National Health Care Institute

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Our reference
2025005677

scientific evidence for the effectiveness of RSVPref3 in preventing hospitalisations in Dutch adults aged ≥60 years with at least one relevant co-morbidity.
Finally, the National Health Care Institute, supported by WAR, is of the opinion that a randomised clinical study of the effectiveness of RSVPreF3 in preventing RSV-related hospitalisations in the patient population for which reimbursement is requested, would be (or would have been) feasible and more appropriate.

In summary, based on a GRADE assessment, the scientific evidence presented is not of sufficient quality to demonstrate added value for RSVPreF3 compared to no vaccination in preventing hospitalisation in adults aged ≥ 60 years with at least one relevant co-morbidity. Thus, RSVPreF3 does not meet the established medical science and medical practice.

Should you need any further information, please do not hesitate to contact us.
The pharmacotherapeutic report is attached.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board