



Title	Trastuzumab in Early Stage Breast Cancer
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Reference	KCE reports 34C (D/2006/10.273/25). http://kce.fgov.be/index_en.aspx?ID=0&SGREF=5211&CREF=7198

Aim

To estimate the cost effectiveness and budget impact from a payer perspective of reimbursing trastuzumab in early stage breast cancer (ESBC).

Conclusions and results

Clinical conclusions:

- Trastuzumab reduces distant recurrence and improves 2 or 3 year disease free survival (DFS) from 75%–78% to 86%–89% in women with ESBC.
- Postanthracycline trastuzumab also causes severe congestive heart failure.
- When administered after anthracyclines, the pooled efficacy data of 1 year of trastuzumab in terms of DFS in ESBC seem weaker when trastuzumab is started sequentially after taxane treatment compared concurrently with a taxane.
- Preanthracycline administration of 9 weeks of trastuzumab proved efficacious in a recently published smaller trial.
- Trastuzumab may not prevent the development of brain metastases.
- In patients over 70 years of age trastuzumab has not been studied sufficiently.

Health-economic conclusions:

- Trastuzumab administered postanthracycline proved effective in most patient subgroups, while the preanthracycline regimen was effective in all subgroups studied. Trastuzumab was more effective in younger women and in women with more advanced disease.
- When the postanthracycline regimen was modeled on patients with a borderline cardiac function, trastuzumab treatment reduces life expectancy in stage I–II patients older than 50.
- Preanthracycline trastuzumab is more cost effective than the postanthracycline options, can lead to cost

savings, and reaches 20% more women in need of treatment for cancer.

- 597 and 491 patients are eligible for pre- and post-anthracycline trastuzumab, respectively, and would cost the healthcare payer 5.17 and 19.96 million euros, respectively.

Recommendations

- Unused trastuzumab can be reduced by marketing smaller vials. This should be discussed with the manufacturer.
- Reimbursement should be conditional on strict inclusion and exclusion criteria and embedding in the quality procedures of the oncology programs in Belgian Hospitals. During treatment cardiac function should be monitored.
- A cancer registry is essential to follow up women treated with trastuzumab in Belgium. This report presents several variables that are needed or useful for this purpose.
- A clinical trial comparing 9 weeks of trastuzumab preanthracycline with the 52-week postchemotherapy regimen should be started without delay.
- See full report for additional recommendations.

Methods

The results in this report are based on published information on efficacy and safety, and epidemiological and costing data, some of which are specific for Belgium. A systematic review of the existing literature was performed. The economic evaluation of trastuzumab was based on a cost-effectiveness analysis and an evaluation of the budget impact from a healthcare payer perspective.