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Minister of Medical Care and Sports  
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2020000267

Date 27 January 2020  
Subject Bevespi® aerosphere 7.2 micrograms / 5 micrograms

**National Health Care  
Institute**

Care II  
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Dear Mr Bruins,

In your letter of 6 January 2020 (CIBG-20-09329), you asked National Health Care Institute to assess whether the product Bevespi® aerosphere 7.2 micrograms / 5 micrograms, a dose aerosol combination preparation, can be included in the medicine reimbursement system (GVS).

Bevespi® is a combination preparation with two active ingredients: the long-acting parasympathomimetic glycopyrronium and the long-acting  $\beta$ 2-sympathicomimetic formoterol.

Bevespi® is registered as a bronchodilating maintenance treatment to relieve symptoms of chronic obstructive pulmonary disease (COPD) in adults.

The dosage of Bevespi® is two inhalations twice a day. Each delivered dose (the dose leaving the mouthpiece) contains 9 micrograms of glycopyrronium bromide (corresponding to 7.2 micrograms of glycopyrronium) and 5 micrograms of formoterol fumarate dihydrate.

The active ingredient glycopyrronium (as bromide) is included in the GVS as a capsule for inhalation powder with a dose of 44 micrograms (Seebri® and Tovanor®), but not as an aerosol. Formoterol fumarate dihydrate (Atimos®) as an aerosol 12 microgs (with a dose of 10.1 microgs) is already included in the GVS.

Bevespi® is eligible for inclusion in the GVS as an alternative, in the form of a fixed dual combination, if the patient is dependent on the use of a long-acting parasympathomimetic (glycopyrronium) and long-acting  $\beta$ 2-sympathicomimetic (formoterol).

Because the active ingredients of Bevespi® have already been approved for inclusion in the GVS, a marginal test will be sufficient.

Based on the proposed pharmacy purchasing price (AIP) of €46.14 per pack (120 inhalation doses/pack), the price is €0.38 per dose and €1.54 (46.14/120\*4) per day. The daily price of the combined use of the separate components is €1.97

(€1.21 per day (Seebri® and Tovanor®) and €0.76 per day for Atimos®). The daily price of glycopyrronium as an aerosol was based on the price of a daily dose of glycopyrronium as an inhalation powder. The proposed price of Bevespi® as a dual combination therapy is therefore lower than the price of the sum of the individual components.

In conclusion, we advise you to include Bevespi® in List 1B of the GVS on technical grounds.

Yours sincerely,

Sjaak Wijma  
*Chair of the Executive Board*

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