

Zorginstituut Nederland

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To the Minister of Medical Care and Sports
PO Box 20350
2500 EJ Den Haag

2020037637

Date 24 September 2020
Subject Enerzair® Breezhaler® (indacaterol/glycopyrronium/mometasone)

National Health Care Institute

Care II
Cardiovascular & Pulmonary

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Our reference

2020037637

Dear Ms van Ark,

In your letter of 7 September 2020 (CIBG-20-0910), you asked Zorginstituut Nederland to assess whether the product indacaterol acetate/glycopyrronium/mometasone furoate (Enerzair® Breezhaler®) can be included in the Medicine Reimbursement System (GVS).

Enerzair® Breezhaler® is a combination preparation with three active ingredients:

indacaterol as acetate, a long-acting beta2-adrenergic agonist; glycopyrronium bromide, a long-acting muscarine receptor agonist; and mometasone furoate, a synthetic corticosteroid.

Enerzair® Breezhaler® is registered for as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.

The dosage of Enerzair® Breezhaler® is one inhalation capsule to be inhaled once daily. The dosage in the capsules contains 150 micrograms of indacaterol (as acetate), combined with 63 micrograms of glycopyrronium bromide, which corresponds to 50 micrograms of glycopyrronium and 160 micrograms of mometasone furoate. Each dose delivered contains 114 micrograms of indacaterol, 58 micrograms of glycopyrronium bromide, which corresponds to 46 micrograms of glycopyrronium and 136 micrograms of mometasone furoate.

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 Enerzair® Breezhaler® is therefore 6 micrograms lower compared to Hirobriz® and Onbrez®.

Glycopyrronium has already been included in cluster 0R03BBCID V of the GVS as an inhalation powder administered through a Breezhaler® under the brand names Seebri® and Tovanor®. COPD can be considered as the main indication of this

cluster. The dose of glycopyrronium in Seebri® and Tovanor® is 50 micrograms of glycopyrronium as bromide, which corresponds to a delivered dose of glycopyrronium of 44 micrograms. The delivered dose of glycopyrronium in Enerzair® Breezhaler® is therefore 2 micrograms higher compared to Seebri® and Tovanor®.

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In 2011, the predecessor of the Zorginstituut, 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 as inhalation powder.

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

The proposed pharmacy purchase price (AIP) of Enerzair® Breezhaler® is €1.95 per daily dosage.

The price per single component is €1.03 for indacaterol per day for a dose of 150 micrograms, €1.11 for glycopyrronium for a delivered dose of 44 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 of €0.29 for a dose of 160 micrograms.

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

In conclusion, the Zorginstituut advises to include Enerzair® Breezhaler® in List 1B of the GVS on technical grounds.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board