



To the State Secretary for Youth, Prevention and Sport

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Health Council Reference: 3790159/4084151/JVDB/ym/066

Annexes: -

Subject: Joint note of the National Health Care Institute and the Health Council on RSV vaccination advice for the elderly

Dear State Secretary,

In March 2024, your predecessor asked the Health Council and the National Health Care Institute for advice on respiratory syncytial virus (RSV) vaccination. Today, you receive the advice of the National Health Care Institute and this joint note on the advice of the Health Council (published on 27 March) and that of the National Health Care Institute.

The Health Council advises on programme-based respiratory syncytial virus (RSV) vaccination for the elderly. The National Health Care Institute advises on the inclusion of the RSV vaccine Arexvy® for high-risk groups in the Medicine Reimbursement System. In this note, the Health Council and the National Health Care Institute briefly discuss the content of their advisory reports and the underlying coherence.

Health Council advice

The Health Council concludes that the burden of disease of RSV infections in the elderly and high-risk groups warrants the consideration of vaccination, that the available vaccines are effective and safe, and that vaccination is acceptable. On this basis, the committee recommends a programme-based offering of RSV vaccination for people aged 75 years and older, and high-risk groups and residents of long-term care institutions aged 60 to 75 years. However, there is currently uncertainty about the duration of the period of protection provided by the vaccination. The effectiveness decreases after several years, so vaccination may need to be repeated after a few years. The committee considers that the introduction of a programme-based vaccine provision should provide sufficient clarity as to the expected period of protection and the timing of any repeat vaccinations. The committee also notes that the cost-effectiveness ratio of vaccination for people aged 75 and older is well above the reference value for preventive interventions. The committee considers that the current high cost-effectiveness ratio is not appropriate for a programme-based vaccine provision. The cost-effectiveness ratio of vaccination for high-risk groups is unknown, but is unlikely to be close to the reference value for preventive interventions.

National Health Care Institute advice

The National Health Care Institute advises to not include the RSV vaccine Arexvy® in the Medicine Reimbursement System (GVS) for active immunisation for the prevention of lower respiratory tract disorders caused by the RSV in adults aged 60 years and older with at least

one relevant co-morbidity, consisting of: chronic obstructive pulmonary disease (COPD), asthma, chronic respiratory/pulmonary disease, type 1 or type 2 diabetes mellitus, chronic heart failure or advanced liver or kidney disease. There is not sufficient scientific evidence for the effectiveness of Arexvy® in preventing hospitalisation in this high-risk group. Arexvy® does not meet the established medical science and medical practice.

Consistency between advisory reports

Both organisations have approached the subject from their own competences and expertise. The Health Council takes stock of the established medical science about vaccinations and advises on an optimal vaccination strategy at the population level. The National Health Care Institute advises on the inclusion of specific vaccines in the Medicine Reimbursement System in case of indicated prevention. Both organisations state that high-risk groups aged 60 years and older have an increased risk of severe disease due to RSV infection. In addition, both organisations conclude that the protection period of the vaccination is unknown.

Based on the current data on the effectiveness and efficacy of Arexvy® for severe illness/hospitalisation, the National Health Care Institute states that there is insufficient evidence to consider the inclusion of Arexvy® in the health insurance package. In a published, randomised study, Arexvy® was compared with placebo in adult patients aged 60 years and older. Of these, 40% had an increased risk due to relevant co-morbidity. However, the results on the prevention of hospitalisations due to respiratory tract disorder have not been analysed for this patient subgroup. As a result, there is no scientifically valid assessment of the clinical relevance of the effect of Arexvy® on these patients. Similarly, the US observational study of the effect of active immunisation with an RSV vaccine, published at the end of 2024, on, among other things, the number of RSV-related hospitalisations in adults aged 60 years and over, is inadequate. Also, no data on vaccine effectiveness in preventing RSV-related hospitalisations in patients aged 60 years and older with demonstrated increased risks have been published in this study. Moreover, since this study was carried out in the United States, it is uncertain whether the results can be applied to the Dutch population. The National Health Care Institute is of the opinion that a randomized controlled trial is desirable and feasible to determine the effectiveness of Arexvy® to prevent hospitalisation, specifically in high-risk groups.

The Health Council has based its assessment on a broader burden of proof on both the burden of disease and the efficacy and effectiveness for a total of three different RSV vaccines. Based on the criteria set out in the vaccination evaluation framework, it is concluded that programme-based vaccination is indicated for people aged 75 years and older, people aged 60 to 75 years who belong to a high-risk group, and residents of long-term care institutions aged 60 to 75 years. For the introduction of a programme-based vaccine provision, the Health Council is of the opinion that there should be sufficient clarity about the expected period of protection and the timing of any repeat vaccinations.

In summary, both organisations consider that the data on effectiveness are currently insufficient to offer programme-based vaccination or to reimburse on an individual indication basis. The Health Council believes that a programme-based vaccine provision may be appropriate if there is sufficient clarity about the expected period of protection and the timing of any repeat vaccinations. The National Health Care Institute may reassess any resubmission based on new data on the efficacy and effectiveness of Arexvy® to prevent hospitalisation in specific high-risk groups.

Please do not hesitate to contact us should you have any further questions.

Yours sincerely,

M.J. Janssen
Chairman Executive Board
of the National Health Care Institute

prof. Dr K. Stronks
Chairman of the Health Council