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To the Minister of Health, Welfare and Sport
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2026005966

**National Health Care
Institute**

Research, Development and
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Date 27 May 2026
Re: GVS advice fezolinetant (Veoza®) for vasomotor symptoms (VMS)
associated with menopause

Contact

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This is a rectification of the letter dated 18 March 2026 (reference 2026005966).
At the request of the NHG, the National Health Care Institute has nuanced the
description of the positioning of fezolinetant in this letter and in the PT report.

Our reference
2026005966

Dear Ms Hermans,

The National Health Care Institute advises you to include fezolinetant (Veoza®) in
the Medicine Reimbursement System (GVS) on List 1B for certain patients with
vasomotor symptoms (VMS) associated with menopause. This advice was
prompted by your request in the letter of 12 August 2025 (CIBG-25-08558). We
have explained below how we reached this advice.

Condition

Approximately 80% of women who go through menopause suffer from
menopausal symptoms. These symptoms are caused by a change in their
hormone levels. In 1 out of 3 women the symptoms are so severe that they affect
their daily lives. The menopause can cause various symptoms. Vasomotor
symptoms include symptoms such as hot flushes and night sweats. These are the
most common menopausal symptoms women experience. Currently, women with
menopausal symptoms are preferably treated with hormone replacement therapy.
However, there are women who cannot be treated with hormone replacement
therapy for various reasons, such as women who have previously had a hormone-
dependent tumour. They should preferably not be treated with hormones, as this
increases the risk of the tumour returning. If hormone replacement therapy is not
recommended, treatment with clonidine may be considered. However, many
women decline this treatment due to the adverse effects. The National Health
Care Institute estimates that about 7.5% of women who wish to be treated for
vasomotor symptoms associated with the menopause are not suitable for
hormone replacement therapy.

Registered indication

Fezolinetant is indicated for the treatment of moderate to severe vasomotor
symptoms (VMS) associated with menopause. The medicinal product is available
in 45 mg film-coated tablets taken once daily.

Claim by the marketing authorisation holder (MAH)

Fezolinetant has an added value compared to no active medical treatment for the

registered indication for patients who are unfit for hormone replacement therapy.

The marketing authorisation holder requests inclusion on List 1B of the Health Insurance Act for patients unfit for hormone replacement therapy due to a contraindication, warning or patients who have discontinued for medical reasons.

Advice

The National Health Care Institute advises you to include fezolinetant for the treatment of women with moderate to severe vasomotor symptoms associated with menopause and for whom hormone replacement is not suitable on List 1B of the GVS. Inclusion will create additional costs from the pharmaceutical budget estimated at €2.3 million in year 3.

In addition, we advise you to place fezolinetant on List 2 of the GVS with the following additional conditions:

Condition for fezolinetant

Only for an insured person with moderate to severe vasomotor symptoms (VMS) associated with menopause for whom hormone replacement therapy is unsuitable or for whom there is a contraindication to hormone replacement therapy.

Substantive assessment

Assessment of interchangeability

Based on the criteria for interchangeability, the National Health Care Institute concluded that fezolinetant is *not* interchangeable with other medicinal products included in the GVS. As a result, fezolinetant cannot be placed on List 1A. The National Health Care Institute has therefore assessed whether fezolinetant can be included on List 1B.

Therapeutic value

The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has concluded that fezolinetant has added value compared to best supportive care for patients who are unsuitable for treatment with hormone replacement therapy. Currently, these patients can also be treated with clonidine, but this medicinal product has many side effects and is not very effective. The reimbursement data shows that this is being prescribed less and less often and therefore, best supportive care was chosen as a comparative treatment in this assessment.

Based on the DAYLIGHT and SKYLIGHT studies, the National Health Care Institute concludes that the use of fezolinetant can reduce the number of hot flushes and improve sleep and quality of life in women with moderate to severe VMS who are unsuitable for hormone replacement treatment and considers this overall as one clinically relevant effect. However, the use increases the risk of severe adverse effects, including liver damage. In addition, the study results show that a proportion of the women do not experience any improvement. In practice, it is therefore important to schedule check-ups regularly after starting treatment with fezolinetant to individually assess whether the medicinal product is having the desired effect

Hormone replacement therapy remains the most effective treatment for women

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experiencing symptoms associated with menopause, according to the physicians' association. Hormone replacement therapy restores the decreasing hormone levels in the woman's body, affecting all menopausal symptoms. In contrast Fezolinetant only reduces VMS because it directly affects the brain's thermo-regulating centre. The physicians' association indicates that hormone replacement is more effective than fezolinetant, as can be seen in published meta-analyses. Providing less effective treatment is not cost-effective and therefore only women who cannot be treated with hormone replacement should be eligible for fezolinetant.

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The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has concluded that fezolinetant for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause in women for whom hormone replacement therapy is not suitable, meets the established medical science and medical practice and as such has added value compared to best supportive care.

Budget impact analysis

The Dutch physicians' associations indicate that 5 to 10% of women who want to be treated for their VMS are not eligible for hormone replacement therapy. The National Health Care Institute estimates that 4931 patients will be treated with fezolinetant for the above indication in year 3 after inclusion in the package. The total costs per person per year are €646. This results in macro costs of € 2.3 million in the third year if the calculations are based on 7.5% of the women who are ineligible for hormone replacement therapy. It may be that the treatment is used for a somewhat broader target group, because there is currently a lot of attention for menopausal symptoms and an increasing number of women decline hormonal treatment, or the assessment of the physicians' association was too low. Therefore, a 20% scenario was also calculated, which would result in macro costs of 6.2 million.

Cost-effectiveness

A limited impact on the macro costs is expected. On this basis, a pharmacoeconomic analysis is not considered relevant.

Appropriate care

Fezolinetant is less effective and more expensive than hormone replacement therapy. Therefore, it is not cost-effective to treat women who can be treated with hormone replacement therapy with fezolinetant. The Dutch Society for Obstetrics and Gynaecology (NVOG) has indicated that only women with a contraindication or women who for medical reasons have to stop hormone replacement therapy should be treated with fezolinetant. The Dutch College of General Practitioners (NHG) has not yet determined the positioning of fezolinetant in primary care. The National Health Care Institute therefore considers it appropriate that for now only gynaecologists prescribe this medicinal product. Health insurance companies may include this in their verification of compliance with List 2 conditions.

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

Annexes:

- Assessment of interchangeability
- Pharmacotherapeutic report
- Budget impact analysis

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