

Zorginstituut Nederland

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Date 24 September 2020
Subject Aectura® Breezhaler® (indacaterol acetate/mometasone furoate)

Our reference
2020029761

Dear Ms van Ark,

In your letter of 14 July 2020 (CIBG-20-0673), you asked Zorginstituut Nederland to assess whether the product indacaterol acetate/mometasone furoate (Aectura® Breezhaler®) can be included in the medicine reimbursement system (GVS).

Aectura® Breezhaler® is a combination preparation with two active ingredients: indacaterol as acetate, a long-acting beta 2-adrenergic agonist, and mometasone furoate, a synthetic corticosteroid.

Aectura® Breezhaler® is registered as a maintenance treatment for asthma in adults and adolescents 12 years and older whose condition is not sufficiently controlled by inhalation corticosteroids and inhaled short-acting beta 2 agonists.

The dosage of Aectura® Breezhaler® is one inhalation capsule to be inhaled once daily. The dosage in the capsules contains 150 micrograms of indacaterol (as acetate), combined with 80, 160 or 320 micrograms of mometasone furoate. Each dose delivered contains 125 micrograms of indacaterol (as acetate) in combination with 62.5, 127.5 or 260 micrograms of mometasone furoate, respectively.

Indacaterol has already been included in cluster 0R03ACCIDC of the GVS as an inhalation powder administered through a Breezhaler® under the brand names Onbrez® and Hirobriz®. Chronic obstructive pulmonary disease (COPD) can be considered as the main indication of this cluster. The dose of indacaterol in Hirobriz® and Onbrez® is 150 micrograms of indacaterol as maleate, which corresponds to a delivered dose of indacaterol of 120 micrograms. The delivered dose of indacaterol in Aectura® Breezhaler® is therefore 5 micrograms higher compared to Hirobriz® and Onbrez®.

In 2011, the Dutch Health Care Insurance Board (CVZ) decided that mometasone furoate can be included as inhalation powder in the 0R03BAD1D cluster of the GVS with a standard dose of 400 micrograms. Asthma can be considered as the main indication of this cluster. After this assessment, mometasone as inhalation powder was not marketed in this form and is therefore not currently included in the GVS.

Atecura® Breezhaler® is eligible for inclusion in the GVS as an alternative, in the form of a fixed combination, if the patient is dependent on the use of a long-acting beta2-adrenergic agonist (indacaterol) and synthetic corticosteroid (mometasone) in this dosage ratio.

Because the active ingredients of Atecura® Breezhaler® have already been approved for inclusion in the GVS, a marginal test will suffice.

The proposed pharmacy purchase price (AIP) of Atecura® Breezhaler® is €0.88 per daily dosage.

The price per single component is €1.03 for indacaterol per day for a dose of 150 micrograms and the cluster limit for mometasone furoate for a delivered dose of 400 micrograms is €0.71 per day. This corresponds to a price equal to €0.14 for a dose of 80 micrograms, €0.29 for 160 micrograms, and €0.57 for 320 micrograms.

The proposed price of Atecura® Breezhaler® as a combination therapy is therefore lower than the price of the sum of the individual components.

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

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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