Medicinrådet

Cost Calculations

Guideline

Version 1.0

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1. Introduction

The health economic analysis must include all treatment-related costs for the intervention and the comparator, including drug costs (Section 2), hospital costs (Section 3), and patient-related costs (Section 4). In some cases, it may also be relevant to include other costs covered by public health insurance or municipal budgets (Section 5).

The cost assessment must be based on expected resource use in Danish clinical practice and Danish unit costs. Resource use must be divided into two separate components:

- quantity consumed (e.g. monthly frequency and/or number of hours)
- unit costs (e.g. DRG tariff or drug cost per administration).

A clear explanation should be provided detailing how every cost was determined, specifying the calculations performed, assumptions made, and sources referenced.

If recommending a new treatment is expected to require substantially increased resource use or pose implementation challenges, the health economic analysis must be supplemented with a qualitative description of these challenges.

If up-to-date Danish unit costs (less than three years old) are not available and only older unit costs exist, these must be adjusted using the net price index excluding energy from Statistics Denmark (Statistics Denmark, 2025b). This does not apply to DRG tariffs, which must be from no earlier than the previous year, see Section 3.3.

The use of foreign cost estimates adjusted for purchasing power parity must be avoided and may only be used when strictly necessary, for example if no Danish cost estimates are available.

As a general rule, resource use must always reflect Danish clinical practice. However, in some cases, adapting the cost assessment to Danish clinical practice may create discrepancies between the treatments effect estimates observed in the clinical study and the cost estimates based on Danish clinical practice (e.g., higher dose reductions in practice or suboptimal subsequent treatment in the study). In such cases, the applicant must thoroughly describe how adapting to Danish clinical practice may influence the interpretation of the ICER, and the model must allow the Danish Medicines Council to adjust all relevant inputs.

The applicant must apply half-cycle correction to account for the fact that costs typically accrue continuously throughout a model cycle rather than at the beginning of a cycle. Half-cycle correction must be applied when the cycle length exceeds one week. However, half-cycle correction must not be applied to drug and administration costs for one-off treatments or drugs administered or dispensed on day 1 of a model cycle.

2. Drug Costs

This section outlines the methodology applicants should adopt when calculating drug costs included in the health economic analysis, including how the Danish Medicines Council approaches dose reductions, treatment interruptions (pauses), wastage, treatment duration, and subsequent treatment.

All drug prices must be reported using list prices (Apotekernes Indkøbspris (AIP)) (Danish Medicines Agencies, 2025), and the calculations must be implemented dynamically with all relevant intermediate calculations included in the health economic model.

Drug costs must be integrated into the model at appropriate time points to accurately reflect the expected treatment pathway in Danish clinical practice, for example expected administration frequency for IV treatment or expected dispensing quantity and frequency for oral treatment.

Assumptions about future changes in drug costs due to patent expiry or other competitive factors must not be included in the analysis, although such information may be briefly mentioned in the submission.

Some treatments require co-medication or pre-medication, which must be included if expected to be part of Danish clinical practice and/or stated in the drug's Summary of Product Characteristics (SmPC).

2.1 Calculation of Drug Costs

2.1.1 Introduction

Regardless of the route of administration, the calculation of drug costs for a given drug must be based on the dose distribution from the most recent pre-specified data cut in the clinical study (or studies). If the patient population is limited to a subpopulation of the overall ITT population, the dose distribution must reflect the dose received by that subpopulation. The applicant must provide a thorough description of whether there may be differences between the dose distribution observed in the clinical study (or studies) and the dose expected to be administered in Danish clinical practice, including how the calculation of drug costs accounts for such differences. See examples of dose distribution calculations in the Appendix.

If a drug is available in multiple packages with differences in strength and/or quantity, the dose distribution, as described above, must form the basis for calculating the distribution across packages. This ensures that drug costs can be calculated as a weighted average across the available packages, see Figure 1. The model must be dynamic, ensuring that the calculation is based on the cheapest package combination when changes occur in the dose distribution or prices.

Figure 1 Basic principle for calculating drug costs per administration

Dose Reduction

If the applied dose distribution is based on planned dose and does not include dose reductions, it may be necessary to incorporate dose reduction before calculating the distribution across packages. When using RDI (relative dose intensity) to represent dose reduction, the RDI must not include treatment interruptions in the numerator or denominator, see Box 1.

Treatment Interruptions (pause)

The proportion of treatment administration interruptions must be calculated separately and subtracted after the distribution across packages has been calculated. Interruptions are defined as the proportion of planned administrations (prior to treatment discontinuation) that are not administered. Interruptions must not be confused with treatment discontinuation, see Section 2.1.4 on treatment duration and discontinuation. If administrations are interrupted, it must be clearly documented how costs related to other resource use (e.g., administration-related costs) are handled, and these assumptions must be easy to modify in the model.

Box 1. Definition and use of dose reduction and treatment interruption in the calculation of drug costs

When using RDI, the applicant must distinguish between dose reduction and treatment administration interruptions, as these must be handled differently in the calculation of drug costs:

- Dose reductions must be subtracted from the planned dose before calculating the distribution across packages. If the dose reduction is based on RDI from the study, the RDI must not include any treatment interruptions in the numerator and/or denominator.
- Treatment interruptions must only be subtracted after the distribution across packages has been calculated.

If an RDI from a study is used to define dose reduction, the applicant must always clearly describe how the RDI (received dose/planned dose) is defined, as the definition of both received dose and planned dose may vary across clinical studies. In some studies, planned treatment interruptions are included in the planned dose, whereas in others they are not. Similarly, in some studies, the received dose may include assumptions about perfect sharing/splitting of tablet packages, see Section 2.1.2.

2.1.2 Drug wastage

When calculating drug wastage, costs must always be minimised, rather than milligrams or the number of packages.

Intravenous treatment
Drug wastage must always be explicitly included for intravenous treatment in hospitals if it is not possible to split vials in Danish clinical practice. This is done by using the dose distribution as the basis for distribution of full vials, after which a weighted average of the price per vial and the distribution of full vials can be calculated. If no wastage is assumed (e.g., perfect vial sharing), clear justification is required, and it must be possible to include drug wastage in the health economic model.

Oral treatment (tablets)
Calculations must be based on the dispensed dose without splitting packages, ensuring that wastage from unused tablets is implicitly included in the calculation of drug costs. Drug costs must not be calculated based on the used dose because splitting tablet packages does not normally occur in Danish clinical practice.

Subcutaneous treatment
As subcutaneous administration may take place either in the hospital or at home, both approaches (intravenous treatment and oral treatment) may be relevant when calculating drug wastage. The applicant must use the approach that most accurately reflects Danish clinical practice and justify the choice thoroughly.

2.1.3 Dosing based on body weight or body surface area

If dosing is based on a patient's body weight or Body Surface Area (BSA), the calculation of drug costs must account for this. For example if dosing is administered as a certain number of mg per kg (continuous dosing) or if the planned dose depends on a given weight threshold (stepwise dosing).

The applicant must describe any differences in the distribution of body weight/BSA between the clinical study (or studies) and Danish clinical practice, and explain how such differences are accounted for in the calculation of drug costs. It must always be possible for the Danish Medicines Council to adjust the weight and/or BSA distribution in the health economic model. The model must be dynamic, ensuring that any changes in these distributions are reflected in the dose distribution and, consequently, in the distribution of, for example, package combinations.

Continuous dosing
The applicant must use the most detailed data available on the distribution of patients' body weight/BSA and the corresponding dose. The data must be stratified into sufficiently narrow intervals to ensure an accurate mapping to the distribution on available pack sizes.

If the applicant is unable to base the calculations on the above, the calculation may instead be based on an appropriate parametric distribution of the patients' body

weight/BSA for the target patient population. The parameters of the distribution must be based on summary statistics from the study population (e.g., mean, median, and standard deviation) and, if relevant, adjusted to reflect the average weight in Danish clinical practice.

Stepwise dosing
If the drug is expected to be dosed differently above/below a fixed threshold (e.g., body weight), the calculation of drug costs must account for both the proportion of patients above and below the threshold and the dose distribution on each side of the threshold. For example, weight-based dosing up to 80 kg and a fixed dose above this threshold.

2.1.4 Treatment duration

The proportion of patients receiving treatment with a given drug in each model cycle must be based on the data that most accurately reflect how and for how long treatment will be used in Danish clinical practice. Such time-on-treatment data may come from the interventional study, observational data sources, or data from comparable drugs with a similar mechanism of action. If multiple relevant data sources are available, the Danish Medicines Council must be able to choose between them in the health economic model. If time-on-treatment data are not available, the applicant may, in certain cases, use an estimate of the average treatment duration or the average number of doses. However, averages should only be used if treatment duration is less than a year and have relatively low discontinuation rates, as an average is not sufficient to accurately model treatment duration in cases of higher discontinuation rates or longer treatment durations.

In some cases, extrapolation of time-on-treatment data will be relevant. This must be done in accordance with the Danish Medicines Council's guideline for health economic analysis and extrapolation.

If criteria for treatment discontinuation are defined in the SmPC or in other relevant clinical guidelines, these must be included in the health economic analysis. If the health economic analysis includes criteria for treatment discontinuation that are not defined in any of the sources mentioned above, the clinical rationale for their inclusion must be clearly stated. It must always be possible to modify the criteria for treatment discontinuation within the health economic model.

Deviation from the use of time-on-treatment data
If the effect data primarily reflects the effect of being on treatment *(rather than an intention-to-treat effect)*, all patients must be assigned costs for the entire period during which effects are accrued. This applies, for example, if the number of QALYs gained in a given health state is driven by an improvement in quality of life estimated among patients on treatment. During the period in which costs are assigned, the calculation of drug costs must continue to follow the requirements set out in this guideline.

2.2 Subsequent Treatment

Drug costs associated with subsequent treatment must be included in the health economic analysis if there are differences between the intervention and the comparator with regard to which subsequent treatments patients receive, the proportion of patients receiving the different subsequent treatments, the duration of subsequent treatment, and/or the timing of subsequent treatment initiation.

The dosage and route of administration of the included drugs must be described and based on the respective SmPCs. Other assumptions used to calculate drug costs must follow Section 2.1. If the total duration of subsequent treatment is less than three years, the associated drug cost may be included as a one-time cost (lump sum) at the time treatment is initiated.

Subsequent treatment must always reflect Danish clinical practice. The applicant must always describe whether and to what extent the effects of subsequent treatment is captured in the effect data used in the health economic analysis. In addition, the analysis must specify the assumed timing of initiation of subsequent treatment, for example whether it occurs immediately after discontinuation of the intervention or comparator, at disease progression, or after a potential wash-out period.

The applicant must describe how the proportion of patients receiving subsequent treatment has been estimated, as well as how patients are distributed across different treatments if more than one subsequent treatment is available. It must always be possible to adjust both the proportion of patients receiving subsequent treatment and the distribution between treatment alternatives within the health economic model.

3. Hospital Costs

The health economic analysis must include costs related to hospital resource use. To distinguish between different types of hospital costs, cost components must be categorised as follows: *administration costs*, *disease management costs, treatment monitoring costs*, and *costs related to the management of adverse events*. In certain cases, other hospital costs may be included if relevant, see Section 3.2.

When including drug costs for subsequent treatment, costs associated with drug administration, disease management, and treatment monitoring must be included. For subsequent treatment, costs related to the management of adverse events should only be included if substantial differences in incidence and associated resource use are expected across the treatment arms.

Hospital resource use related to drug administration, disease management, and treatment monitoring must be calculated based on visit frequencies. These frequencies must reflect expected frequencies in Danish clinical practice, and the assumed duration of each type of contact (e.g., the first six months).

As a general rule, unit costs must be based on the most recently available DRG tariffs, see Section 3.3.

3.1 Management of Adverse Events

Costs related to the management of adverse events must be included in the health economic analysis if such management is expected to entail resource use in Danish clinical practice. It must always be clearly stated how these costs have been included in the health economic model. The applicant must estimate resource use based on the proportion of patients experiencing each adverse event and the associated unit costs (DRG tariffs).

Data used to estimate the proportion of patients experiencing each adverse events must be the same as reported in the section on clinical effect and safety. As a general rule, only costs related to the management of adverse events of grade ≥ 3 should be included, where the difference between the intervention and comparator is ≥ 3%-points. If events are not graded according to the Common Terminology Criteria for Adverse Events (CTCAE), Serious Adverse Events (SAEs) may be used instead. Any deviations must be justified.

3.2 Other Hospital Costs

In cases where relevant hospital costs do not fall within specified categories above (e.g., diagnostic tests), these may be included.

Diagnostic tests
If a recommendation of a new drug requires implementing a new diagnostic test in Danish clinical practice to identify patients eligible for treatment, the cost of testing one patient must be included in the analysis as the average test cost per patient. Test costs must always be calculated as the total testing costs for the entire population divided by the number of patients identified as eligible for treatment.

Palliative care
Cost associated with palliative care must not be included in the health economic analysis. Palliative care varies considerably and is tailored to the individual patient's disease and treatment pathway, both within and outside the hospital setting, and there is limited evidence on the treatment patients actually receive.

3.3 Choice of DRG Tariffs

Relevant DRG tariffs are available on the Danish Health Data Authority's website and/or through its "Interactive DRG" tool (Danish Health Data Authority, 2025a, 2025b). DRG tariffs reflect hospitals' average operating costs within each DRG group and include salaries, consumables, blood tests, and diagnostic tests. These components must therefore not be added separately if they occur during the same hospital visit. Only one DRG tariff may be assigned per hospital visit, corresponding to one DRG hospital stay. For example, contacts occurring within four hours of each other must be considered the same DRG hospital stay in accordance with the DRG tariff guidelines, see also the example in Box 2.

It must always be specified which diagnosis and procedure codes were used to identify the relevant DRG group. If other patient characteristics are relevant for determining the DRG group (e.g., age or contact duration), these must also be specified.

Table 1. Example of the use of DRG tariffs with two contacts

Contacts	Number of tariffs
Monday: Blood test at 8 a.m. Tuesday: CT scan at 10 a.m.	Two tariffs (two stays as > 4 hours between contacts)
Monday: Blood test at 8 a.m. Monday: CT scan at 10 a.m.	One tariff (one stay as <= 4 hours between contacts)

Box 2. Example – Selection of DRG tariff for adverse events using Interactive DRG

When selecting a DRG tariff for adverse events, the primary reason for the patient's hospital episode, i.e. the adverse event, must be entered under "Selected diagnoses." The patient's underlying diagnoses, for example breast cancer, must then be entered in the same field. This ensures that the adverse event is registered as the primary diagnosis ("A"), while the underlying diagnoses are registered as secondary diagnoses ("B"). Any relevant procedures must be entered under "Selected procedures."

3.3.1 Deviation from the use of DRG tariffs

The applicant may supplement the health economic analysis with a micro-based approach if necessary to adequately capture resource use. This must only be submitted as a supplement, and the health economic model must allow for a choice between the use of DRG tariffs and a micro-based approach. If a micro-based approach is used, all relevant individual components of resource use must be identified and valued. These components may include staff time, costs of blood tests, overhead costs, and consumables. The valuation of staff time must be based on the most recent salary data from the Municipal and Regional Wage Data Office (Municipal and Regional Wage Data Office (KRL), 2025). The valuation must be based on that an employee has, on average, 94 effective working hours per month.

4. Patient Costs

4.1 Patient Time

In both cost-utility and cost-minimisation analyses, the application must include costs related to patient time for patients and/or caregivers in accordance with Table 2. When including costs related to patient time, the estimation of time use and valuation of time must follow the guidance provided in section 4.1.1 and 4.1.2.

Table 2. Inclusion/exclusion of costs for patient time

Activity	Inclusion/exclusion	Guideline
Treatment administration, outpatient treatment monitoring or disease management and transport time	Include	Patient time associated with these activities must always be included, as the Danish Medicines Council assumes that patients could have spent this time on other utility-yielding activities. The Danish Medicines Council does not expect quality of life measurements to capture the disutility associated with patients' time spent on these activities. Questionnaires used to measure health-related quality of life rarely capture the burden related to these activities, and questionaries are not always distributed at every administration or treatment activities.
Hospitalisation	In some cases	Patient time associated with hospitalisation must be included if the patient is hospitalised for monitoring. If the patient is hospitalised due to poor general condition, patient time must *not* be included.
Adverse events	Exclude	Patient time associated with the management of adverse events must *not* be included, as the Danish Medical Council assumes that adverse events requiring treatment are of such severity that the patient's time could not have been used on other utility-yielding activities. In addition, reductions in health-related quality of life associated with adverse events (disutilities) may be included separately in the health economic analysis.
Home-based treatment	In some cases	Patient time associated with home-based treatment must be included if the patient is expected to be seated or

Activity	Inclusion/exclusion	Guideline
		bedridden during administration of the drug. If the expected patient time is less than 10 minutes per day, it must not be included.
Subsequent treatment	In some cases	Patient time associated with subsequent treatment must only be included if *substantial* differences in incidence and resource use are expected across the treatment arms. *If patient time for subsequent treatment is included, all guidelines specified in the other rows of the table continue to apply.*
Patient time for caregivers	In some cases	Patient time for all activities (including hospitalisation) must be included for one caregiver if the patient is always expected to be accompanied, for example in the treatment of children or patients with dementia who require an accompanying person. When including patient time for caregivers of children, caregiver time must be excluded from the point at which the patient reaches an average age >18 years in the health economic model. *If patient time for the caregivers is included, all guidelines specified in the other rows of the table continue to apply.*

Box 3. Rationale for the guidance on patient time

Costs related to patient time are included to compensate for the loss of quality of life associated with the patient's time use. When including costs related to patient time, the following conditions should be met:

1. The patient's general condition during the relevant activity is sufficiently good that, in the absence of the activity, the patient could have engaged in other utility-yielding activities (leisure or work). Therefore, a loss of utility is associated with the patient time spent on the activity. *For example, if the*

patient would otherwise have been able to work, go shopping, or participate in social activities instead of receiving treatment.

And

2. The measurement of health-related quality of life is not expected to capture the loss of utility associated with patient time. *For example, the instrument used to measure quality-of-life may not be sufficiently sensitive to capture the loss of utility, or the interval between measurements may be too long for the utility loss related to patient time to be reflected.*

In practice, it is difficult to determine whether criteria 1) and 2) are met. Therefore the Danish Medicines Council applies the guidelines in Table 2 across all submissions to ensure consistency and to prevent issues related to double counting or the exclusion of relevant patient costs.

4.1.1 Estimation of time use

The estimation of time use must be based on the expected number of hours in accordance with the following guidelines:

Drug administration
The SmPC or dosing guidance available at pro.medicin.dk must form the basis for estimating the expected time use associated with the administration of intravenous treatments. Any deviations must be thoroughly justified. In addition to administration time, time required for treatment initiation and any subsequent observation must also be included.

Monitoring and disease management
All outpatient visits (with the exception of less time-consuming routine monitoring) must be assigned a time use of one hour, covering both waiting time and the consultation itself. Less time-consuming routine monitoring must be assigned a time use of 30 minutes (e.g., blood tests and ECG). If, for example, ECG and blood tests are performed on the same day, a maximum of 30 minutes must be assigned.

One day (24 hours) of hospitalisation must be assigned a time use of 16 hours, based on the assumption that the patient sleeps for 8 hours, and that these 8 hours could not have been used for alternative utility-yielding activities had the patient not been hospitalised.

Transport
Time spent on transport to and from the hospital must be based on an average distance of 20 km to the hospital, corresponding to a time use of 90 minutes per hospital visit. It must clearly stated if one or more contacts are assumed to take place during the same hospital visit to avoid double counting transport time.

Caregiver
Time use for one caregiver may be included in certain cases where the patient is expected to require accompaniment at the hospital, for example in the treatment of children or patients with dementia.

4.1.2 Valuation of time use

Based on the average gross hourly salary in Denmark (Statistics Denmark, 2025a) and an average tax rate of 32%[1] (Ministry of Taxation, 2025), patient time are valued at DKK 200 per hour.

4.2 Transport Costs

Transport costs must be included for each hospital visit. Based on the current Danish government reimbursement rates for tax-free travel allowance and assuming a distance of 20 km each way to the hospital, transport costs per hospital visit are valued at DKK 150[2] (Danish Ministry of Taxation, 2025; KL, 2016). Transport costs must be included regardless of whether patient time is included or not and are therefore independent of whether the time could have been used for other utility-yielding activities.

5. Other Costs

In some cases, other costs may be relevant (e.g. costs covered by public health insurance or municipal budgets). The applicant must justify inclusion of additional costs and ensure all assumptions, calculations, and sources meet the same requirements as other cost elements.

General practitioners and specialists
Resource use during visits with general practitioners and specialists must be estimated based on the latest available collective agreement between the Danish General Practitioners' Organisation (PLO) and the Regional Salary and Fee Board (RLTN) for general practice, or the Danish Association of Specialists (FAS) and the Regional Salary and Fee Board for the specialist area (FAPS, 2025; PLO, 2025).

6. References

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[1] The average tax for people with an income in the range of 300,000 and 600,000 DKK.
[2] Rate for tax-free driving allowance, 2025 (own car or motorcycle up to 20,000 km/year) DKK 3.81/km * 40 km.

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7. Appendix

7.1 Examples of Calculating Dose Distributions

Table 1. Dose distribution and combinations of tablets at a given dose [Drug A]

			Combinations of tablets at a given dose	
	Cumulative days with a given dose	Proportion of days with given dose	[Pack A, 5 mg]	[Pack B, 10 mg]
5 mg	5000	5%	1	0
10 mg	70000	70%	0	1
15 mg	20000	20%	1	1
Interruptions (proportion of days with 0 mg before possible treatment discontinuation)	5000	5%	0	0
Average dose			10.3 mg	

Table 2. Dose distribution and vial combinations at a dose of 1.5 mg/kg [Drug B]

			Vial combinations at a given dose	
	Max weight for a given dose	Proportion of patients with a given dose	[Vial A, 40 mg]	[Vial B, 80 mg]
40 mg	27	0%	1	0
80 mg	53	10%	0	1
120 mg	80	49%	1	1
160 mg	107	37%	0	2
200 mg	133	4%	1	2
Average number			0.53	1.40

8. Version log

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Medicinrådet

The Secretariat of the Danish Medicines Council
The Danish Medicines Council, Dampfærgevej 27-29, 3rd floor
2100 Copenhagen Ø

+ 45 70 10 36 00
medicinraadet@medicinraadet.dk

www.medicinraadet.dk