

Budget Impact Analysis

Guideline



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1. General

To inform the Danish Medicines Council of the regional budget impact of introducing a new treatment or extending an indication, the applicant must calculate the total regional budget impact for the relevant patient group.

The calculation consists of two components:

- The annual number of patients expected to be treated with the new treatment over a 5-year period.
- The average drug costs and other regional hospital costs per patient per year for the intervention and comparator, based on the treatment pathway costs from the health economic cost-utility analysis.

The budget impact analysis must assess the magnitude of any additional costs associated with the introduction of the new treatment (intervention) compared with the existing standard treatment (comparator).

A budget impact analysis is not required for cost-minimization analyses.

Cost-minimization analysis is appropriate when the new treatment and the current standard treatment are considered equivalent across all relevant clinical outcomes and safety. Under this framework, the preferred option is the treatment associated with the lowest cost, which can be assessed directly from the incremental costs of the health economic analysis.

2. Calculation

2.1 Number of patients and uptake upon implementation

The number of patients must be based on the expected annual number of patients who will receive the new treatment in Danish clinical practice and should account for any gradual patient uptake. The applicant must always describe how the number is estimated and justify any assumptions related to the gradual patient uptake. The following guidance should be followed:

- **Expected annual number of patients** must be defined as the number of patients in Denmark who are eligible for the new treatment according to the EMA indication, minus those considered unsuitable (e.g., due to age or comorbidity), and minus those expected to decline treatment. In general, the annual number of incident patients must be used. However, if prevalent patients are expected to be offered the new treatment, these must be included in year 1. For example, 100 patients in Year 1 (incident and prevalent) and 20 patients in years 2–5 (incident).



- **Patient uptake upon implementation:** Generally, patient uptake must be 100%. If full patient uptake is not expected from year 1, but instead a gradual implementation over the first years is anticipated, this must be reflected in the number of patients over the time horizon. The reasons behind any gradual implementation must always be clearly justified, for example due to capacity building or increasing familiarity with and management of adverse events. Once the new treatment is expected to be fully implemented, patient uptake must be 100%.

2.2 Time horizon

The time horizon for the budget impact analysis must be 5 years. If costs have not stabilized by Year 5, the applicant must specify the reasons for this, for example factors related to the number of patients or the timing of subsequent treatment costs.

2.3 Calculation and presentation of results

When calculating the budget impact, the applicant must use the Danish Medicines Council's standard Excel sheets. The applicant must calculate the budget impact as the difference between the following two scenarios:

1. The Danish Medicines Council recommends the new treatment as a potential standard treatment for the expected annual number of patients.
2. The Danish Medicines Council does not recommend the new treatment as a potential standard treatment for the expected annual number of patients.

The applicant must estimate the budget impact based on the treatment pathway costs estimated in the health economic analysis as follows:

- Drug costs and other regional hospital costs must be reported separately and in total. Patient costs and municipality costs must not be included, as only regional costs are considered.
- Drug costs must be calculated using list prices (AIP).
- Costs must be estimated without applying discounting.

It may be relevant to conduct sensitivity analyses to explore potential uncertainties, for example related to the number of patients or gradual patient uptake.

If the health economic analysis consists of multiple scenarios, a budget impact analysis must be conducted for each scenario.



3. Version log

Version	Date	Revision
1.0	February 19th 2026	Approved and published.
