Zorginstituut Nederland

Palbociclib (Ibrance®) for the treatment of metastatic breast cancer

Summary of recommendations by *Zorginstituut Nederland* dated 15 December 2016

Zorginstituut Nederland carried out an assessment of the medicine palbociclib (Ibrance®), whereby they came to the following conclusion.
The Zorginstituut advises the Minister of WVS not to include palbociclib in the insured package, unless the product's cost-effectiveness can be improved and the impact on the care budget reduced by means of price negotiations.

Zorginstituut Nederland has completed its assessment of the medicine palbociclib (Ibrance®) for the indication metastatic breast cancer. The Minister of Health, Welfare and Sport (WVS) placed this indication in the so-called 'sluice'. [In brief, what this means is that, by way of an exception for intramural medicines with exceptionally high costs, the Minister can determine that a product does not automatically get included in the insured package, but is instead explicitly excluded from reimbursement. Its inclusion in the package can only take place after a positive assessment by the Zorginstituut, successful price negotiations and agreements on appropriate use.]

The *Zorginstituut* has assessed whether palbociclib fulfils the four package criteria for inclusion in the insured package: effectiveness, cost-effectiveness, necessity and feasibility. This outcome of assessment is the result of an integral assessment of those criteria. In addition, the Zorginstituut also advises the Minister on a proposal for appropriate use drawn up by the professionals and patients' associations.

Package advice (conclusion)

Palbociclib complies with the statutory criterion 'established medical science and medical practice' for patients with hormone receptor-positive, HER2-negative, advanced or metastatic breast cancer who were not previously treated (first line) with hormonal therapy, and also for patients who have already received hormonal therapy treatment (second line).

The relationship between the costs and effects of palbociclib is unfavourable. The applicant presents an ICER of circa €160,000 in the first line and circa €173,000 in the second line per quality-adjusted life-year (QALY) gained. The *Zorginstituut* carried out an extra analysis and expects the ICER to be closer to €200,000 per QALY in the first line and €180,000 in the second line. In view of the limitations on the care budget's growth, it is highly likely that reimbursing palbociclib from the basic insured package will result in the implicit displacement of other, more cost-effective care. On a population level, this results in loss of health. Due to the high price of the product and the relatively large number of patients, treatment with palbociclib will involve considerable medicinal costs, i.e. €118 million, circa €111 million of which will be for patients who have received no prior hormone therapy (first line) and circa €7 million for patients who have received prior hormone therapy (second line). This means the degree of potential displacement is considerable.

Zorginstituut Nederland's advice

In view of the above, the Zorginstituut advises the Minister of WVS not to include palbociclib in the insured package, unless the product's cost-effectiveness can be improved and the impact on the health care budget reduced by means of price negotiations.

The *Zorginstituut* also emphatically draws the Minister's attention to the proposal of the professionals (NVMO/NABON) to explore optimum deployment (= appropriate use) by treating patients only within the framework of research. The proposal is in line with your request for appropriate use proposals, but it cannot be accommodated by a statutory instrument, i.e. conditional inclusion. The place of palbociclib and thus appropriate use can be better substantiated with the outcomes of the research, and the budget impact considerably reduced in the short term and – depending on the outcome – also in the long term. The patients' association (NFK, the Dutch breast cancer association) supports the above-mentioned initiative. The Zorginstituut notes that, broadly speaking, studies that focus on questions about the appropriate use of an intervention on the basis of patient selection are becoming increasingly relevant.

In general the Zorginstituut argues in favour of transparency regarding the negotiation results.

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The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.