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National Health Care Institute
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2023015538

Date 28 April 2023
Subject Medicine Reimbursement System advice lanadelumab (Takhzyro®)

Our reference
2023015538

Dear Mr Kuipers,

In your letter of 2 January 2023 (reference CIBG-23-04902), you asked the National Health Care Institute to assess the inclusion of the medicinal product lanadelumab (Takhzyro®) in the Medicine Reimbursement System (GVS). That assessment has now been completed. Please find the results in the attached GVS report and budget impact analysis.

Lanadelumab is available as a solution for injection. One vial for injection contains 300 mg lanadelumab per 2 ml solution. It is licensed for the routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older. The recommended starting dose is 300 mg subcutaneously every 2 weeks. Reducing the administration frequency to 300 mg every 4 weeks may be considered if no more seizures occur, especially where the body weight is low.

According to the marketing authorisation holder, lanadelumab is eligible for placement on List 1B of the GVS.

Review of interchangeability
Lanadelumab is not interchangeable with the other medicinal products in the GVS that are used for the treatment of HAE and that have been placed in a cluster of interchangeable medicinal products. This is because the indication scope is not identical in that lanadelumab has not been studied in acute attacks of HAE, which is the main indication for the said cluster. As a result, it is not eligible for placement on List 1A of the GVS.

There was then a review of whether lanadelumab is eligible for inclusion on List 1B.

Therapeutic value
Based on a Cochrane systematic review, it was concluded that the beneficial effects in reducing the number of attacks and thus improving the quality of life, as well as the adverse effects of lanadelumab (Takhzyro®), are comparable to the C1 esterase inhibitors Berinert® and Cinryze® for the long-term prevention of HAE attacks. Based on that equivalent therapeutic value, lanadelumab meets the established medical science and medical practice.

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Budget impact analysis
Taking into account the substitution of Berinert® (SC) and Cinryze® due to the reimbursement of lanadelumab, including lanadelumab (Takhzyro®) on list 1B of the GVS will be accompanied by savings on the pharmaceutical budget of about €4 million. These savings are most likely overestimates due to uncertainty about therapy compliance and the number of treatments patients will receive/administer per year in daily practice. Additionally, the number of HAE patients is expected to increase further in the Netherlands.

Based on the estimated budget impact, the market authorisation holder received an exemption for the pharmacoeconomic analysis.

Advice
Based on the above considerations, we recommend that you include lanadelumab (Takhzyro®) on List 1B of the GVS.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board