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Date 03 December 2020
Subject GVS advice tafamidis (Vyndaqel®)

Our reference
2020048168

Dear Ms van Ark,

In your letter of 7 April 2020 (CIBG-20-0120), you requested Zorginstituut Nederland to assess whether tafamidis 61 mg free acid (Vyndaqel®) is interchangeable with another product that is included in the medication reimbursement system (GVS). The Zorginstituut, advised by the Scientific Advisory Board (WAR), has completed this assessment.

Tafamidis 61 mg free acid is indicated for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). It is available as a capsule and contains 61 mg of tafamidis (free acid). The recommended dosage is one capsule once a day, added to the standard treatment.

The Zorginstituut advises you not to include tafamidis 61 mg free acid (Vyndaqel®) in the GVS.

Review of interchangeability
To determine the placement of a medicinal product in the GVS, its interchangeability with medicinal products already included in the GVS must first be assessed.

The tafamidis capsule 61 mg (free acid) is registered under the same brand name as the tafamidis capsule 20 mg (Vyndaqel®). The tafamidis capsules 20 mg are already included in the GVS on List 1B. Vyndaqel® capsule 20 mg is registered for the treatment of transthyretin amyloidosis in adults with stage 1 symptomatic polyneuropathy, to delay peripheral neurologic impairment. The reimbursement of tafamidis capsule 20 mg is limited to the registered indication via List 2 of the Health Insurance Regulation. Tafamidis 20 mg is not registered for the treatment of cardiomyopathy. For the tafamidis capsules 61 mg (free acid), reimbursement is now requested for the use in case of cardiomyopathy.

On the basis of the above, tafamidis 61 mg free acid (Vyndaqel 61 mg®) cannot be placed on List 1A. It should be reviewed whether tafamidis (Vyndaqel® 61mg)

is eligible for inclusion on List 1B.

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Therapeutic value
The Zorginstituut has concluded that tafamidis 61 mg free acid has a therapeutic added value compared to placebo in the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM) and NYHA class I or II. The added value consists of a reduced risk of death and a better quality of life.
For patients with ATTR-CM who are maintaining NYHA class III despite optimal treatment with the standard therapy, the application of tafamidis meglumine 61 mg free acid per day has a lower value compared to placebo; the treatment with tafamidis is associated with a greater risk of cardiovascular-related hospitalizations.

Budget impact analysis
The total additional costs charged to the pharmaceutical budget are estimated at €172 to €421 million in the third year after inclusion in the package. There is no substitution within the pharmaceutical budget. Because it is not yet clear how the diagnostics for ATTR-CM will develop, the number of patients eligible for treatment with tafamidis is uncertain. Since ATTR-CM patients will, on average, live longer as a result of treatment with tafamidis, and more patients are likely to be treated due to improved diagnostics, it is expected that the number of patients will rise further in the future. As a result, the budget impact may increase in the future.

Pharmaco-economic analysis
The cost-effectiveness analysis provided by the market authorisation holder is of insufficient quality, despite the fact that the market authorisation holder has been given and has made use of the opportunity to improve it. In particular, the Zorginstituut has observed uncertainties about the validity and transparency of the pharmaco-economic analysis.
The Zorginstituut cannot provide a realistic estimate of cost-effectiveness, nor can it give you an indication of the price reduction required to get close to an acceptable cost-effectiveness.

Unfortunately, this means that the Zorginstituut cannot give advice on possible price negotiations you might conduct. This is essential for you and for the Zorginstituut, because reimbursement of tafamidis 61 mg free acid at the current asking price by the market authorisation holder leads to a very high budget impact.

The Zorginstituut therefore advises you not to include tafamidis 61 mg free acid (Vyndaqel®) in the GVS. The Zorginstituut remarks that it is aware that the outcome of the assessment by the Zorginstituut is disappointing for both patients and treating physicians. The Zorginstituut therefore invites the market authorisation holder to better substantiate the cost-effectiveness.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board