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To the Minister of Medical Care and Sports  
PO Box 20350  
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2021002191

Date 22 February 2021  
Subject GVS review Trixeo® aerosphere

**National Health Care  
Institute**

Care II  
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2021002191

Dear Ms van Ark,

In your letter of 9 February 2021 (CIBG-21-01418), you asked National Health Care Institute to assess whether the product formoterol/glycopyrronium/budesonide (Trixeo® aerosphere), a dose aerosol combination preparation, can be included in the medicine reimbursement system (GVS).

Trixeo® is a combination preparation with three active ingredients: formoterol fumarate dihydrate, a long-acting  $\beta_2$  agonist; glycopyrronium bromide, a long-acting muscarine antagonist and budesonide, an inhalational corticosteroid.

Trixeo® Aerosphere is registered for the maintenance treatment of adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) that cannot be adequately treated by a combination of an inhaled corticosteroid and a long-acting  $\beta_2$  agonist, or a combination of a long-acting  $\beta_2$  agonist and a long-acting muscarine antagonist.

The dosage of Trixeo® is two inhalations twice daily. Each delivered dose (the dose leaving the mouthpiece) contains 5 micrograms of formoterol fumarate dihydrate, 9 micrograms of glycopyrronium bromide (equivalent to 7.2 micrograms of glycopyrronium) and 160 micrograms of budesonide.

The combination aerosol of glycopyrronium bromide and formoterol fumarate dihydrate has already been included as a fixed dual combination in the GVS (Bevespi®), with a dose corresponding to that of Trixeo® (7.2 micrograms / 5 micrograms) already included in the GVS. Budesonide as an aerosol 200 micrograms (generic) is also already included in the GVS.

Trixeo® is eligible for inclusion in the GVS as an alternative, in the form of a fixed triple combination, if the patient is dependent on the use of a long-acting  $\beta_2$  agonist (formoterol), a long-acting muscarine antagonist (glycopyrronium), and an inhalation corticosteroid (budesonide) in this dosage ratio.

Based on the proposed pharmacy purchasing price (AIP) of €56.00 per pack (120 inhalation doses/pack), the price is €0.47 per dose and €1.87 (€56.00/120\*4) per

day. The daily price of the combined use of the combination aerosol Bevespi® (€1.54 per day) and the individual component budesonide (€0.33 per day) is €1.87 euro. The proposed price of Trixeo® as triple combination therapy is thus equal to the price of the dual combination therapy Bevespi® in combination with budesonide as an individual component.

In conclusion, the National Health Care Institute advises you to include Trixeo® Aerosphere in List 1B of the GVS on technical grounds.

Yours sincerely,

Sjaak Wijma  
*Chair of the Executive Board*

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