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To the Minister for Medical Care and Sport
PO Box 20350
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2019059737

Date 16 December 2019
Subject A four-component meningococcal B vaccine (Bexsero®) for the active immunisation of patients with complement deficiency or hyposplenias/asplenia (functional) against invasive meningococcal disease caused by *Neisseria meningitidis* group B

National Health Care Institute

Care II
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Our reference
2019059737

Dear Mr Bruins,

In your letter of 11 November 2019 (CIBG-19-09084), you asked the National Health Care Institute to assess whether the four-component meningococcal B vaccine (4CMenB; Bexsero®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed its substantive assessment. The considerations involved are included in the Medicine Reimbursement System report which, together with the pharmaco-therapeutic report and the budget impact analysis, is attached to this letter.

Bexsero® is indicated for the active immunisation of patients aged two months and above against invasive meningococcal disease caused by *Neisseria meningitidis* group B.

The manufacturer has requested inclusion in List 1B for the active immunisation of patients with complement deficiency (congenital or acquired through use of the medicinal product eculizumab) or hyposplenias/asplenia (functional) against invasive meningococcal disease caused by *N. meningitidis* group B.

Preceding current assessment

In 2018, at the request of the State Secretary of Health, Welfare and Sport, the National Health Care Institute assessed the effectiveness and cost-effectiveness of Bexsero® for vaccination of the general population against invasive meningococcal disease caused by *Neisseria meningitidis* group B. This assessment took place in coordination with the Health Council of the Netherlands, for the purposes of this vaccine's inclusion in the National Immunisation Programme. The Health Council recommended that 4CMenB (Bexsero®) should not be included in the National Immunisation Programme.¹ As this concerned a reimbursement application for vaccination of the general population, the National Health Care Institute was unable to issue a ruling concerning the inclusion of Bexsero® in the Medicine Reimbursement System. Vaccines are only eligible for reimbursement from the Medicine Reimbursement System in cases of indicated prevention, i.e.

¹ Health Council. Vaccination against meningococci. 2018.

the vaccination of individual patients who run an increased risk of infection.² Accordingly, in 2018, the National Health Care Institute conducted an exploratory analysis to investigate the case for indicated prevention. Two high-risk groups were found to have a higher risk of invasive meningococcal disease with a severe course than the general population. These were patients with complement deficiency (congenital or acquired through the use of the medicinal product eculizumab) or those with hyposplenias/asplenia (functional). The National Health Care Institute advised the State Secretary to consider reimbursing these high-risk groups for the necessary vaccines (including Bexsero®) via the Medicine Reimbursement System. It also indicated that it would like to receive a specific request for inclusion in the Dutch insured package.³ This application has now been submitted.

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The outcome of the assessment

Assessment of interchangeability

None of the medicinal products included in the Medicine Reimbursement System are interchangeable with 4CMenB (Bexsero®). Based on this criterion, 4CMenB (Bexsero®) cannot be placed on List IA. The National Health Care Institute then assessed whether 4CMenB (Bexsero®) is eligible for inclusion on List 1B. In this matter, it was advised by the Scientific Advisory Board (WAR).

Therapeutic value

The National Health Care Institute has concluded that the 4CMenB vaccine for the active immunisation of patients with complement deficiency or hyposplenias/asplenia (functional) against invasive meningococcal disease caused by *Neisseria meningitidis* group B has added value compared to non-vaccination.

Budget impact analysis

Taking into account the various assumptions with regard to patient numbers, market penetration, etc., the inclusion of 4CMenB (Bexsero®) on List 1B of the Medicine Reimbursement System for the assessed indication will be associated with additional costs of €580,000 to €920,000, charged to the pharmaceutical budget. In the maximum scenario it will take three years to vaccinate the entire prevalent population, thereafter only incidental patients will need to be vaccinated on an annual basis.

The costs of vaccinating incidental patients alone are associated with annual additional costs of €244,000 up to a maximum of €271,000, charged to the pharmaceutical budget.

There is uncertainty about the patient numbers involved, and about the likelihood of prevalent patients being vaccinated.

Cost-effectiveness

In view of the budget impact of €580,000 to €920,000, exemption from pharmaco-economic analysis has been granted.

Advice concerning inclusion in the Medicine Reimbursement System

The National Health Care Institute recommends that 4CMenB (Bexsero®) for the active immunisation of patients with complement deficiency (congenital or acquired through use of the medicinal product eculizumab) or hyposplenias/asplenia (functional) against invasive meningococcal disease caused by *Neisseria meningitidis* group B be included in List 1B and List 2 of the Health Insurance Regulation and that the conditions stated below be imposed. Inclusion in List 1B will lead to additional costs.

² National Health Care Institute. Prevention guaranteed. 2007.

³ National Health Care Institute. The National Health Care Institute's opinion on the effectiveness (cost effectiveness) of meningococcal vaccines. 2018.

Condition for four-component meningococcal B vaccine (Bexsero®)

Insured individuals aged two months and above with:

- 1 a congenital complement deficiency;
- 2 an indication for use of the medicinal product eculizumab.
- 3 hyposplenias/asplenia (functional), who run a high risk of invasive meningococcal disease.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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