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Our reference
2022001532

Date 24 February 2022
Subject Medicine Reimbursement System advice vericiguat (Verquvo®)

Dear Mr Kuipers,

In your letter of 15 September 2021 (CIBG-21-02477), you asked the National Health Care Institute to assess whether the product vericiguat (Verquvo®) can be included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed the substantive assessment. The considerations are included in the pharmacotherapeutic report attached to this letter.

Vericiguat is indicated for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction that have stabilised after a recent episode of decompensation requiring intravenous treatment. The marketing authorisation holder is asking for vericiguat to be included in List 1B of the Health Insurance Regulation for the registered indication.

Outcome of the substantive assessment: no additional value
The effectiveness of vericiguat added to the standard treatment in the aforementioned patients was researched in one randomised comparative study (the VICTORIA study). In the Dutch situation, the desired place of vericiguat in the treatment plan is that the medicinal product must be given after triple therapy and an SGLT2 inhibitor. Since only a few patients used an SGLT2 inhibitor in the VICTORIA study, it is not possible to determine what the additional effect of vericiguat would be in the Dutch situation.

The results show that vericiguat has a statistically and clinically relevant effect on the compounded outcome measure 'reducing the risk of cardiovascular mortality or first hospitalisation for heart failure'. However, the effect shown in this composite outcome measure is mainly driven by a reduction in the number of hospitalisations for heart failure. Vericiguat has no statistically significant effect on cardiovascular mortality. Vericiguat also has no statistically significant effect on other outcome measures: the risk of death from any cause and the quality of life.

On the basis of all the above considerations, the National Health Care Institute has come to the final conclusion that vericiguat does not have any added value as an addition to the standard treatment for the registered indication.

Advice on inclusion in the Medicine Reimbursement System
Because no added value has been established for vericiguat added to the standard treatment for the registered indication, it does not meet the criterion of 'established medical science and medical practice'. For that reason, the National Health Care Institute advises that vericiguat should not be included in the Medicine Reimbursement System.

Future developments
The National Health Care Institute is of course prepared to reconsider the package eligibility of vericiguat if additional research data not previously assessed by the National Health Care Institute leads to scientific publications.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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24 February 2022

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