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Our reference
2020018327

Date 28 April 2020
Subject GVS assessment of 12 SQ-HDM SLIT (Itulazax®)

Dear Mr van Rijn,

In your letter of 9 March 2020 (CIBG-20-0120), you requested Zorginstituut Nederland to assess whether Itulazax® is interchangeable with any other product that is included in the medication reimbursement system (GVS). The Zorginstituut, advised by the Scientific Advisory Board (WAR), has completed this assessment. The considerations are included in the GVS report attached to this letter.

Itulazax® (12 SQ-HDM SLIT) is indicated for use in adult patients for the treatment of moderate to severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. At indication, the patient has a clinical history of symptoms, despite the use of symptom-relieving medication, and tests positive for sensitivity to a member of the birch homologous group (skin prick test and/or specific IgE test).

Itulazax® is available as a melting tablet (sublingual tablet; lyophilisate). Each melting tablet contains 12 SQ-Bet* per lyophilisate standardised allergen extract of birch pollen (Betula verrucosa). The recommended adult dose (18-65 years) is one lyophilisate for oral use daily.

Review of interchangeability
The GVS already includes three medicinal products for the treatment of moderate to severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. These are allergen extracts of birch pollen intended for subcutaneous immunotherapy: Alutard SQ® Berkpollen, Alutard SQ® 3 Boompollen and Pollinex® Boompollen. In 2008, the Health Care Insurance Board (CVZ) established that Alutard® and Pollinex® could be considered interchangeable (CFH report 08/21).
Based on the current criteria, Itulazax® is not interchangeable with Alutard® or Pollinex® due to a difference in the route of administration.

Based on the above, Itulazax® cannot be placed on List 1A. It should be reviewed whether Itulazax® is eligible for inclusion on List 1B.

Therapeutic value

* SQ-Bet is the dose unit for Itulazax®. SQ is a standardisation method for the biological strength, amount of major allergen and complexity of allergen extract. *Bet is an abbreviation for Betula

Zorginstituut Nederland has concluded that Itulazax® has an equal therapeutic value compared to subcutaneous allergen extracts of birch pollen (Alutard® and Pollinex®) for the treatment of moderate to severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group in adult patients.
The price of Itulazax® is equal to the price of the other available subcutaneous medicines.

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Pharmaco-economic analysis
Based on the estimated budget impact, the product is exempt from pharmaco-economic analysis.

Advice
Itulazax® is not interchangeable with any product in the GVS. When a substance is not interchangeable and has an equal therapeutic value, the substance can be placed on List 1B only if there are no additional costs. Because the price of Itulazax® is equal to the price of the subcutaneous medicinal products currently used in these patients (e.g. Alutard®) and complete substitution does not lead to additional costs, the Zorginstituut advises to include the sublingual standardised allergen extract of tree pollen (Itulazax®; SLIT) on List 1B.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board