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Our reference
2022039995

Date 19 October 2022
Subject GVS advice relugolix + oestradiol + norethisteronacetate (Ryeqo®)

Dear Mr Kuipers,

In your letter of 2 August 2022, you asked the National Health Care Institute to assess whether Ryeqo® is interchangeable with a product already included in the health insurance package [Medicine Reimbursement System (GVS)]. If that was not the case, you asked to assess the therapeutic value for the indication for which reimbursement was requested. Finally, you requested that the cost per patient for the standard therapy and the new therapy be tested for this medicinal product, provided that the costs are covered by the extramural pharmacy budget. The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has recently completed the requested assessment. You will find the considerations and conclusions regarding your question in the enclosed GVS report.

The combination preparation *relugolix* + *oestradiol* + *norethisteronacetate* (Ryeqo®) is registered for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. It is available as a tablet. Each tablet contains 40 mg relugolix, 1 mg oestradiol, and 0.5 mg norethisteronacetate. The first tablet must be taken within 5 days of of the onset of menstrual bleeding to prevent irregular and/or heavy bleeding. Discontinuation should be considered when the patient enters menopause.

The market authorisation holder is asking for inclusion on List 1B of the Health Insurance Regulation (Rzv).

Interchangeability
In assessing whether Ryeqo® is interchangeable with medicinal products already included in the GVS, it has been established that this is not the case.

Therapeutic value
The National Health Care Institute has concluded that Ryeqo® complies with the established medical science and medical practice when treating severe menstrual blood loss due to uterine fibroids in adult women of reproductive age. However, based on specific advice from the occupational group regarding appropriate medication use in this patient population, the National Health Care Institute has determined that Ryeqo® only has an equal value, compared to the current

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standard treatment with a GnRH agonist + 'add-back' therapy (oestradiol/dydrogesteron or tibolone), for adult women of reproductive age who are expected to enter menopause within 2–3 years and for whom conservative primary line medication has failed and surgical treatment/invasive procedure is not desired or possible.

Budget impact analysis
Based on the current known price of €98.58 per 28 tablets and a recommended dosage of 1 tablet per day, the cost of Ryeqo® is €1,285 per patient per year. Based on the current price level, treatment with a GnRH agonist + 'add-back' therapy is estimated to cost €1,361 per patient per year. Taking into account the various assumptions about patient numbers and duration of treatment, inclusion in GVS List 1B of relugolix + E2 + NETA (Ryeqo®) for the treatment of severe menstrual blood loss due to uterine fibroids in the earlier strictly defined patient population will be accompanied by a saving of approximately €0.1 million in the third year after inclusion in the reimbursed package.

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

Advice
On the basis of the above considerations, the National Health Care Institute recommends that you include the *relugolix + oestradiol + norethisteronacetate* (Ryeqo®) combination preparation in List 1B of the Rzv. The National Health Care Institute hereby recommends the following reimbursement conditions.

Conditions *relugolix + oestradiol + norethisteronacetate* (Ryeqo®)
Only for adult insured persons in their childbearing years with severe menstrual blood loss due to uterine fibroids for whom menopause is expected to start within 2 – 3 years and where conservative primary line medication has failed and surgical treatment/invasive procedure is not desired or possible.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

Appendices:
- GVS advice
- Pharmacotherapeutic report
- Budget impact analysis